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

FORM 10-Q

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

For the quarterly period ended September 30, 2015

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 October 23, 2015, there were 71,457,059 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)

	September 30, 2015	December 31, 2014 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,709	$ 8,391
Marketable securities, current	42,705	50,209
Collaboration receivable	4,032	7,248
Prepaid expenses and other current assets	1,785	832
Total current assets	62,231	66,680
Property and equipment, net	404	557
Other assets	1,329	1,159
Total assets	$ 63,964	$ 68,396
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 436	$ 2,074
Accrued clinical and development expenses	5,898	5,998
Accrued liabilities	3,202	3,180
Deferred revenue, current	14,722	14,722
Total current liabilities	24,258	25,974
Warrant liability	19,295	3,961
Deferred revenue, non-current	51,153	62,194
Deferred rent	153	243
Total liabilities	94,859	92,372
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
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: 71,431,059 shares at September 30, 2015 and 62,898,233 shares at December 31, 2014	71	63
Additional paid-in capital	368,190	349,236
Accumulated other comprehensive loss	(3)	(13)
Accumulated deficit	(399,153)	(373,262)
Total stockholders' equity (deficit)	(30,895)	(23,976)
Total liabilities and stockholders' equity (deficit)	$ 63,964	$ 68,396

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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$ 3,680	$ 3,680	$ 11,041	$ 11,041
Operating expenses:				
Research and development	8,081	8,906	28,902	27,223
General and administrative	2,372	2,407	7,468	7,518
Total operating expenses	10,453	11,313	36,370	34,741
Loss from operations	(6,773)	(7,633)	(25,329)	(23,700)
Interest income (expense), net	27	27	99	97
Other income (expense), net	315	(341)	(661)	7,781
Loss before provision (benefit) for income taxes	(6,431)	(7,947)	(25,891)	(15,822)
Provision (benefit) for income taxes	—	(202)	—	(202)
Net loss	(6,431)	(7,745)	(25,891)	(15,620)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	15	(13)	10	(24)
Comprehensive loss	$ (6,416)	$ (7,758)	$ (25,881)	$ (15,644)
Net loss per common share:				
Basic	$ (0.09)	$ (0.13)	$ (0.37)	$ (0.26)
Diluted	$ (0.09)	$ (0.15)	$ (0.37)	$ (0.37)
Weighted average number of shares used in per common share calculations:				
Basic	71,382	59,845	69,833	59,500
Diluted	71,382	61,494	69,833	63,419

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)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$ (25,891)	$ (15,620)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	753	1,034
Stock-based compensation expense	4,792	3,932
Change in common stock warrant value	659	(7,781)
(Gain) loss on sale of investments, property and equipment	14	—
Changes in operating assets and liabilities:		
Collaboration receivable	3,216	13,631
Prepaid expenses and other assets	(1,123)	258
Accounts payable	(1,638)	1,725
Accrued clinical and development expenses	(100)	(3,302)
Accrued liabilities	22	(464)
Deferred rent	(90)	20
Deferred revenue	(11,041)	(11,042)
Net cash (used in) provided by operating activities	(30,427)	(17,609)
Cash flows from investing activities:		
Acquisition of property and equipment	(109)	(212)
Acquisition of marketable securities	(46,622)	(43,275)
Proceeds from sale of marketable securities	1,997	13,234
Proceeds from maturities of marketable securities	51,634	46,715
Net cash (used in) provided by investing activities	6,900	16,462
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of offering expenses	28,845	5,108
Net cash provided by financing activities	28,845	5,108
Net increase (decrease) in cash and cash equivalents	5,318	3,961
Cash and cash equivalents, beginning of period	8,391	7,279
Cash and cash equivalents, end of period	$ 13,709	$ 11,240

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, 2014 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, 2014 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 3, 2015.

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 provide 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 are related to its collaboration arrangement with Merck KGaA, which was entered in February 2012. The collaboration with Merck KGaA provides for various types of payments to the Company, including non-refundable 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 receives reimbursement for Merck KGaA's 70% share for eligible worldwide development expenses for evofosfamide (formerly TH-302). Such reimbursement is reflected as a reduction of operating expenses.

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 have been determined to be a single unit of accounting and as such the revenue relating to this unit of accounting is recorded as deferred revenue and recognized ratably over the term of its estimated performance period under the agreement, which is the product development period. The Company determines the estimated performance period and is periodically reviewed based on the progress of the related product development plan. The effect of a change made to an estimated performance period, and the related ratably recognized revenue, 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 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.

The Company recognizes revenue from milestone payments when: (i) the milestone event is substantive and its achievability has substantive uncertainty at the inception of the agreement, and (ii) the Company does not have ongoing performance obligations related to the achievement of the milestone earned. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either the Company's performance subsequent to the inception of the arrangement to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the Company's performance subsequent to the inception of the arrangement to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangements. See Note 3, "Collaboration Arrangements," for analysis of milestone events deemed to be substantive or non-substantive.

NOTE 2 — NET LOSS PER COMMON 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 common 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Numerator:				
Net loss - basic	$ (6,431)	$ (7,745)	$ (25,891)	$ (15,620)
Less: noncash income from change in fair value of common stock warrants	—	(1,558)	—	(7,781)
Net loss - diluted	(6,431)	(9,303)	(25,891)	(23,401)
Denominator:				
Weighted average common shares outstanding	71,382	59,845	69,833	59,500
Dilutive effect of warrants	—	1,649	—	3,919
Weighted-average common shares outstanding and dilutive potential common shares — diluted	71,382	61,494	69,833	63,419
Net loss per share				
Basic	$ (0.09)	$ (0.13)	$ (0.37)	$ (0.26)
Diluted	$ (0.09)	$ (0.15)	$ (0.37)	$ (0.37)

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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Shares issuable upon exercise of warrants	12,136	649	12,136	—
Shares issuable upon exercise of stock options	10,287	8,173	10,287	8,173
Shares issuable related to the 2004 Purchase Plan	40	33	40	33

NOTE 3 — COLLABORATION ARRANGEMENTS

On February 3, 2012, the Company entered into a global license and co-development agreement with Merck KGaA, Darmstadt, Germany, to co-develop and commercialize evofosfamide, the Company's small molecule hypoxia-targeted drug candidate. Under the terms of the 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 is eligible to earn additional potential milestone payments of up to $100 million in regulatory and development milestones, and $340 million in commercialization milestones.

In the United States, the Company has primary responsibility for development of evofosfamide in the soft tissue sarcoma indication. The Company and Merck KGaA will jointly develop evofosfamide in all other cancer indications being pursued. Merck KGaA will pay 70% of worldwide development expenses for evofosfamide. Subject to FDA approval in the United States, Merck KGaA will initially be responsible for commercialization of evofosfamide with the Company receiving a tiered, double-digit royalty on sales. Under the royalty-bearing portion of the agreement, Threshold retains the option to co-promote evofosfamide in the United States. Additionally, the Company retains the option to co-commercialize evofosfamide in the United States, upon the achievement of certain sales and regulatory milestones, allowing the Company to participate in up to 50% of the profits in the United States depending on total sales. Outside of the United States, Merck KGaA will be solely responsible for the commercialization of evofosfamide with the Company receiving a tiered, double-digit royalty on sales in these territories. The agreement will continue on a country-by-country and product-by-product basis until the later of the last to expire patent covering such product containing evofosfamide in such country or ten years following the commercial launch of a product containing evofosfamide in such country, unless terminated earlier. Merck KGaA has the right to terminate the agreement on limited notice to the Company, and each party has the right to terminate the agreement following an uncured material breach by the other party.

The Company's deliverables under the Merck KGaA agreement, which include delivery of the rights and license for evofosfamide and performance of research and development activities, have been determined to be a single unit of accounting. The delivered license does 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 global license and co-development agreement, which is required for Merck KGaA to fully realize the value from the delivered license. Therefore, the revenue relating to this unit of accounting will be recorded as deferred revenue and recognized over the estimated performance period under the agreement, which is the product development period. The Company has recorded $110 million of the upfront payment and milestones payments as deferred revenue and is amortizing them ratably over its estimated period of performance, which the Company currently estimates to end on March 31, 2020. As a result, the Company recognized $3.7 million and $11.0 million of revenue during the three and nine months ended September 30, 2015, respectively, and $3.7 million and $11.0 million of revenue during the three and nine months ended September 30, 2014, respectively. The Company will periodically review and, if necessary, revise the estimated periods of performance of its collaboration. The Company also earned $3.8 million and $9.5 million reimbursement for eligible worldwide development expenses for evofosfamide from Merck KGaA during the three and nine months ended September 30, 2015, respectively, compared to $4.8 million and $14.2 million during the three and nine months ended September 30, 2014, respectively. Such earned reimbursement has been reflected as a reduction of research and development expenses.

Of the remaining potential future milestones, $100 million are related to regulatory and development milestones and $340 million are related to commercialization milestones that may be received under the Merck KGaA Agreement. Regulatory milestones include the filing and acceptance of regulatory applications for marketing approval in major markets. Development milestones include primarily the initiation of various phases of clinical trials. Commercialization milestones include the achievement of first commercial sales in a particular market or annual product sales in excess of a pre-specified threshold. At the inception of the collaboration agreement the Company assessed regulatory and development milestones to be substantive where there was substantive scientific and regulatory uncertainty of achievement, the amounts of payments assigned were considered to be commensurate with the enhancement that occurred subsequent to inception of the Merck KGaA agreement, of the value of the delivered rights and license of evofosfamide and the Company's performance is necessary to the achievement of the milestone. Accordingly, the Company will recognize payments related to the achievement of such milestones, if any, when such milestone is achieved. Regulatory and development milestones that do not meet these conditions were considered non-substantive and payments related to the achievement of such milestones, if any, will be recorded as deferred revenue and amortized ratably over the estimated period of performance. Under the Merck KGaA agreement, Merck KGaA will initially be responsible for commercialization activities and the Company initially may not be involved in the achievement of these commercialization milestones. These commercialization milestones would typically be achieved after the completion of the Company's regulatory and development activities. If there are no future development obligations, the Company expects to account for the commercialization milestones in the same manner as royalties, with revenue recognized upon achievement of the milestone.

NOTE 4 — STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock

On February 18, 2015, the Company completed an underwritten public offering of 8.3 million shares of its common stock and accompanying warrants to purchase up to 8.3 million shares of common stock. Net proceeds from the sale of common stock and accompanying warrants, excluding the proceeds, if any, from the exercise of the warrants issued in the offering, were approximately $28.1 million after deducting the underwriting discount and offering expenses payable by the Company.

The warrants issued in the February 2015 offering carry an initial exercise price of $10.86 per share and are exercisable through the date that is five years from the issuance date. On the 30th trading day following the earlier of (i) the date two years from the issuance date or (ii) the later to occur of (a) the date on which top-line efficacy data from the Company's Phase 3 clinical trial of evofosfamide plus doxorubicin versus doxorubicin alone in patients with locally advanced unresectable or metastatic soft tissue sarcoma is publicly announced by the Company or (b) the date on which top-line efficacy data from the Phase 3 MAESTRO clinical trial of evofosfamide in combination with gemcitabine in patients with previously untreated, locally advanced unresectable or metastatic pancreatic adenocarcinoma is publicly announced by the Company, the warrant exercise price will be adjusted to equal the average of the volume-weighted average price of the Company's common stock for each of the 20 trading days immediately preceding the applicable date, provided that in no event will the exercise price be adjusted above $10.86 or below $3.62. After the date of foregoing adjustment to the warrant exercise price (such date, the "Adjustment Date"), the exercise price of the warrants will then be subject to price-based anti-dilution protection such that to the extent the Company's issues and sells any shares of common stock, or any securities convertible or exchangeable for shares of common stock (in each case subject to certain exceptions), at a price per share below the warrant exercise price then in effect, the warrant exercise price will be adjusted downward to equal the price at which such securities are issued and sold by the Company (but in no event will the warrant exercise price be reduced below $3.62 per share). The exercise price of the warrants is also subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Company's common stock. The warrants must be exercised for cash, except that if the Company fails to maintain an effective registration statement covering the exercise of the warrants, the warrants may be exercised on a net, or cashless basis. In addition, subject to the satisfaction of certain conditions set forth in the warrants, at the Company's option, the Company has the right to force the holders of the warrants to exercise their warrants in full if the volume-weighted average price of the Company's common stock for any 20 consecutive trading-day period beginning after the 90th day following the Adjustment Date exceeds $18.00 per share.

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 September 30, 2015 and February 18, 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 February 2015 offering. The fair value of these warrants on September 30, 2015 and February 18, 2015 was determined using a Monte-Carlo simulation model that accounted for the estimated changes to the exercise price between the issuance date and the Adjustment Date along with the following key level 3 inputs:

	September 30, 2015	February 18, 2015
Risk-free interest rate	1.23 %	1.52 %
Expected life (in years)	4.38	5.00
Dividend yield	—	—
Volatility	50 %	50 %
Stock price	$ 4.07	$ 4.26

On February 18, 2015, the Company determined the fair value of the February 2015 warrants to be $14.7 million and classified that amount of the net proceeds from the February 2015 offering to warrant liability. During the three and nine months ended September 30, 2015, the change in fair value of $0.3 million and $1.7 million of noncash income, respectively, related to the February 2015 warrants was recorded as other income (expense) in the Company's consolidated statement of operations.

At both September 30, 2015 and December 31, 2014, the Company also had warrants outstanding to purchase 3.8 million shares of common stock, having an exercise price of $2.46 per share, which warrants were initially issued by the Company in an underwritten public offering in March 2011. The fair value of these warrants on September 30, 2015 and December 31, 2014 was determined using a Black Scholes valuation model with the following key level 3 inputs:

	September 30, 2015	December 31, 2014
Risk-free interest rate	0.08 %	0.67 %
Expected life (in years)	0.46	1.21
Dividend yield	—	—
Volatility	53 %	49 %
Stock price	$ 4.07	$ 3.18

During the three and nine months ended September 30, 2015, the change in fair value of $38,000 of noncash income and $2.4 million of noncash expense, respectively, related to the March 2011 warrants was recorded as other income (expense) in the Company's condensed consolidated statement of operations.

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 September 30, 2015 and December 31, 2014:

(in thousands)	Fair Value as of September 30, 2015	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
February 2015 warrants	$ 12,965	$ —	$ —	$ 12,965
March 2011 warrants	6,330	—	—	6,330
Total common stock warrants	$ 19,295	$ —	$ —	$ 19,295

(in thousands)	Fair Value as of December 31, 2014	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
March 2011 warrants	3,961	—	—	3,961
Total common stock warrants	$ 3,961	$ —	$ —	$ 3,961

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, 2014	$ 3,961
Initial fair value of common stock warrants related to February 2015 offering	14,692
Change in fair value of common stock warrants during nine months ended September 30, 2015	659
Exercise of warrants during nine months ended September 30, 2015	(17)
Balance at September 30, 2015	$ 19,295

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 in the unaudited consolidated statements of operations for the three and nine months ended September 30, 2015 and 2014 as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Amortization of stock-based compensation:				
Research and development	$ 846	$ 663	$ 2,837	$ 2,180
General and administrative	630	535	1,955	1,752
	$ 1,476	$ 1,198	$ 4,792	$ 3,932

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 nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Employee Stock Options:				
Risk-free interest rate	1.77%	1.96%	1.70%	1.83%
Expected term (in years)	6.08	6.08	5.99	5.98
Dividend yield	—	—	—	—
Volatility	79%	94%	82%	94%
Weighted-average fair value of stock options granted	$ 2.98	$ 3.30	$ 3.08	$ 2.90

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Employee Stock Purchase Plan (ESPP):				
Risk-free interest rate	0.45%	0.22%	0.39%	0.20%
Expected term (in years)	1.25	1.25	1.24	1.24
Dividend yield	—	—	—	—
Volatility	50%	46%	50%	49%
Weighted-average fair value of ESPP purchase rights	$ 1.55	$ 1.46	$ 1.58	$ 1.60

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 volatilities of the Company. 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 $1.5 million and $4.8 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 nine months ended September 30, 2015, respectively, and $1.2 million and $3.9 million of stock-based compensation for the three and nine months ended September 30, 2014, respectively. As of September 30, 2015, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's equity incentive plans was approximately $12.0 million before forfeitures. This cost will be recorded as compensation expense on a straight-line basis over the remaining weighted average requisite service period of approximately 2.6 years.

Non-employee Stock-based Compensation Expense

The Company accounts for equity instruments issued to non-employees in accordance with ASC 505,*"Equity."* The equity instruments consisting of stock options are valued using the Black-Scholes option pricing model. The values attributable to these options are amortized over the service period and the unvested portion of these options is remeasured at each vesting date. In connection with the grant of stock options to non-employees, the Company recorded stock-based compensation of approximately $32,000 and $0.1 million for the three and nine months ended September 30, 2015, respectively, and $17,000 and $0.1 million for the three and nine months ended September 30, 2014, respectively.

Equity Incentive Plans

Equity Incentive Plans At September 30, 2015, 2,236,211 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, 2014	8,168,942	$ 3.69	—	—
Granted	2,278,500	$ 4.38	—	—
Exercised	(68,759)	$ 1.98	—	—
Forfeitures	(91,218)	$ 4.53	—	—
Outstanding at September 30, 2015	10,287,465	$ 3.84	7.11	$ 8,850,855
Vested and expected to vest September 30, 2015	10,215,027	$ 3.84	7.10	$ 8,842,746
Exercisable at September 30, 2015	6,481,218	$ 3.50	6.14	$ 8,345,365

The total intrinsic value of stock options exercised during the nine months ended September 30, 2015 and 2014 were $0.2 million and $0.2 million, respectively, as determined at the date of the option exercise. Cash received from stock option exercises was $0.1 million and $0.1 million for the nine months ended September 30, 2015 and 2014, respectively. The Company issues new shares of common stock upon exercise of options. In connection with these exercises, there was no tax benefit realized by the Company due to the Company's current loss position.

2004 Employee Stock Purchase Plan On January 1, 2015, 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 nine months ended September 30, 2015, plan participants had purchased 154,067 shares at an average purchase price of $3.49 for total cash proceeds of $0.5 million. At September 30, 2015, 126,837 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 September 30, 2015 and December 31, 2014:

(in thousands)	Fair Value as of September 30, 2015	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 4,867	$ 4,867	$ —	$ —
Certificates of deposit	841	—	841	—
Corporate debt securities	18,128	—	18,128	—
Government securities	17,253	—	17,253	—
Municipal securities	1,933	—	1,933	—
Commercial paper	13,392	—	13,392	—
Total cash equivalents and marketable securities	$ 56,414	$ 4,867	$ 51,547	$ —

(in thousands)	Fair Value as of December 31, 2014	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 3,369	$ 3,369	$ —	$ —
Certificates of deposit	2,505	—	2,505	—
Corporate debt securities	28,081	—	28,081	—
Government securities	19,123	—	19,123	—
Commercial paper	5,499	—	5,499	—
Total cash equivalents and marketable securities	$ 58,577	$ 3,369	$ 55,208	$ —

The Company invests in highly-liquid, investment-grade securities. The following is a summary of the Company's available-for-sale securities at September 30, 2015 and December 31, 2014:

As of September 30, 2015 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 4,867	$ —	$ —	$ 4,867
Certificates of deposit	841	—	—	841
Corporate debt securities	18,136	2	(10)	18,128
U.S. Government securities	17,249	4	—	17,253
Municipal securities	1,932	1	—	1,933
Commercial paper	13,392	—	—	13,392
	56,417	7	(10)	56,414
Less cash equivalents	13,709	—	—	13,709
Total marketable securities	$ 42,708	$ 7	$ (10)	$ 42,705

As of December 31, 2014 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 3,369	$ —	$ —	$ 3,369
Certificates of deposit	2,505	—	—	2,505
Corporate debt securities	28,094	1	(14)	28,081
U.S. Government securities	19,123	3	(3)	19,123
Commercial paper	5,499	—	—	5,499
	58,590	4	(17)	58,577
Less cash equivalents	8,368	—	—	8,368
Total marketable securities	$ 50,222	$ 4	$ (17)	$ 50,209

There were no realized gains or losses in the three and nine months ended September 30, 2015 and 2014, respectively.

As of September 30, 2015, the weighted average maturity for the Company's available for sale securities was 3.3 months, with the longest maturity being May 2016.

The following table provides the breakdown of the marketable securities with unrealized losses at September 30, 2015 (in thousands):

	In loss position for less than twelve months	
As of September 30, 2015 (in thousands):	Fair Value	Unrealized Loss
Corporate debt securities	11,234	(10)

The Company determined the fair value of the liability associated with its February 2015 and March 2011 warrants to purchase in aggregate 12.1 million shares of outstanding common stock using a Monte Carlo Simulation Model and a Black-Scholes Model, respectively. See detailed discussion in Note 4 — Stockholders' Equity (Deficit).

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,	
2015	$ 191
2016	768
2017	260
Thereafter	
Total	$ 1,219

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 September 30, 2015.

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.

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 clinical development of evofosfamide (formerly TH-302) and tarloxotinib bromide (proposed International Nonproprietary Name), or tarloxotinib (formerly referred to as TH-4000 or PR610) and their expected uses and benefits;
- anticipated clinical developmental events for evofosfamide and tarloxotinib, including the timing of the commencement, conduct and completion of clinical trials for evofosfamide and tarloxotinib, and the timing of any efficacy and/or safety analyses from ongoing trials;
- anticipated milestone payments from Merck KGaA;
- the success of any clinical trials that we and/or Merck KGaA commence;
- our and Merck KGaA's potential receipt of regulatory approvals, and our and Merck KGaA's satisfaction of ongoing regulatory review;
- our and Merck KGaA's ability to timely develop a viable commercial formulation of evofosfamide;
- whether any product candidates that we and/or Merck KGaA are able to commercialize are safer or more effective than other marketed products, treatments or therapies;
- uncertainties associated with obtaining and enforcing patents and other intellectual property rights;
- the costs and timing of obtaining drug supply for our pre-clinical and clinical activities;
- anticipated expenses, including clinical trial, research and development and personnel costs;
- the anticipated sufficiency of our cash resources and our need for additional capital;
- our projected financial performance; and
- the clinical development of [18-F]-HX4 and its expected uses and benefits.

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 biotechnology company using our expertise in the tumor microenvironment to discover and develop therapeutic agents that selectively target tumor cells for the treatment of patients living with cancer. Threshold's lead investigational small molecule, evofosfamide (formerly TH-302), is being evaluated in two pivotal Phase 3 clinical trials, one registrational Phase 2 clinical trial, and multiple earlier-stage clinical trials. We have a global license and co-development agreement for evofosfamide with Merck KGaA, Darmstadt, Germany, with an option to co-commercialize in the United States. Evofosfamide is a hypoxia-activated prodrug thought to be activated under severe hypoxic conditions, a feature of many cancers. We believe that by virtue of targeting tumor hypoxia, evofosfamide may have broad clinical applicability across many types of solid tumors and some hematological malignancies. We are also engaged in the development of tarloxotinib, a hypoxia-activated, irreversible epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) exclusively licensed from the University of Auckland, New Zealand. We are conducting two Phase 2 proof-of-concept clinical trials of tarloxotinib in EGFR-dependent cancer types. In October 2015, we announced that the U.S. Patent and Trademark Office issued the first two U.S. patents protecting tarloxotinib.

Evofosfamide is currently under evaluation in two pivotal Phase 3 trials: one in combination with doxorubicin versus doxorubicin alone in patients with locally advanced unresectable or metastatic soft tissue sarcoma, which we refer to as the 406 trial, and the other in combination with gemcitabine versus gemcitabine plus placebo in patients with locally advanced unresectable or metastatic pancreatic cancer, which we refer to as the MAESTRO trial (**M**etastatic or unr**ES**ectable pancrea**T**ic adenoca**R**cin**O**ma). Both Phase 3 trials are being conducted under Special Protocol Assessment (SPA) agreements with the U.S. Food and Drug Administration (FDA). The FDA and the European Commission have granted evofosfamide Orphan Drug designation for the treatment of soft tissue sarcoma and pancreatic cancer. The FDA has also granted Fast Track designation for evofosfamide for both soft tissue sarcoma and pancreatic cancer. The primary endpoint for both trials is overall survival. We currently expect to report top-line results for both trials around the end of 2015 and prepare for the potential submission of marketing applications for evofosfamide, assuming the data from the trials are supportive.

In June 2014, we announced the initiation of a 440-patient, randomized, double-blind, placebo-controlled trial of evofosfamide in combination with pemetrexed in patients with second-line advanced non-squamous non-small cell lung cancer (which we refer to as the 415 trial). The international Phase 2 trial is designed to support registration and will compare the combination of evofosfamide plus pemetrexed versus the combination of pemetrexed plus placebo as second-line therapy in this patient population. The study's primary efficacy endpoint is overall survival and secondary endpoints include safety and assessment of anti-tumor activity as determined by progression-free survival and objective response rate. Enrollment in the study is ongoing.

We are conducting a Phase 1/2 open label clinical trial of evofosfamide to determine the maximum tolerated dose, dose limiting toxicity, safety, tolerability, clinical activity, and pharmacokinetics of evofosfamide in patients with relapsed/refractory multiple myeloma (which we refer to as the 408 trial). The 408 trial is evaluating evofosfamide in combination with the proteasome inhibitor bortezomib (Velcade®) plus low-dose dexamethasone in patients with relapsed/refractory multiple myeloma. To date, a total of 62 patients have been enrolled in the trial. In December 2014, preliminary results from trial were reported at December 2014 American Society of Hematology annual meeting including that the recommended Phase 2 dose of evofosfamide in combination with bortezomib and low-dose dexamethasone was determined to be 340 mg/m^2. Updated data were presented at the 2015 annual meeting of the American Society of Clinical Oncology suggesting activity of evofosfamide plus dexamethasone and bortezomib in patients with treatment-resistant multiple myeloma. Threshold Plans to initiate dosing in the final arm of the trial in which approximately 38 additional patients will receive the combination regimen of evofosfamide plus dexamethasone in combination with the immunomodulatory drug pomalidomide (Pomalyst®).

We are in the process of closing a single-arm, multi-center Phase 2 clinical trial evaluating the efficacy and safety of evofosfamide in up to 40 patients with advanced melanoma, which we refer to as the 413 trial. The study was also designed to investigate range of biomarkers including serum, tumor, and PET imaging hypoxia biomarkers that may predict treatment outcomes and be associated with tumor response to evofosfamide therapy. Since initiation of the 413 trial in August 2013, the treatment landscape has changed with the approval of new therapies for the treatment of advanced melanoma, which has posed a challenge to achieving an acceptable patient recruitment rate and the appropriate patient population in our trial. A total of 11 patients have been enrolled to date. We currently have no further plans for evaluating evofosfamide for the treatment of advanced melanoma.

With respect to tarloxotinib, we initiated two Phase 2 proof-of-concept clinical trials of tarloxotinib in August 2015. The first trial is being conducted in collaboration with the Academic Thoracic Oncology Medical Investigators Consortium (ATOMIC) and is evaluating tarloxotinib in up to 37 patients with mutant EGFR non-small cell lung cancer who have been previously treated with an EGFR tyrosine kinase inhibitor and are progressing on treatment, but have not acquired the T790M resistance mutation. The second trial is evaluating tarloxotinib in up to 69 patients with recurrent or metastatic squamous cell carcinoma of the head and neck or skin. Enrollment in these trials is ongoing and preliminary data for both trials are expected to be available in the first half of 2016.

We are also working to broaden the potential applicability of evofosfamide as well as to discover additional therapeutics that will selectively target cancer cells. We also seek to optimize patient selectivity for our hypoxia-targeted therapeutics through the development of our [18F]-HX4 investigational hypoxia Positron Emission Tomography (PET) tracer. [18F]-HX4 is a radiolabeled tracer that we acquired from Siemens Healthcare Molecular Imaging to potentially identify and quantify the degree of hypoxia in tumors *in vivo*.

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 license and co-development agreement with Merck KGaA. As of September 30, 2015 and December 31, 2014, we had cash, cash equivalents and marketable securities of $56.4 million and $58.6 million, respectively.

We expect to continue to devote substantial resources to research and development in future periods as we complete our current clinical trials, start additional clinical trials under our collaboration with Merck KGaA or on our own and continue our discovery efforts. Research and development expenses net of reimbursements of Merck KGaA's 70% share of total evofosfamide development expenses are expected to increase in 2015 compared to 2014 due primarily to the continued execution of existing clinical trials and anticipated commencement of new clinical trials for evofosfamide. 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, milestone payment forecasts and spending assumptions. Although 70% of the collaboration expenditures related to the development of evofosfamide are expected to be funded by Merck KGaA, we expect that we will need to raise additional capital to complete the clinical development of evofosfamide, to continue to develop tarloxotinib, and to support new in-house development programs or to in-license or otherwise acquire and develop additional products or programs. Research and development expenses may fluctuate significantly from period to period as a result of the progress and results of our clinical trials.

Results of Operations

Revenue. For the three and nine months ended both September 30, 2015 and September 30, 2014, we recognized $3.7 million and $11.0 million in revenue, respectively, from the amortization of the aggregate of $110 million in upfront and milestone payments earned in 2013 and 2012 from our collaboration with Merck KGaA. We are amortizing the upfront payment and milestones earned over the period of performance (product development period). We will periodically review and, if necessary, revise the estimated periods of performance of our collaboration. We expect revenue to remain unchanged in 2015 compared to 2014 due to the amortization of milestone payments earned in 2013 and 2012.

Research and Development. Research and development expenses were $8.1 million for the three months ended September 30, 2015 compared to $8.9 million for the three months ended September 30, 2014, in each case net of the reimbursement for Merck KGaA's 70% share of total development expenses for evofosfamide. The $0.8 million decrease in expenses was due primarily to a $1.1 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 $0.1 million in consulting expenses, partially offset by an increase of $0.4 million in employee related expenses. Research and development expenses were $28.9 million for the nine months ended September 30, 2015 compared to $27.2 million for the nine months ended September 30, 2014. The $1.7 million increase in expenses was due primarily to an increase of $1.5 million in employee related expenses and a $0.6 million increase in clinical development expenses net of the reimbursement for Merck KGaA's 70% share of total development expenses for evofosfamide, partially offset by a decrease of $0.5 million in consulting expenses.

During the three and nine months ended September 30, 2015 and 2014, we were engaged in two primary research and development programs: the development of evofosfamide, which is the subject of two ongoing pivotal Phase 3 clinical trials and multiple Phase 2 and Phase 1 clinical trials; and our discovery research program aimed at identifying new drug candidates. During the three and nine months ended September 30, 2015, we were also engaged in preclinical evaluation of tarloxotinib as well as clinical activities related to our two ongoing Phase 2 proof-of-concept studies of tarloxotinib. Research and development expenses consist primarily of costs of conducting clinical trials, salaries and related costs for personnel including non-cash 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Evofosfamide	$ 5,197	$ 7,669	$ 21,491	$ 23,078
Tarloxotinib	1,670	—	3,578	—
Discovery Research	1,214	1,237	3,833	4,145
Total Research and Development Expenses	$ 8,081	$ 8,906	$ 28,902	$ 27,223

Research and development expenses associated with our internally discovered compound evofosfamide were $5.2 million and $21.5 million for the three and nine months ended September 30, 2015, respectively, and $7.7 million and $23.1 million for the three and nine months ended September 30, 2014, respectively, in each case net of the reimbursement for Merck KGaA's 70% share of total development expenses for evofosfamide. The decrease of $2.5 million and $1.6 million during the three and nine months ended September 30, 2015, respectively, compared to the same periods in 2014, net of reimbursement for Merck KGaA's 70% share of total development expenses for evofosfamide, was due primarily to a decrease in development costs for the 415 and 406 trials partially offset by an increase in development costs for the MAESTRO trial. Evofosfamide continues to progress through the 406 trial, the MAESTRO trial, the 415 trial that was initiated in June 2014, and various other earlier stage trials.

Research and developments expenses associated with tarloxotinib, which we licensed rights to September 2014, were $1.7 million and $3.6 million for the three and nine months ended September 30, 2015, respectively, and were related to preclinical studies and clinical trial activities for our two ongoing Phase 2 proof-of-concept clinical trials of tarloxotinib. Discovery research and development expenses were $1.2 million and $3.8 million for the three and nine months ended September 30, 2015, respectively, compared to $1.2 million and $4.1 million for the three and nine months ended September 30, 2014, respectively. We continue to focus our efforts towards discovering and developing new drug candidates from our hypoxia targeted therapeutic technology.

The largest component of our total operating expenses is our ongoing investment in our research and development activities, primarily with respect to the clinical development of evofosfamide, and we expect to continue to devote substantial resources to research and development in future periods as we complete our current clinical trials of evofosfamide and tarloxotinib, start additional clinical trials of evofosfamide, conduct additional development of tarloxotinib if the results of our ongoing Phase 2 proof of concept studies of tarloxotinib are supportive of continued development, and continue our discovery efforts under our collaboration with Merck as well as on our own. Research and development expenses, net of reimbursements of Merck KGaA's 70% share of total evofosfamide development expenses, are expected to increase in 2015 compared to 2014 due primarily to the continued execution of existing clinical trials and anticipated commencement of new clinical trials for evofosfamide. Expenses will fluctuate based upon many factors including the degree of collaborative activities, timing of manufacturing batches of evofosfamide and tarloxotinib API and drug product, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event.

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 may include entering into collaborations with third parties, such as our evofosfamide collaboration with Merck KGaA, to participate in the development and commercialization of our product candidates. In these situations, 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 Merck KGaA 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 and Merck KGaA's prior and ongoing clinical studies and the willingness of Merck KGaA 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 and Merck KGaA 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 a very 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. 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 $2.4 million and $7.5 million for the three and nine months ended September 30, 2015, respectively, compared to $2.4 million and $7.5 million for the three and nine months ended September 30, 2014. We currently expect our general and administrative expenses to slightly increase in 2015 compared to 2014 due to increased employee-related and consulting expenses to support activities related to our collaboration with Merck KGaA and the clinical development of evofosfamide and tarloxotinib.

Interest Income (Expense), Net. Interest income (expense), net for the three months and nine months ended September 30, 2015 was $27,000 and $0.1 million, respectively, compared to $27,000 and $0.1 million of interest income for same periods in 2014.

Other Income (Expense). Other income (expense) for the three months ended September 30, 2015 was non-cash income of $0.3 million compared to non-cash expense of $0.3 million for the three months ended September 30, 2014. The non-cash income during the three months ended September 30, 2015 was due to a net decrease in the fair value of the outstanding warrants as result of a decrease in the underlying price of the common stock during those periods. Other income (expense) for the nine months ended September 30, 2015 was non-cash expense of $0.6 million compared to non-cash income of $7.8 million, for the nine months ended September 30, 2014. The non-cash expense during the nine months ended September 30, 2015 was due to a net increase in the fair value of the outstanding warrants as result of an increase in the underlying price of the common stock, whereas the non-cash income during the nine months ended September 30, 2014 was due to a decrease in the fair value of the outstanding warrants as a result of a decrease in the underlying price of the common stock. ASC 815 *"Derivatives and Hedging"* requires that stock warrants with certain terms need to be accounted for as a liability with changes to their fair value recognized in the consolidated statement of operations.

Liquidity and Capital Resources

We have 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 license and co-development agreement with Merck KGaA. To date we have received $110 million in upfront and milestone payments from our collaboration with Merck KGaA. We had cash, cash equivalents and marketable securities of $56.4 million and $58.6 million at September 30, 2015 and December 31, 2014, respectively, available to fund operations.

In February 2015, we completed an underwritten public offering of 8.3 million shares of our common stock and accompanying warrants to purchase up to 8.3 million shares of our common stock. Net proceeds from the sale of common stock and accompanying warrants, excluding the proceeds, if any, from the exercise of the warrants issued in the offering, were approximately $28.1 million after deducting the underwriting discount and offering expenses payable by us.

Net cash used in operating activities for the nine months ended September 30, 2015 was $30.4 million compared to net cash used in operating activities of $17.6 million for the nine months ended September 30, 2014. The increase of $12.8 million in cash used in operations was primarily attributable to the $12.5 million of milestone payment received from the Merck KGaA collaboration during the nine months ended September 30, 2014.

Net cash provided by investing activities for the nine months ended September 30, 2015 was $6.9 million compared with net cash provided by investing activities of $16.5 million for the nine months ended September 30, 2014. The $9.6 million decrease in cash provided by investing activities was due primarily to a decrease in proceeds from the sales and maturities of marketable securities net of an increase in the purchase of marketable securities.

Net cash provided by financing activities for the nine months ended September 30, 2015 and 2014 was $28.8 million and $5.1 million, respectively. The $23.7 million increase 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, partially offset by $4.4 million of proceeds received from the exercise of warrants during the nine months ended September 30, 2014.

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, milestone payment forecasts and spending assumptions. Although 70% of the collaboration expenditures related to the development of evofosfamide are expected to be funded by Merck KGaA, we expect that we will need to raise additional capital to complete the clinical development of evofosfamide, to continue to develop tarloxotinib, and to support new in-house development programs or to in-license or otherwise acquire and develop additional products or programs.

We may seek to raise capital through a variety of sources, including:

- the public equity market, including pursuant to our "at-the-market" sales agreement with Cowen and Company, LLC, or Cowen as discussed below;
- private equity financing;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

Our ability to raise additional funds will depend, in part on the outcome of our clinical trials and other clinical and regulatory events, as well as factors related to financial, economic, and market conditions, collaboration or license agreement with others and factors related to financial, economic and market conditions, many of which are beyond our control. In addition, our ability to raise additional capital may be dependent upon our common stock remaining listed on the NASDAQ Capital Market. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through additional arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail or eliminate some or all of our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. In addition, we may have to delay, reduce the scope of or eliminate some of our research and development, which could delay the time to market for any of our product candidates, if adequate funds are not available.

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

"At-the-Market" Sales Agreements

On November 2, 2015, we entered into a sales agreement, with 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 will 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 will 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. The number of shares we are able to sell under the Cowen Sales Agreement will be limited in practice based on the trading volume of our common stock. In addition, the issuance and sale of common stock under the Cowen Sales Agreement, if any, is subject to the effectiveness of our registration statement on Form S-3 to be filed with the Securities and Exchange Commission. Accordingly, we have not yet sold any common stock pursuant to the Cowen Sales Agreement. In connection with our entry into the Cowen Sales Agreement, we terminated our prior at market issuances sales agreement that we entered into with MLV & Co. LLC on August 1, 2014, or the MLV Sales Agreement. We did not sell any common stock under the MLV 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 nine months ended September 30, 2015, 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, 2014, which we filed with Securities and Exchange Commission on March 3, 2015.

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, 2014, which we filed with the SEC on March 3, 2015.

Recent Accounting Pronouncements Not Yet Adopted

In August 2014, the Financing Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This guidance is effective for annual periods ending after December 15, 2016, and, as such, will be applicable to us in 2017. Early adoption is permitted. We do not expect this standard to have a material impact on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue From Contracts With Customers, requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. Early adoption is not permitted. The updated standard becomes effective for us in the first quarter of fiscal 2018. We have not yet selected a transition method and are currently evaluating the effect that the updated standard will have onour consolidated financial statements and related disclosures.

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 nine months ended September 30, 2015, 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, 2014.

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 September 30, 2015, 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 September 30, 2015 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 September 30, 2015 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 are substantially dependent upon the success of evofosfamide (formerly TH-302). If we and Merck KGaA are unable to successfully develop and obtain regulatory approval for evofosfamide, our ability to generate revenue from product sales will be significantly delayed.

Our development activities are primarily focused on evofosfamide and substantially all of our efforts and expenditures over the next few years are expected to be devoted to evofosfamide. Accordingly, our future prospects are substantially dependent on the successful development, regulatory approval and commercialization of evofosfamide. In addition, in February 2012, we entered into a global license and co-development agreement for evofosfamide with Merck KGaA, with an option to co-commercialize in the United States. The success of this collaboration and the activities of Merck KGaA will significantly impact the development and potential commercialization of evofosfamide. In addition, evofosfamide is not expected to be commercially available in the near term, if at all. Further, the commercial success of evofosfamide 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. If we and Merck KGaA are unable to successfully develop, obtain regulatory approval for and commercialize evofosfamide, our ability to generate revenue from product sales will be significantly delayed and our business would be materially and adversely affected, and we may not be able to earn sufficient revenues to continue as a going concern.

In addition, the failure of evofosfamide to achieve successful clinical trial endpoints, delays in clinical trial enrollment or events or in the clinical development of evofosfamide generally, unanticipated adverse side effects related to evofosfamide or any other adverse developments or information related to evofosfamide, including inconclusive results from the ongoing Phase 3 clinical trials, would significantly harm our business, our prospects and the value of our common stock. Evofosfamide is currently the subject of two ongoing pivotal Phase 3 clinical trials being conducted under special protocol assessments, or SPAs, with the U.S. Food and Drug Administration, or FDA: the "406 trial" evaluating evofosfamide in combination with doxorubicin versus doxorubicin alone in patients with soft tissue sarcoma, and the MAESTRO trial of evofosfamide in combination with gemcitabine in patients with previously untreated, locally advanced unresectable or metastatic pancreatic adenocarcinoma, being conducted by Merck KGaA. There is no guarantee that the results of either of the ongoing Phase 3 clinical trials will be positive. Negative or inconclusive results in either of the Phase 3 clinical trials could cause the FDA to require that we or Merck KGaA repeat such trial or conduct additional clinical trials, or we and/or Merck KGaA could determine to abandon the development of evofosfamide for the soft tissue sarcoma and/or pancreatic cancer indications or otherwise. Negative or inconclusive results in either of the Phase 3 clinical trials or other clinical trials of evofosfamide could also result in Merck KGaA terminating our license and co-development agreement for evofosfamide, in which case, we would become responsible for the costs of development and commercialization of evofosfamide, and there can be no assurance we would be able to do fund those costs, or to find another collaborator for the continued development and commercialization of evofosfamide. Even if we believe that the data from required Phase 3 clinical trials are positive, the FDA could require additional trials or other testing before approving evofosfamide for marketing. In this regard, the FDA has substantial discretion in the approval process and may refuse to approve any application or decide that our or Merck KGaA's data is insufficient for approval and require additional preclinical, clinical or other studies. Varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of evofosfamide. The FDA could also require additional studies or trials to satisfy particular safety concerns noted in our or Merck KGaA's preclinical or clinical testing. Even if the FDA or other regulatory agency approves evofosfamide, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product and may impose ongoing commitments or requirements for post-approval studies, including additional research and development and clinical trials. The FDA and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval. We and Merck KGaA will need to obtain regulatory approval from authorities in foreign countries to market evofosfamide in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we or Merck KGaA fail to obtain approvals from foreign jurisdictions, the geographic market for evofosfamide would be limited.

Although we have obtained agreement with the FDA on an SPA for our pivotal Phase 3 clinical trial of evofosfamide in combination with doxorubicin versus doxorubicin alone in patients with soft tissue sarcoma and Merck KGaA has obtained agreement with the FDA on an SPA for the pivotal Phase 3 clinical trial of evofosfamide in combination with gemcitabine for the treatment of previously untreated locally advanced unresectable or metastatic pancreatic cancer, an agreement on an SPA does not guarantee any particular outcome from regulatory review, including any regulatory approval.

We have obtained an agreement with the FDA on an SPA for the 406 trial of evofosfamide. Merck KGaA has also obtained an agreement with the FDA on an SPA for the MAESTRO trial of evofosfamide. The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a new drug application, or NDA, and provides a product sponsor with an agreement confirming that the design and size of a trial will be appropriate to form the primary basis of an efficacy claim for an NDA if the trial is performed according to the SPA. Reaching agreement on an SPA is not an indication of approvability. Even if we believe that the data from a clinical trial are supportive, an SPA is not a guarantee of approval, and we cannot be certain that the design of, or data collected from, a trial will be adequate to demonstrate safety and efficacy, or otherwise be sufficient to support regulatory approval. There can be no assurance that the terms of an SPA will ultimately be binding on the FDA, and the FDA is not obligated to approve an NDA, if any, even if the clinical outcome is positive. The FDA retains significant latitude and discretion in interpreting the terms of an SPA and the data and results from a clinical trial, and can require trial design changes or additional studies if issues arise essential to determining safety or efficacy. Data may subsequently become available that causes the FDA to reconsider the previously agreed upon scope of review and the FDA may have subsequent safety or efficacy concerns that override an SPA, and we can give no assurance that as clinical trials proceed or as part of an NDA review process, if any, the FDA will determine that a previously approved SPA is still valid. As a result, we do not know how the FDA will interpret the parties' respective commitments under the SPA agreements, how it will interpret the data and results from the 406 trial and the MAESTRO trial, or whether evofosfamide will receive any regulatory approvals.

Additionally, an SPA may be changed only with written agreement of the FDA and sponsor, and any further changes we or Merck KGaA may propose to our respective protocols will remain subject to the FDA's approval. The FDA may not agree to any such amendment and, even if they agree, they may request other amendments to the trial design that could require additional cost and time, as well as increase the degree of difficulty in reaching clinical endpoints. As a result, even with an SPA, we cannot be certain that the trial results from the 406 trial or the MAESTRO trial will be found to be adequate to support an efficacy claim and product approval. Therefore, despite the potential benefits of SPA agreements, significant uncertainty remains regarding the clinical development of and regulatory approval process for evofosfamide and it is possible that we and Merck KGaA might never receive any regulatory approvals for evofosfamide.

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 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 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 also may not be confirmed by later analysis or in subsequent larger clinical trials, including in the 406 trial the 415 trial and the MAESTRO trial. In particular, the results that achieved the primary endpoint for progression-free survival in the Phase 2b trial of evofosfamide in pancreatic cancer may not predict the results of overall survival for patients in the same study or subsequent studies, including in the MAESTRO trial. Likewise, the results in the Phase 1/2 trial of evofosfamide in patients with soft tissue sarcoma may not predict the results of overall survival for patients in the same study or subsequent studies, including in the 406 trial. As a result, despite the results reported in earlier clinical trials for evofosfamide, we do not know whether the ongoing Phase 3 clinical trials or other clinical trials that we or Merck KGaA may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market evofosfamide. Our and Merck KGaA's failure to successfully complete clinical trials and obtain regulatory approval for evofosfamide would materially and adversely affect our business and our stock price.

We are dependent upon our collaborative relationship with Merck KGaA to further develop, manufacture and commercialize evofosfamide.

Our success in developing, manufacturing and commercializing evofosfamide depends on our relationship with Merck KGaA. On February 3, 2012, we entered into a global license and co-development agreement for evofosfamide with Merck KGaA, Darmstadt, Germany, with an option to co-commercialize in the United States. In the United States, we have primary responsibility for development of evofosfamide in the soft tissue sarcoma indication. We and Merck KGaA will jointly develop evofosfamide in all other cancer indications being pursued. We have rights to co-promote evofosfamide in the United States, which we can exercise by giving notice during specified periods, and have the right to co-commercialize evofosfamide if certain development or sales milestones are achieved.

We are subject to a number of risks associated with our dependence on our collaborative relationship with Merck KGaA, including:

- our ability, together with Merck KGaA, to achieve developmental and commercial milestones that will trigger payments to us under the agreement;
- our ability to fund 30% of the global development expenses of evofosfamide;
- we are not able to control any decisions by Merck KGaA regarding the amount and timing of resource expenditures for the development and commercialization of evofosfamide;
- Merck KGaA may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon evofosfamide, repeat or conduct new clinical trials or require a new formulation of evofosfamide for clinical testing;
- possible disagreements with Merck KGaA as to development plans, clinical trials, regulatory marketing or sales;
- our need to develop a sales force to co-promote or co-commercialize evofosfamide in the United States if we chose to do so, or our reliance on Merck KGaA to promote evofosfamide in the United States;
- our inability to co-promote or co-commercialize evofosfamide in any country outside the United States, which makes us solely dependent on Merck KGaA to promote and commercialize evofosfamide in foreign countries;
- if evofosfamide is approved for commercial sale and we exercise our co-promotion or co-commercialization rights for evofosfamide in the United States, if we do not receive timely and accurate information from Merck KGaA regarding sales activities, expenses and resulting operating profits and losses, our estimates at a given point of time could be incorrect and we could be required to record adjustments in future periods or restate our financial results for prior periods;
- loss of significant rights if we fail to meet our obligations under the collaboration agreement;
- Merck KGaA may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- adverse regulatory or legal action against Merck KGaA resulting from failure to meet healthcare industry compliance requirements in the promotion and sale of evofosfamide, including federal and state reporting requirements;
- Merck KGaA could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;
- changes in key management personnel at Merck KGaA, including Merck KGaA's representatives on the joint steering committee or other committees that are administering the agreement; and
- possible disagreements with Merck KGaA regarding interpretation or enforcement of the agreement that could result in the delay or termination of the research, development or commercialization of evofosfamide or that could result in costly litigation or arbitration that diverts management's attention and resources.

We have limited ability to direct Merck KGaA in its development of evofosfamide and we may be unable to obtain any remedy against Merck KGaA if they fail to do so, or to do so in a manner that we think is inadequate. Merck KGaA may not have sufficient expertise to develop, promote or obtain reimbursement for oncology products in the United States and may fail to devote appropriate resources to this task. Merck KGaA's development plans may be slower than or different from our plans were, when we were developing evofosfamide on our own, leading to changes and delays in development and in the achievement of milestones that would impact payments to us under our agreement with Merck KGaA. In addition, Merck KGaA may establish a sales and marketing infrastructure for evofosfamide that is not appropriate for the sales opportunity or establish this infrastructure too early or late in view of the ultimate timing of potential regulatory approvals. We are at risk with respect to the success or failure of Merck KGaA's development and commercial decisions related to evofosfamide as well as the extent to which Merck KGaA succeeds in the execution of its strategy. Merck KGaA's development of other products may affect its incentives to develop and commercialize evofosfamide and cause it to take actions that may be different from those we would take.

Under the terms of the agreement, we and Merck KGaA must agree on the development plan for evofosfamide. If we and Merck KGaA cannot agree, clinical trial progress could be significantly delayed. Further, we are required to fund 30% of the global development expenses of evofosfamide; if we cease funding development of evofosfamide under the collaboration agreement, then we will be entitled to receive a royalty, but will lose our right to co-commercialize evofosfamide and share in profits, which could substantially harm our business, financial condition and prospects.

Merck KGaA has the right to terminate the agreement on 90 days' prior written notice, or following our uncured material breach. If Merck KGaA terminates the agreement at its election, then we would become responsible for the costs of development and commercialization of evofosfamide, and there can be no assurance we would be able to do fund those costs, or to find another collaborator for the continued development and commercialization of evofosfamide. If we are unable to maintain our collaborative relationship with Merck KGaA, we may be unable to continue development, manufacturing and any marketing activities for evofosfamide at our own expense.

Even if we were able to continue these activities at our expense, this would significantly increase our capital and infrastructure requirements, would necessarily impose delays on our evofosfamide development program, may limit the indications we are able to pursue and could prevent us from effectively developing and commercializing evofosfamide. In turn, this could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing evofosfamide, which are now being largely funded by Merck KGaA. In the future, we may not be able to locate third-party collaborators to develop and market evofosfamide and we may lack the capital and resources necessary to develop evofosfamide alone. Disputes with Merck KGaA may delay or prevent us from further developing, manufacturing or commercializing evofosfamide, and could lead to litigation against Merck KGaA, which could be time consuming and expensive.

Delays in our or Merck KGaA's 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 or Merck KGaA's 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 planned clinical trials 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; and
- disagreements with Merck KGaA on development plans.

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 and/or Merck KGaA do not successfully complete our clinical trials on schedule, the price of our common stock may 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 and/or Merck KGaA can obtain regulatory approval for a product candidate, we and/or Merck KGaA 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 or Merck KGaA successfully completing clinical testing within the time frames we have planned or anticipated, or at all. We or Merck KGaA may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us or Merck KGaA from receiving regulatory approval or commercializing our product candidates, including the following:

- our or Merck KGaA's clinical trials may produce negative or inconclusive results, and we or Merck KGaA may decide, or regulators may require us and Merck KGaA, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;
- clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- enrollment in clinical trials for our product candidates may be slower than we anticipate, resulting in significant delays and additional expense;
- we, or Merck KGaA 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, some of our clinical trials are 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 ongoing 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, as part of our study protocol for the 406 trial, an IDMC conducted pre-planned interim efficacy and safety analyses of unblinded data for the 406 trial in September 2014 and recommended that the 406 trial should continue as planned to its natural conclusion. The recommended termination or modification of any of our or Merck KGaA's ongoing late-stage clinical trials by an IDMC or DSMB, could materially and adversely impact the future development of evofosfamide, 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 and other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. We and Merck KGaA 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 or Merck KGaA will obtain regulatory approval for any of our product candidates. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenues and to achieve profitability.

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

Our product candidates are based on targeting the microenvironment of solid tumors 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 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 our or Merck KGaA's 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 we and Merck KGaA are using in 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 and/or Merck KGaA may be required to repeat some or all of our respective Phase 3 clinical trials of evofosfamide, or we and Merck KGaA 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 and Merck KGaA have received orphan drug designation for evofosfamide, we may not receive orphan drug marketing exclusivity for evofosfamide. Even if we and/or Merck KGaA obtain orphan drug exclusivity, orphan drug exclusivity would afford us and Merck KGaA 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 and Merck KGaA have received orphan drug designation for evofosfamide for the treatment of soft tissue sarcoma and 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 and Merck KGaA 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 soft tissue sarcoma and/or 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 and/or Merck KGaA.

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 and Merck KGaA 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. Although we have obtained a fast track designation from the FDA for evofosfamide for the treatment of previously untreated patients with metastatic or locally advanced unresectable soft tissue sarcoma, and 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 or Merck KGaA's fast track designation at any time. If we and/or Merck KGaA lose fast track designation for evofosfamide, the approval process may be delayed. In addition, fast track designation does not guarantee that we or Merck KGaA 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. 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 to discuss our potential [18F]-HX4 companion diagnostic development plans, and therefore cannot yet know what the FDA 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.

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

We are focused on the design and development of novel cyotoxic prodrug compounds for the treatment of cancer. However, evofosfamide and tarloxotinib are currently our only product candidates in clinical development and we may be unable to discover and develop additional product candidates suitable for clinical testing. Likewise our strategy may include acquiring or in-licensing 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 may not 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 upon our discovering and/or identifying and obtaining product candidates, our ability to develop those product candidates and the availability of funding 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.

Even if we obtain regulatory approval, our marketed drugs will be subject to ongoing regulatory review. If we or Merck KGaA fail tœomply with continuing United States and foreign regulations, 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 and /or Merck KGaA may develop, we and Merck KGaA 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 the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. Manufacturers of our products, if approved, will be subject to ongoing FDA requirements 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.

The FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses and marketing of pharmaceutical products.

Even if we and/or Merck KGaA obtain regulatory approval for evofosfamide, we and/or Merck KGaA would be subject to ongoing requirements by the FDA and comparable foreign 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 the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign 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 in the United States will be heavily scrutinized by the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, state attorneys general, members of Congress 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 the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities. In the United States, 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.

These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs. 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.

Our license and co-development agreement with Merck KGaA gives us the right, under certain circumstances, to co-promote or co-commercialize evofosfamide. 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 evofosfamide, if approved, and if we exercise our rights to do so, 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.

We have incurred losses in each year since our inception in 2001, and we expect to incur losses for the foreseeable future. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. For the nine months ended September 30, 2015, we had an operating loss of $25.3 million and a net loss of $25.9 million, including $0.7 million in non-cash expense related to the change in the fair value of outstanding warrants. Clinical trials and activities associated with discovery research are costly. 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, such as Merck KGaA, 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.

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

Our quarterly and annual results of operations are likely to fluctuate based on the timing of milestones and payments under our license and co-development agreement with Merck KGaA. 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.

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

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

- the achievement of certain milestone events under, and the continued effectiveness of, our collaborative arrangement with Merck KGaA;
- the extent of product development funding under our collaborative arrangement with Merck KGaA;
- the terms and timing of any future collaborative, licensing, acquisition or other arrangements that we may establish;
- the scope, rate of progress and cost of our clinical trials and other research and 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, milestone payment forecasts and spending assumptions. Although 70% of the collaboration expenditures related to development of evofosfamide are expected to be funded by Merck KGaA, we expect that we will need to raise additional capital to complete the clinical development of evofosfamide, to develop tarloxotinib, and to support new in-house development programs or to in-license or otherwise acquire and develop additional product candidates or programs.

We may seek to raise capital through a variety of sources, including:

- the public equity market, including pursuant to our "at-the-market" sales agreement, with Cowen and Company, LLC, or Cowen;
- private equity financing;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

Our ability to raise additional funds will depend, in part on the outcome of our clinical trials and other clinical and regulatory events, as well as factors related to financial, economic, and market conditions, collaboration or license agreements with others and factors related to financial, economic and market conditions, many of which are beyond our control. In addition, our ability to raise additional capital may be dependent upon our common stock remaining listed on the NASDAQ Capital Market. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through additional arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail or eliminate some or all of our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. In addition, we may have to delay, reduce the scope of or eliminate some of our research and development, which could delay the time to market for any of our product candidates, if adequate funds are not available.

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

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly our Chief Executive Officer, Dr. Harold E. Selick, and our Chief Scientific Officer, Dr. Mark D. Matteucci. We do not have an employment agreement with Drs. Selick or Matteucci. The loss of the services of Drs. Selick or Matteucci or one or more of our other key employees could delay or have an impact on the successful completion of our clinical trials or the development of additional product candidates.

As of September 30, 2015, we had 64 employees. Our success will depend on our ability to retain and motivate remaining personnel and hire additional qualified personnel when required. Competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

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 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 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. Under our license and co-development agreement with Merck KGaA, Merck KGaA has exclusive rights to manufacture evofosfamide for clinical and commercial use, except that we have the right to obtain clinical supply of evofosfamide for clinical trials for United States approval of evofosfamide for soft tissue sarcoma and for any other clinical trials for which we are responsible. For these latter cases, we can obtain clinical supply directly from existing or new suppliers. To date, however, we have relied on, and we expect to continue to rely on, a limited number of third party single source contract manufacturers and excipient suppliers for the evofosfamide API and evofosfamide drug product to meet our and Merck KGaA's 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 and Merck KGaA's clinical trials. While we have developed plans to meet our and Merck KGaA's clinical supply needs for our ongoing clinical trials of evofosfamide, we base our estimates for the amount of drug product we will need on assumptions about trial enrollment and trial dose levels. If we are not successful in having sufficient quantities of evofosfamide API and drug product manufactured, or if manufacturing is interrupted at our single source contract manufacturers and excipient suppliers for evofosfamide API and evofosfamide drug product 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 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 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. 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 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, Merck KGaA may need to enter into agreements for additional supplies of evofosfamide to commercialize it or develop such capability itself. We cannot be certain that Merck KGaA can do so on favorable terms, if at all. Merck KGaA will need to satisfy all current good manufacturing practice, or cGMP, regulations, including passing specifications. Merck KGaA's 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 or Merck KGaA as applicable, 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 and/or Merck KGaA 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 or Merck KGaA 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 and/or Merck KGaA 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 planned or 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 planned or 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 and 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 and foreign agencies for compliance with cGMP regulations, similar foreign regulations and other regulatory standards. We do not have control over our contract manufacturers' compliance with these regulations and standards. Any failure by our third-party manufacturers or suppliers to comply with applicable regulations could result in sanctions being imposed on them (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, warning letters, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

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

We may use clinical research organizations to assist in conduct of our clinical trials. There are numerous alternative sources to provide these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This risk is heightened for clinical trials conducted outside of the United States, where it may be more difficult to ensure that clinical trials are conducted in compliance with FDA requirements. Any third-party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to submit NDAs to the FDA, 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 protectour 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, Merck KGaA, Auckland Uniservices Ltd. 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 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 sale for soft tissue sarcoma, evofosfamide could potentially compete with doxorubicin or the combination of doxorubicin and ifosfamide, generic products sold by many manufacturers. If approved for commercial sale for treatment-resistant non-small cell lung cancer, tarloxotinib could potentially compete with other EGFR-TKIs currently in late-stage clinical development including AstraZeneca's AZD-9291, 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 recent 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 or Merck KGaA's 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 future profitability.

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

We may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

Our research and development activities use biological and hazardous materials that are dangerous to human health and safety or the environment. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from these materials. We are also subject to regulation by the Occupational Safety and Health Administration, or OSHA, the California and federal environmental protection agencies and to regulation under the Toxic Substances Control Act. OSHA or the California or federal environmental protection 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

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

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

- adverse results or delays in our or Merck KGaA's clinical trials of evofosfamide;
- announcements of FDA non-approval of our product candidates, or delays in the FDA or other foreign regulatory agency review process;
- our or Merck KGaA's failure to meet milestones that would have given rise to payments under our agreement with Merck KGaA;
- announcements by Merck KGaA related to the development of evofosfamide or announcements related to our agreement with Merck KGaA;
- adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing processes or sales and marketing activities;
- announcements regarding our research and development of product candidates, including clinical trial results or delays in the any future clinical trials, or announcements regarding the results of or delays in clinical trials of our product candidates, and investor perceptions thereof;
- announcements of technological innovations, patents or new products by us or our competitors;
- regulatory developments in the United States and foreign countries;
- any lawsuit involving us or our product candidates;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
- developments concerning any strategic alliances or acquisitions we may enter into;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts or lack of analyst coverage;
- deviations in our operating results from the estimates of analysts;
- sales of our common stock by us, including under our sales agreement with Cowen;
- sales of our common stock by our executive officers, directors and significant stockholders or sales of substantial amounts of common stock; and
- loss of any of our key scientific or management personnel.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. 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 September 30, 2015, we had 71,431,059 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. To the extent that we sell shares of our common stock pursuant to the sales agreement with Cowen, 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 March 16, 2011, we issued warrants to purchase an aggregate of 5,725,227 shares of our common stock, at an exercise price of $2.46 per share. As of September 30, 2015, warrants to purchase 1,889,062 shares of common stock issued in March 2011 had been exercised. 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 will be subject to adjustment (including to as low as $3.62 per share). In addition, as of September 30, 2015, there were 10,287,465 shares of our common stock issuable upon the exercise of outstanding options having a weighted-average exercise price of $3.84 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, our preferred shares rights agreement 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.

In addition, in August 2006, our board of directors adopted a preferred shares rights agreement, or the rights plan, the provisions of which could make it more difficult for a potential acquirer to consummate a transaction without the approval of our board of directors. The rights plan could also reduce the price that investors might be willing to pay for shares of our common stock and result in the market price being lower than it would be without the rights plan. In addition, the existence of the rights plan itself may deter a potential acquiror from acquiring us. As a result, either by operation of the rights plan or by its potential deterrent effect, mergers and acquisitions of us that our stockholders may consider in their best interests may not occur.

We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable 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

On November 2, 2015, we entered into a Sales Agreement with Cowen and Company, LLC, or Cowen, which provides that, upon the terms and subject to the conditions and limitations set forth in the 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. The issuance and sale of these shares by the Company under the Sales Agreement, if any, is subject to the effectiveness of our registration statement on Form S-3 to be filed with the Securities and Exchange Commission (the "2015 Form S-3 Registration Statement"). We make no assurances as to if or whether the 2015 Form S-3 Registration Statement will become effective or, if it does become effective, as to the continued effectiveness of the 2015 Form S-3 Registration Statement.

Cowen may sell the common stock by any method that is deemed to be an"at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on The Nasdaq Capital Market or any other trading market for our common stock, or sales to or through a market maker other than on an exchange. If authorized by us in writing, Cowen may also sell our shares of common stock by any other method permitted by law, including negotiated transactions. Subject to the terms and conditions of the Sales Agreement, Cowen will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions that we may impose). We are not obligated to make any sales of common stock under the Sales Agreement. The offering of our common stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all of our common stock subject to the Sales Agreement or (ii) the termination of the Sales Agreement as permitted therein. The Sales Agreement may be terminated by us or Cowen at any time upon 10 days' notice to the other party, or by Cowen at any time in certain circumstances, including the occurrence of a material adverse change with respect to us. We will pay Cowen an aggregate commission rate equal to up to 3.0% of the gross proceeds of the sales price per share for common stock sold through Cowen under the Sales Agreement. We have also provided Cowen with customary indemnification rights and expense reimbursements for up to $[50,000] of expenses.

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which is filed herewith as Exhibit 10.1 and is incorporated herein by reference.

In connection with our entry into the Sales Agreement with Cowen, we terminated that certain At Market Issuance Sales Agreement, dated August 1, 2014, by and between us and MLV & Co., LLC, or the MLV Sales Agreement. We did not sell any common stock under the MLV Sales Agreement.

The foregoing shall not constitute an offer to sell or the solicitation of an offer to buy the securities discussed herein, nor shall there be any offer, solicitation, or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state

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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
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as subsequently amended (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K (File No. 001-32979) filed on March 6, 2014)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-114376), filed on April 9, 2004)
10.1	Sales Agreement, dated November 2, 2015, by and between Threshold Pharmaceuticals, Inc. and Cowen and Company, LLC.
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: November 2, 2015

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

Date: November 2, 2015

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

EXHIBIT INDEX

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THRESHOLD PHARMACEUTICALS, INC.

$50,000,000

SALES AGREEMENT

November 2, 2015

Cowen and Company, LLC
599 Lexington Avenue
New York, NY 10022

Ladies and Gentlemen:

Threshold Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), confirms its agreement (this "**Agreement**") with Cowen and Company, LLC ("**Cowen**"), as follows:

1. Issuance and Sale of Placement Shares. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through Cowen, acting as agent and/or principal, shares (the "**Placement Shares**") of the Company's common stock, par value $0.001 per share (the "**Common Stock**"), having an aggregate offering price of up to $50,000,000. Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this Section 1 on the amount of the Placement Shares issued and sold under this Agreement shall be the sole responsibility of the Company, and Cowen shall have no obligation in connection with such compliance. The issuance and sale of the Placement Shares through Cowen will be effected pursuant to the Registration Statement (as defined below) to be filed by the Company and after such Registration Statement has been declared effective by the Securities and Exchange Commission (the "**Commission**"), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement (as defined below) to issue the Placement Shares.

The Company shall file, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "**Securities Act**"), with the Commission a registration statement on Form S-3, including a prospectus specifically relating to the Placement Shares (the "**Placement Share Prospectus**"), and which incorporates by reference, to the extent provided for under Form S-3, documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the "**Exchange Act**"). Following the date that such registration statement is declared effective by the Commission, the Company shall furnish to Cowen, for use by Cowen, copies of the Placement Share Prospectus, as supplemented, if at all, by any prospectus supplement. Except where the context otherwise requires, such registration statement, as amended when it becomes effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such

registration statement pursuant to Rule 430B or 462(b) of the Securities Act, is herein called the "**Registration Statement.**" The Placement Share Prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by any prospectus supplement, in the form in which such Placement Share Prospectus and/or any prospectus supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any "issuer free writing prospectus," as defined in Rule 433 of the Securities Act regulations ("**Rule 433**"), relating to the Placement Shares that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g), is herein called the "**Prospectus**." Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant to the Electronic Data Gathering Analysis and Retrieval System ("**EDGAR**").

2. Placements. Each time that the Company wishes to issue and sell Placement Shares hereunder (each, a "**Placement**"), it will notify Cowen by email notice (or other method mutually agreed to in writing by the parties) (a "**Placement Notice**") containing the parameters in accordance with which it desires the Placement Shares to be sold, which shall at a minimum include the number of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one Trading Day (as defined in Section 3) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters necessary is attached hereto as **Schedule 1**. The Placement Notice shall originate from any of the individuals from the Company set forth on **Schedule 2** (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from Cowen set forth on **Schedule 2**, as such **Schedule 2** may be amended from time to time. The Placement Notice shall be effective upon receipt by Cowen unless and until (i) in accordance with the notice requirements set forth in Section 4, Cowen declines to accept the terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) in accordance with the notice requirements set forth in Section 4, the Company suspends or terminates the Placement Notice, (iv) the Company issues a subsequent Placement Notice with parameters superseding those on the earlier dated Placement Notice, or (v) this Agreement has been terminated under the provisions of **Section 11**. The amount of any discount, commission or other compensation to be paid by the Company to Cowen in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in **Schedule 3.** It is expressly acknowledged and agreed that neither the Company nor Cowen will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to Cowen and Cowen does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified

therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by Cowen. Subject to the terms and conditions herein set forth, upon the Company's delivery of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, Cowen, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Stock Market, LLC ("**Nasdaq**") to sell such Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. Cowen will provide written confirmation to the Company (including by email correspondence to each of the individuals of the Company set forth on Schedule 2, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the volume-weighted average price of the Placement Shares sold, the compensation payable by the Company to Cowen pursuant to **Section 2** with respect to such sales, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by Cowen (as set forth in **Section 5(a)**) from the gross proceeds that it receives from such sales. Cowen may sell Placement Shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including without limitation sales made through Nasdaq, on any other existing trading market for the Common Stock or to or through a market maker. If expressly authorized by the Company in a Placement Notice, Cowen may also sell Placement Shares in negotiated transactions. Notwithstanding the provisions of **Section 6(jj)**, Cowen shall not purchase Placement Shares for its own account as principal unless expressly authorized to do so by the Company in a Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that Cowen will be successful in selling Placement Shares, and (ii) Cowen will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by Cowen to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Placement Shares as required under this **Section 3**. For the purposes hereof, "**Trading Day**" means any day on which the Company's Common Stock is purchased and sold on the principal market on which the Common Stock is listed or quoted.

4. Suspension of Sales.

(a) The Company or Cowen may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on **Schedule 2**), suspend any sale of Placement Shares; *provided, however*, that such suspension shall not affect or impair either party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. Each of the parties agrees that no such

notice under this Section 4 shall be effective against the other unless it is made to one of the individuals named on **Schedule 2** hereto, as such schedule may be amended from time to time.

(b) Notwithstanding any other provision of this Agreement, during any period in which the Company is in possession of material non-public information, the Company and Cowen agree that (i) no sale of Placement Shares will take place, (ii) the Company shall not request the sale of any Placement Shares, and (iii) Cowen shall not be obligated to sell or offer to sell any Placement Shares.

5. Settlement.

(a) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the third (3rd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "**Settlement Date**" and the first such settlement date, the "**First Delivery Date**"). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "**Net Proceeds**") will be equal to the aggregate sales price received by Cowen at which such Placement Shares were sold, after deduction for (i) Cowen's commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, (ii) any other amounts due and payable by the Company to Cowen hereunder pursuant to Section 7(g) (Expenses) hereof, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(b) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting Cowen's or its designee's account (provided Cowen shall have given the Company written notice of such designee a reasonable period of time prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System ("**DWAC**") or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradeable, transferable, registered shares in good deliverable form. On each Settlement Date, Cowen will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. Cowen will be responsible for providing DWAC instructions or instructions for delivery by other means with regard to the transfer of Placement Shares being sold. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Placement Shares on a Settlement Date (other than as a result of a failure by Cowen to provide instructions for delivery), the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 9(a) (Indemnification and Contribution) hereto, it will (i) hold Cowen harmless against any loss, claim, damage, or reasonable, documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company and (ii) pay to Cowen (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with, Cowen that as of the effective date of the Registration Statement,

each Representation Date (as defined in Section 6(m)), each date on which a Placement Notice is given, and any date on which Placement Shares are sold hereunder:

(a) Compliance with Registration Requirements. The Registration Statement and any Rule 462(b) Registration Statement have been declared effective by the Commission under the Securities Act. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the best knowledge of the Company, contemplated or threatened by the Commission. The Company meets the requirements for use of Form S-3 under the Securities Act. The sale of the of the Placement Shares hereunder meets the requirements or General Instruction I.B.1 of Form S-3.

(b) No Misstatement or Omission. The Prospectus when filed complied and, as amended or supplemented, if applicable, will comply in all material respects with the Securities Act. Each of the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus and any post-effective amendments or supplements thereto, at the time it became effective or its date, as applicable, and as of each of the Settlement Dates, if any, complied in all material respects with the Securities Act and did not and, as of each Settlement Date, if any, did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of its date and as of each of the Settlement Dates, if any, will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to Cowen furnished to the Company in writing by Cowen expressly for use therein. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required.

(c) Offering Materials Furnished to Cowen. The Company has delivered to Cowen one complete copy of the Registration Statement and a copy of each consent and certificate of experts filed as a part thereof, and conformed copies of the Registration Statement (without exhibits) and the Prospectus, as amended or supplemented, in such quantities and at such places as Cowen has reasonably requested.

(d) Not an Ineligible Issuer. The Company currently is not an "ineligible issuer," as defined in Rule 405 of the rules and regulation of the Commission. The Company agrees to notify Cowen promptly upon the Company becoming an "ineligible issuer."

(e) Distribution of Offering Material By the Company. The Company has not distributed and will not distribute, prior to the completion of Cowen's distribution of the Placement Shares pursuant to this Agreement, any offering material in connection with the offering and sale of the Placement Shares other than the Prospectus or the Registration Statement.

(f) The Sales Agreement. This Agreement has been duly authorized, executed and delivered by, and is a valid and binding agreement of, the Company, enforceable in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(g) Authorization of the Placement Shares. The Placement Shares, when issued and delivered, will be duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable.

(h) No Applicable Registration or Other Similar Rights. Except as otherwise described in the Prospectus, there are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(i) No Material Adverse Change. Except as otherwise disclosed in the Prospectus, subsequent to the respective dates as of which information is given in the Prospectus: (i) there has been no material adverse change, or any development that could reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, operations or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity (any such change is called a "**Material Adverse Change**"); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, not in the ordinary course of business nor entered into any material transaction or agreement not in the ordinary course of business: and (iii) there has been no dividend or distribution of any kind declared, paid or made by the Company or, except for regular quarterly dividends publicly announced by the Company or dividends paid to the Company or other subsidiaries, by any of its subsidiaries on any class of capital stock or repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

(j) Independent Accountants. Ernst & Young LLP, who has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) and supporting schedules filed with the Commission or incorporated by reference as a part of the Registration Statement and included in the Prospectus, is an independent registered public accounting firm as required by the Securities Act and the Exchange Act.

(k) Preparation of the Financial Statements. The financial statements filed with the Commission as a part of or incorporated by reference in the Registration Statement and included in the Prospectus present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries as of and at the dates indicated and the results of their operations and cash flows for the periods specified. Such financial statements and supporting schedules have been prepared in accordance with generally accepted accounting principles as applied in the United States applied on a consistent basis throughout the periods involved, except as may be

expressly stated in the related notes thereto. No other financial statements or supporting schedules are required to be included in or incorporated in the Registration Statement.

(l) XBRL. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the each Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(m) Incorporation and Good Standing of the Company and its Subsidiary. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Delaware and has corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Prospectus and to enter into and perform its obligations under this Agreement. The subsidiaries set forth on **Schedule 4** are the Company's only subsidiaries. The Company is duly qualified as a foreign corporation to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except for such jurisdictions where the failure to so qualify or to be in good standing would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change. Except as described in the Prospectus, all of the issued and outstanding equity interests of the Company's subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim.

(n) Capital Stock Matters. The Common Stock conforms in all material respects to the description thereof contained in the Prospectus. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with federal and state securities laws. None of the outstanding shares of Common Stock were issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those accurately described in all material respects in the Prospectus. The description of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Prospectus accurately and fairly presents in all material respects the information required to be shown with respect to such plans, arrangements, options and rights.

(o) Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor any of its subsidiaries is in violation of its charter or by-laws or is in default (or, with the giving of notice or lapse of time, would be in default) ("**Default**") under any indenture, mortgage, loan or credit agreement, note, contract, franchise, lease or other instrument to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound, or to which any of the property or assets of the Company or any of its subsidiaries is subject (each, an "**Existing Instrument**"), except for such Defaults as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change. The Company's execution, delivery and performance of this

Agreement and consummation of the transactions contemplated hereby and by the Prospectus (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws of the Company or any subsidiary, (ii) will not conflict with or constitute a breach of, or Default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument, except for such conflicts, breaches, Defaults, liens, charges or encumbrances as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any subsidiary. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act, or that may be required under applicable state securities or blue sky laws and from the Financial Industry Regulatory Authority ("**FINRA**") or Nasdaq.

(p) No Material Actions or Proceedings. Except as disclosed in the Prospectus, there are no legal or governmental actions, suits or proceedings pending or, to the best of the Company's knowledge, threatened (i) against or affecting the Company or any of its subsidiaries, (ii) which has as the subject thereof any officer or director of, or property owned or leased by, the Company or any of its subsidiaries or (iii) relating to environmental or discrimination matters, where in any such case (A) there is a reasonable possibility that such action, suit or proceeding might be determined adversely to the Company or such subsidiary and (B) any such action, suit or proceeding, if so determined adversely, would reasonably be expected to result in a Material Adverse Change or adversely affect the consummation of the transactions contemplated by this Agreement. No material labor dispute with the employees of the Company or any of its subsidiaries exists or, to the Company's knowledge, is threatened or imminent.

(q) All Necessary Permits, etc. Except as otherwise disclosed in the Propsectus, each of the Company and its subsidiaries possess such valid and current certificates, authorizations or permits issued by the appropriate state, federal or foreign regulatory agencies or bodies necessary to conduct their respective businesses as currently conducted by it and described in the Registration Statement and Prospectus, other than those the failure to possess or own would not result in a Material Adverse Change, and neither the Company nor any subsidiary has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, could result in a Material Adverse Change.

(r) Tax Law Compliance. The Company and its consolidated subsidiaries have filed all necessary federal, state and foreign income, property and franchise tax returns and have paid all taxes required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except as may be being contested in good faith and by appropriate proceedings and except where the failure to do so would not reasonably be expected to result in a Material Adverse Change. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 6(k) above in

respect of all federal, state and foreign income, property and franchise taxes for all periods as to which the tax liability of the Company or any of its consolidated subsidiaries has not been finally determined.

(s) Company Not an "Investment Company". The Company has been advised of the rules and requirements under the Investment Company Act of 1940, as amended (the "**Investment Company Act**"). The Company is not, and after receipt of payment for the Placement Shares will not be, an "investment company" within the meaning of Investment Company Act.

(t) Insurance. Except as otherwise described in the Prospectus, each of the Company and its subsidiaries are insured by insurers of recognized financial responsibility with policies in such amounts and with such deductibles and covering such risks as are generally deemed prudent and customary for their businesses as currently conducted and as described in the Registration Statement and Prospectus. The Company has no reason to believe that it or any subsidiary will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Change.

(u) No Price Stabilization or Manipulation. The Company has not taken and will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares.

(v) Related Party Transactions. There are no business relationships or related-party transactions involving the Company or any subsidiary or any other person required to be described in the Prospectus which have not been described as required.

(w) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the Settlement Dates, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(x) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any director, officer, employee or agent of the Company or any subsidiary has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended; or (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment.

(y) Compliance with Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Money Laundering Laws**"), except as would not reasonably be expected to result in a Material Adverse Change, and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(z) Compliance with OFAC. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of its subsidiaries is currently subject to any U.S. sanctions administered by the Office of Foreign Office Control of the U.S. Department of the Treasury ("**OFAC**"); and the Company will not, directly or indirectly, use the proceeds of the offering of the Placement Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(aa) Company's Accounting System. The Company maintains a system of "internal control over financial reporting" (as such term is defined in Rule 13a-15(f) of the General Rules and Regulations under the Exchange Act (the "**Exchange Act Rules**")) that complies with the requirements of the Exchange Act and has been designed by their respective principal executive and principal financial officers, or under their supervision, and is designed to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. To the knowledge of the Company, the Company's internal control over financial reporting is effective. Except as described in the Prospectus, since the end of the Company's most recent audited fiscal year, there has been (A) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (B) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(bb) Disclosure Controls. The Company maintains disclosure controls and procedures (as such is defined in Rule 13a-15(e) of the Exchange Act Rules) that comply with the requirements of the Exchange Act; such disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company in reports that it files or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management to allow timely decisions regarding disclosures. The Company has conducted

evaluations of the effectiveness of its disclosure controls as required by Rule 13a-15 of the Exchange Act.

(cc) Compliance with Environmental Laws. Except as otherwise described in the Prospectus, and except as would not, individually or in the aggregate, result in a Material Adverse Change (i) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign law or regulation relating to pollution or protection of human health or the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including without limitation, laws and regulations relating to emissions, discharges, releases or, to the Company's knowledge, threatened releases of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum and petroleum products (collectively, "**Materials of Environmental Concern**"), or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Materials of Environmental Concern (collectively, "**Environmental Laws**"), which violation includes, but is not limited to, noncompliance with any permits or other governmental authorizations required for the operation of the business of the Company or its subsidiaries under applicable Environmental Laws, or noncompliance with the terms and conditions thereof, nor has the Company or any of its subsidiaries received any written communication, whether from a governmental authority, citizens group, employee or otherwise, that alleges that the Company or any of its subsidiaries is in violation of any Environmental Law; (ii) there is no claim, action or cause of action filed with a court or governmental authority, no investigation with respect to which the Company has received written notice, and no written notice by any person or entity alleging potential liability for investigatory costs, cleanup costs, governmental responses costs, natural resources damages, property damages, personal injuries, attorneys' fees or penalties arising out of, based on or resulting from the presence, or release into the environment, of any Material of Environmental Concern at any location owned, leased or operated by the Company or any of its subsidiaries, now or in the past (collectively, "**Environmental Claims**"), pending or, to the Company's knowledge, threatened against the Company or any of its subsidiaries or any person or entity whose liability for any Environmental Claim the Company or any of its subsidiaries has retained or assumed either contractually or by operation of law; and (iii) to the best of the Company's knowledge, there are no past or present actions, activities, circumstances, conditions, events or incidents, including, without limitation, the release, emission, discharge, presence or disposal of any Material of Environmental Concern, that reasonably could result in a violation of any Environmental Law or form the basis of a potential Environmental Claim against the Company or any of its subsidiaries or against any person or entity whose liability for any Environmental Claim the Company or any of its subsidiaries has retained or assumed either contractually or by operation of law.

(dd) Intellectual Property. Except as otherwise disclosed in the Prospectus, to the Company's knowledge, the Company and its subsidiaries own or possess the valid and enforceable right to use all (i) patents, patent applications, trademarks, trademark registrations, service marks, service mark registrations, Internet domain name registrations, copyrights, copyright registrations, licenses, trade secret rights ("**Intellectual Property Rights**") and (ii) inventions, software, works of authorships, trade names, databases, formulae, know how, Internet domain names and other intellectual property (including trade secrets and other unpatented and/or unpatentable proprietary confidential information, systems, or procedures) (collectively, "**Intellectual Property Assets**") necessary to conduct their respective businesses

as currently conducted, and as proposed to be conducted and described in the Prospectus except as would not reasonably be expected to result in a Material Adverse Change. The Company and its subsidiaries have not received written notice of any challenge, which is to their knowledge still pending, by any other person to the rights of the Company and its subsidiaries with respect to any Intellectual Property Rights or Intellectual Property Assets owned or used by the Company or its subsidiaries except as would not reasonably be expected to result in a Material Adverse Change. Except as described in the Prospectus, to the knowledge of the Company, the Company and its subsidiaries' respective businesses as now conducted do not give rise to any infringement of, any misappropriation of, or other violation of, any valid and enforceable Intellectual Property Rights of any other person except as would not reasonably be expected to result in a Material Adverse Change. Except as described in the Prospectus, to the Company's knowledge, no claim has been made against the Company alleging the infringement by the Company of any patent, trademark, service mark, trade name, copyright, trade secret, license in or other intellectual property right or franchise right of any person which claim, if the subject of an unfavorable decision would result in a Material Adverse Change. The Company has taken all reasonable steps to protect, maintain and safeguard its Intellectual Property Rights, including the execution of appropriate nondisclosure and confidentiality agreements. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other person in respect of, the Company's right to own, use, or hold for use any of the Intellectual Property Rights as owned, used or held for use in the conduct of the business as currently conducted.

(ee) Clinical Studies. The clinical, pre-clinical and other studies and tests conducted by or, to the knowledge of the Company, on behalf of the Company were, and, if still pending, are being, conducted in accordance in all material respects with all statutes, laws, rules and regulations, as applicable (including, without limitation, the U.S. Federal and Drug Administration's (the "**FDA**") Good Laboratory Practices and Good Clinical Practices as well as all other applicable rules, regulations, or requirements of the FDA or any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA), except where the failure to do so would not, individually or in the aggregate, result in a Material Adverse Change. Except as set forth in the Prospectus, the Company has not received any written notices or other written correspondence from the FDA or any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA requiring the Company to terminate or suspend any ongoing clinical or pre-clinical studies or tests. Except as set forth in the Registration Statement and Prospectus, the Company has not received any Form 483 or other adverse finding from the FDA or any other regulator with respect to any clinical site, clinical trial protocol, or clinical investigator, other than any such Form 483 or adverse finding that would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

(ff) Listing. The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Stock is registered pursuant to Section 12(b) or Section 12(g) of the Exchange Act and is listed on the Nasdaq, and the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Exchange, nor has the Company received any notification that the Commission or Nasdaq is contemplating terminating such registration or listing.

(gg) Brokers. Except for Cowen with respect to commissions as described on Schedule 3, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(hh) No Outstanding Loans or Other Indebtedness. Except as described in the Prospectus, there are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees or indebtedness by the Company to or for the benefit of any of the officers or directors of the Company or any of the immediate family members of any of them.

(ii) No Reliance. The Company has not relied upon Cowen or legal counsel for Cowen for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(jj) Cowen Purchases. The Company acknowledges and agrees that Cowen has informed the Company that Cowen may, to the extent permitted under the Securities Act, the Exchange Act and this Agreement, purchase and sell shares of Common Stock for its own account while this Agreement is in effect.

(kk) FINRA Exemption. To enable Cowen to rely on Rule 5110(b)(7)(C)(i) of FINRA, the Company represents that the Company (i) has a non-affiliate, public common equity float of at least $150 million or a non-affiliate, public common equity float of at least $100 million and annual trading volume of at least three million shares and (ii) has been subject to the Exchange Act reporting requirements for a period of at least 36 months.

(ll) Compliance with Laws. The Company has not been advised, and has no reason to believe, that it and each of its subsidiaries are not conducting business in compliance with all applicable laws, rules and regulations of the jurisdictions in which it is conducting business, except where failure to be so in compliance would not reasonably be expected to result in a Material Adverse Change.

Any certificate signed by an officer of the Company and delivered to Cowen or to counsel for Cowen in connection with this Agreement shall be deemed to be a representation and warranty by the Company to Cowen as to the matters set forth therein.

The Company acknowledges that Cowen and, for purposes of the opinions to be delivered pursuant to Section 7 hereof, counsel to the Company and counsel to Cowen, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

7. Covenants of the Company. The Company covenants and agrees with Cowen that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by Cowen under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), (i) the Company will notify Cowen promptly of the time when any subsequent amendment to the Registration Statement, other than

documents incorporated by reference or amendments not related to any Placement Shares, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus related to any Placement Shares or for additional information related to any Placement Shares, (ii) the Company will prepare and file with the Commission, promptly upon Cowen's request, any amendments or supplements to the Registration Statement or Prospectus that, in Cowen's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by Cowen (*provided, however*, that the failure of Cowen to make such request shall not relieve the Company of any obligation or liability hereunder, or affect Cowen's right to rely on the representations and warranties made by the Company in this Agreement); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus, other than documents incorporated by reference, relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to Cowen within a reasonable period of time before the filing and Cowen has not reasonably objected thereto (*provided, however*, that (A) the failure of Cowen to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect Cowen's right to rely on the representations and warranties made by the Company in this Agreement, (B) the Company has no obligation to provide Cowen any advance copy of such filing or to provide Cowen an opportunity to object to such filing if the filing does not name Cowen or does not relate to the transaction herein provided, and (C) the only remedy Cowen shall have with respect to the failure by the Company to provide Cowen with such copy or the filing of such amendment or supplement despite Cowen's objection shall be to cease making sales under this Agreement) and the Company will furnish to Cowen at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iv) the Company will cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act.

(b) Notice of Commission Stop Orders. The Company will advise Cowen, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.

(c) Delivery of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by Cowen under the Securities Act with respect to a pending sale of the Placement Shares, (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material

fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify Cowen to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance.

(d) Listing of Placement Shares. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by Cowen under the Securities Act with respect to a pending sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on Nasdaq and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as Cowen reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; *provided, however,* that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to Cowen and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as Cowen may from time to time reasonably request and, at Cowen's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided, however,* that the Company shall not be required to furnish any document (other than the Prospectus) to Cowen to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Expenses. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, in accordance with the provisions of Section 11 hereunder, will pay the following expenses all incident to the performance of its obligations hereunder, including, but not limited to, expenses relating to (i) the preparation, printing and filing of the Registration Statement and each amendment and supplement thereto, of each Prospectus and of each amendment and supplement thereto, (ii) the preparation, issuance and delivery of the Placement Shares, (iii) the qualification of the Placement Shares under securities laws in accordance with the provisions of Section 7(d) of this Agreement, including filing fees (provided, however, that any fees or disbursements of counsel for Cowen in connection therewith shall be paid by Cowen except as set forth in (viii) below), (iv) the printing and

delivery to Cowen of copies of the Prospectus and any amendments or supplements thereto, and of this Agreement, (v) the fees and expenses incurred in connection with the listing or qualification of the Placement Shares for trading on Nasdaq, (vi) the filing fees and expenses, if any, of the Commission, (vii) the filing fees and associated legal expenses of Cowen's outside counsel for filings with the FINRA Corporate Financing Department, (viii) the reasonable fees and disbursements of Cowen's counsel in an aggregate amount not to exceed $50,000.

(h) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(i) Notice of Other Sales. During the pendency of any Placement Notice given hereunder, and for 5 Trading Days following the termination of any Placement Notice given hereunder, the Company shall provide Cowen notice as promptly as reasonably possible before it offers to sell, contracts to sell, sells, grants any option to sell or otherwise disposes of any shares of Common Stock (other than Placement Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire Common Stock; *provided*, that such notice shall not be required in connection with the (i) issuance, grant or sale of Common Stock, options to purchase shares of Common Stock or any other equity awards, or Common Stock issuable upon the exercise of options or other equity awards pursuant to the any stock option, stock bonus, employee stock purchase or other stock plan or arrangement described in the Prospectus, (ii) the issuance, grant or sale of Common Stock, or securities convertible into or exercisable for Common Stock, in connection with any joint venture, commercial, strategic or collaborative relationship, or the acquisition or license by the Company of the securities, businesses, property or other assets of another person or entity, (iii) the issuance or sale of Common Stock pursuant to any dividend reinvestment plan that the Company may adopt from time to time provided the implementation of such is disclosed to Cowen in advance or (iv) any shares of Common Stock issuable upon the exchange, conversion or redemption of securities or the exercise or vesting of warrants, options or other rights in effect or outstanding.

(j) Change of Circumstances. The Company will, at any time during a fiscal quarter in which the Company intends to tender a Placement Notice or sell Placement Shares, advise Cowen promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided to Cowen pursuant to this Agreement.

(k) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by Cowen or its agents in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as Cowen may reasonably request.

(l) Required Filings Relating to Placement of Placement Shares. To the extent that the filing of a prospectus supplement with the Commission with respect to a placement of Placement Shares is required under Rule 424(b) under the Securities Act, the Company agrees that on or before such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b)

under the Securities Act (each and every filing under Rule 424(b), a "**Filing Date**"), which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through Cowen, the Net Proceeds to the Company and the compensation payable by the Company to Cowen with respect to such Placement Shares (provided that the Company may satisfy its obligations under this Section 7(l)(i) by effecting a filing in accordance with the Exchange Act with respect to such information), and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.

(m) Representation Dates; Certificate. On or prior to the First Delivery Date and, thereafter, each time the Company (i) amends or supplements the Registration Statement or the Prospectus relating to the Placement Shares (other than a prospectus supplement filed in accordance with **Section 7(l)** of this Agreement) by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of document(s) by reference to the Registration Statement or the Prospectus relating to the Placement Shares; (ii) files an annual report on Form 10-K under the Exchange Act; (iii) files its quarterly reports on Form 10-Q under the Exchange Act; or (iv) files a current report on Form 8-K under the Exchange Act containing amended audited financial information (other than information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144 under the Exchange Act) (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "**Representation Date**"); the Company shall furnish Cowen with a certificate, in the form attached hereto as Exhibit 7(m) within three (3) Trading Days of any Representation Date if requested by Cowen. The requirement to provide a certificate under this Section 7(m) shall be automatically waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date, including for purposes of Sections 7(n) and 7(o) hereof) and the next occurring Representation Date; *provided*, *however*, that such waiver shall not apply for any Representation Date on which the Company files its annual report on Form 10-K. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver and did not provide Cowen with a certificate under this Section 7(m), then before the Company delivers the Placement Notice or Cowen sells any Placement Shares, the Company shall provide Cowen with a certificate, in the form attached hereto as Exhibit 7(m), dated the date of the Placement Notice.

(n) Legal Opinion . On or prior to the First Delivery Date and within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) *for which no waiver is applicable*, the Company shall cause to be furnished to Cowen a written opinion and negative assurance letter of Cooley LLP ("**Company Counsel**"), or other counsel reasonably satisfactory to Cowen, in form and substance reasonably satisfactory to Cowen and its counsel, dated the date that such opinion and negative assurance letter are required to be delivered (the "**Opinion Date**"), substantially similar to the forms attached hereto as Exhibit 7(n)(i) (solely with respect to the opinion and negative assurance letter to be delivered on or prior to the First Delivery Date) and Exhibit 7(n)(ii) (for opinions and negative assurance letters to be delivered in connection with all

subsequent Representation Dates), respectively, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided*, *however*, that (1) in lieu of such opinions and negative assurance letters for subsequent Representation Dates, counsel may furnish Cowen with a letter (a "**Reliance Letter**") to the effect that Cowen may rely on a prior opinion or negative assurance letter delivered under this Section 7(n) to the same extent as if it were dated the date of such Reliance Letter (except that statements in such prior opinion and/or negative assurance letter shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented at such Representation Date) and (2) the Company shall not be required to furnish to Cowen any such negative assurance letter if LeClairRyan, A Professional Corporation, or other outside counsel for Cowen ("**Cowen Counsel**"), does not also concurrently deliver a negative assurance letter to Cowen dated as of the Opinion Date, which negative assurance letter of Cowen Counsel shall cover statements substantially similar to those covered by such negative assurance letter of Company Counsel.

(o) Comfort Letter. On or prior to the First Delivery Date and within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) *for which no waiver is applicable*, the Company shall cause its independent accountants to furnish Cowen letters (the "**Comfort Letters**"), dated the date the Comfort Letter is delivered, in form and substance satisfactory to Cowen, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to Cowen in connection with registered public offerings (the first such letter, the "**Initial Comfort Letter**") and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(p) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares or (ii) sell, bid for, or purchase the Placement Shares to be issued and sold pursuant to this Agreement, or pay anyone any compensation for soliciting purchases of the Placement Shares other than Cowen; provided, however, that the Company may bid for and purchase shares of its Common Stock in accordance with Rule 10b-18 under the Exchange Act.

(q) Insurance. The Company and its subsidiaries shall maintain, or cause to be maintained, insurance in such amounts and covering such risks as is reasonable and customary for the business for which it is engaged.

(r) Compliance with Laws. The Company and each of its subsidiaries shall maintain, or cause to be maintained, all material environmental permits, licenses and other authorizations required by federal, state and local law in order to conduct their businesses as described in the Prospectus, and the Company and each of its subsidiaries shall conduct their businesses, or cause their businesses to be conducted, in substantial compliance with such permits, licenses and authorizations and with applicable environmental laws, except where the failure to maintain or

be in compliance with such permits, licenses and authorizations could not reasonably be expected to result in a Material Adverse Change.

(s) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor its subsidiaries will be or become, at any time prior to the termination of this Agreement, an "investment company," as such term is defined in the Investment Company Act, assuming no change in the Commission's current interpretation as to entities that are not considered an investment company.

(t) Securities Act and Exchange Act. The Company will use its best efforts to comply with all requirements imposed upon it by the Securities Act and the Exchange Act as from time to time in force, so far as necessary to permit the continuance of sales of, or dealings in, the Placement Shares as contemplated by the provisions hereof and the Prospectus.

(u) No Offer to Sell. Other than the Placement Share Prospectus and any free writing prospectus (as defined in Rule 405 under the Securities Act) approved in advance by the Company and Cowen in its capacity as principal or agent hereunder, neither Cowen nor the Company (including its agents and representatives, other than Cowen in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Placement Shares hereunder.

(v) Sarbanes-Oxley Act. The Company and its subsidiaries will use their best efforts to comply with all effective applicable provisions of the Sarbanes-Oxley Act.

8 . Conditions to Cowen's Obligations. The obligations of Cowen hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by Cowen of a due diligence review satisfactory to Cowen in its reasonable judgment, and to the continuing satisfaction (or waiver by Cowen in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall be effective and shall be available for (i) all sales of Placement Shares issued pursuant to all prior Placement Notices and (ii) the sale of all Placement Shares contemplated to be issued by any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company or any of its subsidiaries of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification from the Commission or any other federal or state governmental authority with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the

occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, the related Prospectus or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. Cowen shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in Cowen's reasonable opinion is material, or omits to state a fact that in Cowen's opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Change or any development that could reasonably be expected to result in a Material Adverse Change, or any downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of Cowen (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(e) Company Counsel Legal Opinion. Cowen shall have received the opinions and negative assurance letters of Company Counsel required to be delivered pursuant to Section 7(n) on or before the date on which such delivery of such opinion and negative assurance letter is required pursuant to Section 7(n).

(f) Cowen Counsel Legal Opinion. Cowen shall have received from Cowen Counsel such opinion or opinions, on or before the date on which the delivery of the Company Counsel legal opinion is required pursuant to Section 7(n), with respect to such matters as Cowen may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

(g) Comfort Letter. Cowen shall have received the Comfort Letter required to be delivered pursuant to Section 7(o) on or before the date on which such delivery of such Comfort Letter is required pursuant to Section 7(o).

(h) Representation Certificate. Cowen shall have received the certificate required to be delivered pursuant to Section 7(m) on or before the date on which delivery of such certificate is required pursuant to Section 7(m).

(i) Secretary's Certificate. On or prior to the First Delivery Date, Cowen shall have received a certificate, signed on behalf of the Company by its corporate Secretary, in form and substance satisfactory to Cowen and its counsel.

(j) No Suspension. Trading in the Common Stock shall not have been suspended on Nasdaq.

(k) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(m), the Company shall have furnished to Cowen such appropriate further information, certificates and documents as Cowen may have reasonably requested. All such opinions, certificates, letters and other documents shall have been in compliance with the provisions hereof. The Company will furnish Cowen with such conformed copies of such opinions, certificates, letters and other documents as Cowen shall have reasonably requested.

(l) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(m) Approval for Listing. The Placement Shares shall either have been (i) approved for listing on Nasdaq, subject only to notice of issuance, or (ii) the Company shall have filed an application for listing of the Placement Shares on Nasdaq at, or prior to, the issuance of any Placement Notice.

(n) No Termination Event. There shall not have occurred any event that would permit Cowen to terminate this Agreement pursuant to Section 11(a).

9. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless Cowen, the directors, officers, partners, employees and agents of Cowen and each person, if any, who (i) controls Cowen within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, or (ii) is controlled by or is under common control with Cowen (a "**Cowen Affiliate**") from and against any and all losses, claims, liabilities, expenses and damages (including, but not limited to, any and all reasonable investigative, legal and other expenses incurred in connection with, and any and all amounts paid in settlement (in accordance with Section 9(c)) of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), as and when incurred, to which Cowen, or any such person, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based, directly or indirectly, on (x) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or the Prospectus or any amendment or

supplement to the Registration Statement or the Prospectus or in any free writing prospectus or in any application or other document executed by or on behalf of the Company or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Common Stock under the securities laws thereof or filed with the Commission, (y) the omission or alleged omission to state in any such document a material fact required to be stated in it or necessary to make the statements in it not misleading or (z) any breach by any of the indemnifying parties of any of their respective representations, warranties and agreements contained in this Agreement; *provided*, *however*, that this indemnity agreement shall not apply to the extent that such loss, claim, liability, expense or damage arises from the sale of the Placement Shares pursuant to this Agreement and is caused directly or indirectly by an untrue statement or omission made in reliance upon and in conformity with the Agent's Information (as defined below). This indemnity agreement will be in addition to any liability that the Company might otherwise have.

(b) Cowen Indemnification. Cowen agrees to indemnify and hold harmless the Company and its directors and each officer of the Company that signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 9(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Agent's Information (as defined below).

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 9 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 9, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 9 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 9 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to

it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 9 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding.

(d) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 9 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or Cowen, the Company and Cowen will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than Cowen, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and Cowen may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and Cowen on the other. The relative benefits received by the Company on the one hand and Cowen on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by Cowen from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and Cowen, on the other, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or Cowen, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company

and Cowen agree that it would not be just and equitable if contributions pursuant to this Section 9(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 9(d) shall be deemed to include, for the purpose of this Section 9(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 9(c) hereof. Notwithstanding the foregoing provisions of this Section 9(d), Cowen shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 9(d), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of Cowen, will have the same rights to contribution as that party, and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 9(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 9(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 9(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 9(c) hereof.

10. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 9 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of Cowen, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

11. Termination.

(a) Cowen shall have the right by giving notice as hereinafter specified at any time to terminate this Agreement if (i) any Material Adverse Change, or any development that would reasonably be expected to result in a Material Adverse Change has occurred that, in the reasonable judgment of Cowen, may materially impair the ability of Cowen to sell the Placement Shares hereunder, (ii) the Company shall have failed, refused or been unable to perform any agreement on its part to be performed hereunder; *provided, however,* in the case of any failure of the Company to deliver (or cause another person to deliver) any certification, opinion, or letter required under Sections 7(m), 7(n), or 7(o), Cowen's right to terminate shall not arise unless such failure to deliver (or cause to be delivered) continues for more than thirty (30) days from the date such delivery was required; (iii) any other condition of Cowen's obligations hereunder is not

fulfilled; or (iv), any suspension or limitation of trading in the Placement Shares or in securities generally on Nasdaq shall have occurred. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Applicable Law; Consent to Jurisdiction) and Section 17 (Waiver of Jury Trial) hereof shall remain in full force and effect notwithstanding such termination. If Cowen elects to terminate this Agreement as provided in this Section 11(a), Cowen shall provide the required notice as specified in Section 12 (Notices).

(b) The Company shall have the right, by giving ten (10) days notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(c) Cowen shall have the right, by giving ten (10) days notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 11, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through Cowen on the terms and subject to the conditions set forth herein; *provided* that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 11(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; *provided, however,* that any such termination by mutual agreement shall in all cases be deemed to provide that Section 7(g), Section 9, Section 10, Section 16 and Section 17 shall remain in full force and effect.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided, however,* that such termination shall not be effective until the close of business on the date of receipt of such notice by Cowen or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

12. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified in this Agreement, and if sent to Cowen, shall be delivered to Cowen at Cowen and Company, LLC, 599 Lexington Avenue, New York, NY 10022, fax no. 646-562-1124, Attention: General Counsel with a copy to LeClairRyan, A Professional Corporation, E-mail: james.seery@leclairryan.com, attention: James T. Seery; or if sent to the Company, shall be delivered to Threshold Pharmaceuticals, Inc. E-mail: bselick@thresholdpharm.com, attention: Harold E. Selick, with a copy to Cooley LLP, E-mail: cmills@cooley.com, attention: Chadwick

L. Mills. Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally, by e-mail or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day (as defined below), or, if such day is not a Business Day on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "**Business Day**" shall mean any day on which Nasdaq and commercial banks in the City of New York are open for business.

13. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and Cowen and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 9 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided*, *however*, that Cowen may assign its rights and obligations hereunder to an affiliate of Cowen without obtaining the Company's consent.

14. Adjustments for Share Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share split, share dividend or similar event effected with respect to the Common Stock.

15. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto), together with that certain letter agreement between the Company and Cowen dated the date hereof and that certain Confidentiality Agreement, dated October 2, 2015, by and between the Company and Cowen (the "**CDA**"), constitute the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Moreover, the Company and Cowen agree that all exchanges of information hereunder shall be governed by the terms of the CDA, which CDA the parties agree is and shall hereby be amended to remain in full force and effect at all times during the term of this Agreement. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and Cowen. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

16. Applicable Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York without regard to

the principles of conflicts of laws. Each party hereby irrevocably submits to the non-exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof (certified or registered mail, return receipt requested) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

17. Waiver of Jury Trial. The Company and Cowen each hereby irrevocably waives any right it may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or any transaction contemplated hereby.

18. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) Cowen has been retained solely to act as sales agent in connection with the sale of the Placement Shares and that no fiduciary, advisory or agency relationship between the Company and Cowen has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether Cowen has advised or is advising the Company on other matters;

(b) the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) the Company has been advised that Cowen and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that Cowen has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and

(d) the Company waives, to the fullest extent permitted by law, any claims it may have against Cowen, for breach of fiduciary duty or alleged breach of fiduciary duty and agrees that Cowen shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, partners, employees or creditors of the Company.

19. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile or electronic transmission.

20. Definitions. As used in this Agreement, the following term has the meaning set forth below:

(a) "*Agent's Information"* means, solely the following information furnished to the Company by Cowen expressly for inclusion in the Prospectus: the third sentence in the eighth paragraph under the caption "Plan of Distribution" in the Prospectus.

[Remainder of Page Intentionally Blank]

If the foregoing correctly sets forth the understanding between the Company and Cowen, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and Cowen.

Very truly yours,

COWEN AND COMPANY, LLC

By: /s/ Grant Miller
Name: Grant Miller
Title: Head of Equity Capital Markets

ACCEPTED as of the date first-above written:

THRESHOLD PHARMACEUTICALS, INC.

By: /s/ Harold E. Selick, Ph.D.
Name: Harold E. Selick, Ph.D.
Title: Chief Executive Officer

SCHEDULE 1

FORM OF PLACEMENT NOTICE

From: [ ]
Cc: [ ]
To: [ ]
Subject: Cowen at the Market Offering—Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between Threshold Pharmaceuticals, Inc. (the "Company"), and Cowen and Company, LLC ("Cowen") dated November 2, 2015 (the "Agreement"), I hereby request on behalf of the Company that Cowen sell up to [ ] shares of the Company's common stock, par value $0.001 per share, at a minimum market price of $_____ per share. Sales should begin on the date of this Notice and shall continue until [DATE] [all shares are sold][the aggregate sales price of the shares reaches $[●].

SCHEDULE 2

Notice Parties

The Company
Harold E. Selick, Ph.D. bselick@thresholdpharm.com
Joel A. Fernandes jfernandes@thresholdpharm.com
Mark Hopkins, Ph.D., J.D. mhopkins@thresholdpharm.com

Cowen
Robert Sine Director robert.sine@cowen.com
William Follis Director william.follis@cowen.com

SCHEDULE 3

Compensation

Cowen shall be paid compensation equal to up to 3% of the gross proceeds from the sales of Placement Shares pursuant to the terms of this Agreement.

SCHEDULE 4

Subsidiaries

THLD Enterprises (UK), Limited_

Exhibit 7(m)

OFFICER CERTIFICATE

The undersigned, the duly qualified and elected _____, of **Threshold Pharmaceuticals, Inc.**, a Delaware corporation (the "**Company**"), does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(m) of the Sales Agreement dated November 2, 2015 (the "**Sales Agreement**") between the Company and Cowen and Company, LLC, that to the best of the knowledge of the undersigned.

(i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Change, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; and

(ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Sales Agreement.

THRESHOLD PHARMACEUTICALS, INC.

By:
Name:
Title:

Date:

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: November 2, 2015

/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: November 2, 2015

/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 September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harold E. Selick, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 2, 2015

/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 September 30, 2015, 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: November 2, 2015

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