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

# FORM 10-Q

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

**For the quarterly period ended June 30, 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 July 24, 2015, there were 71,334,779 shares of common stock, par value $0.001 per share, of Threshold Pharmaceuticals, Inc. outstanding.

**Threshold Pharmaceuticals, Inc.**

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**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

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

| | June 30, 2015 | December 31, 2014 (Note 1) |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 10,569 | $ 8,391 |
| Marketable securities, current | 56,450 | 50,209 |
| Collaboration receivable | 3,647 | 7,248 |
| Prepaid expenses and other current assets | 1,500 | 832 |
| Total current assets | 72,166 | 66,680 |
| Marketable securities, non-current | | — |
| Property and equipment, net | 424 | 557 |
| Other assets | 1,264 | 1,159 |
| Total assets | $ 73,854 | $ 68,396 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| Current liabilities: | | |
| Accounts payable | $ 635 | $ 2,074 |
| Accrued clinical and development expenses | 7,720 | 5,998 |
| Accrued liabilities | 2,451 | 3,180 |
| Deferred revenue, current | 14,722 | 14,722 |
| Total current liabilities | 25,528 | 25,974 |
| Warrant liability | 19,627 | 3,961 |
| Deferred revenue, non-current | 54,833 | 62,194 |
| Deferred rent | 169 | 243 |
| Total liabilities | 100,157 | 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: 71,334,779 shares at June 30, 2015 and 62,898,233 shares at December 31, 2014 | 71 | 63 |
| Additional paid-in capital | 366,366 | 349,236 |
| Accumulated other comprehensive gain (loss) | (18) | (13) |
| Accumulated deficit | (392,722) | (373,262) |
| Total stockholders' equity (deficit) | (26,303) | (23,976) |
| Total liabilities and stockholders' equity (deficit) | $ 73,854 | $ 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Revenue | $ 3,680 | $ 3,680 | $ 7,361 | $ 7,361 |
| Operating expenses: | | | | |
| Research and development | 10,141 | 8,664 | 20,821 | 18,317 |
| General and administrative | 2,480 | 2,477 | 5,096 | 5,111 |
| Total operating expenses | 12,621 | 11,141 | 25,917 | 23,428 |
| Loss from operations | (8,941) | (7,461) | (18,556) | (16,067) |
| Interest income (expense), net | 39 | 30 | 72 | 70 |
| Other income (expense), net | 596 | 6,665 | (976) | 8,122 |
| Net loss | (8,306) | (766) | (19,460) | (7,875) |
| Other comprehensive income (loss): | | | | |
| Unrealized gain (loss) on available-for-sale securities | (3) | 4 | (5) | (11) |
| Comprehensive loss | $ (8,309) | $ (762) | $ (19,465) | $ (7,886) |
| Net loss per common share: | | | | |
| Basic | $ (0.12) | $ (0.01) | $ (0.28) | $ (0.13) |
| Diluted | $ (0.12) | $ (0.12) | $ (0.28) | $ (0.25) |
| Weighted average number of shares used in per common share calculations: | | | | |
| Basic | 71,334 | 59,347 | 69,046 | 59,325 |
| Diluted | 72,815 | 62,998 | 69,046 | 63,433 |

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

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2015 | 2014 |
| **Cash flows from operating activities:** | | |
| Net loss | $ (19,460) | $ (7,875) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | |
| Depreciation and amortization | 503 | 726 |
| Stock-based compensation expense | 3,316 | 2,734 |
| Change in common stock warrant value | 974 | (8,122) |
| (Gain) loss on sale of investments, property and equipment | 14 | — |
| Changes in operating assets and liabilities: | | |
| Collaboration receivable | 3,601 | 13,831 |
| Prepaid expenses and other assets | (773) | (699) |
| Accounts payable | (1,439) | 1,202 |
| Accrued clinical and development expenses | 1,722 | (271) |
| Accrued liabilities | (729) | (650) |
| Deferred rent | (74) | 34 |
| Deferred revenue | (7,361) | (7,361) |
| Net cash (used in) provided by operating activities | (19,706) | (6,451) |
| **Cash flows from investing activities:** | | |
| Acquisition of property and equipment | (55) | (171) |
| Acquisition of marketable securities | (39,479) | (33,137) |
| Proceeds from sale of marketable securities | 1,997 | 8,214 |
| Proceeds from maturities of marketable securities | 30,907 | 30,355 |
| Net cash (used in) provided by investing activities | (6,630) | 5,261 |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of common stock and warrants, net of offering expenses | 28,514 | 374 |
| Net cash provided by financing activities | 28,514 | 374 |
| Net increase (decrease) in cash and cash equivalents | 2,178 | (816) |
| Cash and cash equivalents, beginning of period | 8,391 | 7,279 |
| Cash and cash equivalents, end of period | $ 10,569 | $ 6,463 |

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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| **Numerator:** | | | | |
| Net loss - basic | $ (8,306) | $ (766) | $ (19,460) | $ (7,875) |
| Less: noncash income from change in fair value of common stock warrants | (308) | (6,665) | — | (8,122) |
| Net loss - diluted | (8,614) | (7,431) | (19,460) | (15,997) |
| **Denominator:** | | | | |
| Weighted average common shares outstanding | 71,334 | 59,347 | 69,046 | 59,325 |
| Dilutive effect of warrants | 1,481 | 3,651 | — | 4,108 |
| Weighted-average common shares outstanding and dilutive potential common shares — diluted | 72,815 | 62,998 | 69,046 | 63,433 |
| Net loss per share | | | | |
| Basic | $ (0.12) | $ (0.01) | $ (0.28) | $ (0.13) |
| Diluted | $ (0.12) | $ (0.12) | $ (0.28) | $ (0.25) |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Shares issuable upon exercise of warrants | 8,300 | — | 12,146 | — |
| Shares issuable upon exercise of stock options | 10,151 | 8,161 | 10,151 | 8,161 |
| Shares issuable related to the 2004 Purchase Plan | 73 | 71 | 73 | 71 |

**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 $7.4 million of revenue during the three and six months ended June 30, 2015, respectively, and $3.7 million and $7.4 million of revenue during the three and six months ended June 30, 2014, respectively. The Company will periodically review and, if necessary, revise the estimated periods of performance of its collaboration. The Company also earned $3.6 million and $5.6 million reimbursement for eligible worldwide development expenses for evofosfamide from Merck KGaA during the three and six months ended June 30, 2015, respectively, compared to $3.5 million and $9.4 million during the three and six months ended June 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. Final determination of whether a development or regulatory milestone is substantive will depend upon the Company's role in achieving the milestone. The specific role and responsibilities related to the regulatory and development activities for certain of these milestones have yet to be determined and may change during the development period. 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 commencing with the date six months following the issuance date and continuing 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 June 30, 2015 and February 18, 2015, the Company had warrants outstanding to purchase 8,300,000 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 June 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:

| | June 30, 2015 | February 18, 2015 |
|---|---|---|
| Risk-free interest rate | 1.52 % | 1.52 % |
| Expected life (in years) | 4.64 | 5.00 |
| Dividend yield | — | — |
| Volatility | 50 % | 50 % |
| Stock price | $ 4.04 | $ 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 six months ended June 30, 2015, the change in fair value of $0.3 million and $1.5 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 June 30, 2015 and December 31, 2014, the Company also had warrants outstanding to purchase 3,846,165 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 June 30, 2015 and December 31, 2014 was determined using a Black Scholes valuation model with the followingkey level 3 inputs:

| | June 30, 2015 | December 31, 2014 |
|---|---|---|
| Risk-free interest rate | 0.28 % | 0.67 % |
| Expected life (in years) | 0.71 | 1.21 |
| Dividend yield | — | — |
| Volatility | 51 % | 49 % |
| Stock price | $ 4.04 | $ 3.18 |

During the three and six months ended June 30, 2015, the change in fair value of $0.2 million of noncash income and $2.5 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 June 30, 2015 and December 31, 2014:

| (in thousands) | Fair Value as of June 30, 2015 | Basis of Fair Value Measurements | | |
|---|---|---|---|---|
| | | Level 1 | Level 2 | Level 3 |
| February 2015 warrants | $ 13,242 | $ — | $ — | $ 13,242 |
| March 2011 warrants | 6,385 | — | — | 6,385 |
| Total common stock warrants | $ 19,627 | $ — | $ — | $ 19,627 |

| (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 six months ended June 30, 2015 | 974 |
| Exercise of warrants during six months ended June 30, 2015 | — |
| Balance at June 30, 2015 | $ 19,627 |

**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 six months ended June 30, 2015 and 2014 as follows (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Amortization of stock-based compensation: | | | | |
| Research and development | $ 1,174 | $ 846 | $ 1,991 | $ 1,517 |
| General and administrative | 721 | 622 | 1,325 | 1,217 |
| | $ 1,895 | $ 1,468 | $ 3,316 | $ 2,734 |

***Valuation Assumptions***

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. This fair value is being amortized ratably over the requisite service periods of the awards, which is generally the vesting period. The fair value of employee stock options and employee purchase rights under the 2004 Purchase Plan was estimated using the following weighted-average assumptions for the three and six months ended June 30, 2015 and 2014:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Employee Stock Options: | | | | |
| Risk-free interest rate | 1.69% | 1.81% | 1.70% | 1.82% |
| Expected term (in years) | 5.58 | 5.97 | 5.98 | 5.97 |
| Dividend yield | — | — | — | — |
| Volatility | 79% | 94% | 83% | 94% |
| Weighted-average fair value of stock options granted | $ 2.65 | $ 2.79 | $ 3.08 | $ 2.89 |

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Employee Stock Purchase Plan (ESPP): | | | | |
| Risk-free interest rate | 0.38% | 0.18% | 0.38% | 0.18% |
| Expected term (in years) | 1.24 | 1.23 | 1.24 | 1.23 |
| Dividend yield | — | — | — | — |
| Volatility | 51% | 53% | 51% | 53% |
| Weighted-average fair value of ESPP purchase rights | $ 1.59 | $ 1.79 | $ 1.59 | $ 1.79 |

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 $1.9 million and $3.3 million of stock-based compensation expense related to stock options and purchase rights, under the Company's equity incentive plans and 2004 Purchase Plan, for the three and six months ended June 30, 2015, respectively, and $1.5 million and $2.7 million of stock-based compensation for the three and six months ended June 30, 2014, respectively. As of June 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 $13.4 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 2.7 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 $17,000 and $41,000 for the three and six months ended June 30, 2015, respectively, and $19,000 and $55,000 for the three and six months ended June 30, 2014, respectively.

***Equity Incentive Plans***

***Equity Incentive Plans*** At June 30, 2015, 2,379,326 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 | 2,105,500 | $ 4.38 | — | — |
| Exercised | (61,873) | $ 1.83 | — | — |
| Forfeitures | (61,333) | $ 4.88 | — | — |
| Outstanding at June 30, 2015 | 10,151,236 | $ 3.83 | 7.33 | $ 8,726,000 |
| Vested and expected to vest June 30, 2015 | 10,051,806 | $ 3.83 | 7.31 | $ 8,714,000 |
| Exercisable at June 30, 2015 | 6,032,323 | $ 3.41 | 6.24 | $ 8,158,000 |

The total intrinsic value of stock options exercised during the six months ended June 30, 2015 and 2014 were $0.2 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 six months ended June 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 six months ended June 30, 2015, plan participants had purchased 74,673 shares at an average purchase price of $3.43 for total cash proceeds of $0.3 million. At June 30, 2015, 206,231 shares were authorized and available for issuance under the 2004 Purchase Plan.

**NOTE 6 —MARKETABLE SECURITIES AND FAIR VALUE**

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

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

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

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

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

The following table sets forth the Company's financial assets (cash equivalents and marketable securities) at fair value on a recurring basis as of June 30, 2015 and December 31, 2014:

| (in thousands) | Fair Value as of June 30, 2015 | Basis of Fair Value Measurements | | |
|---|---|---|---|---|
| | | Level 1 | Level 2 | Level 3 |
| Money market funds | $ 6,024 | $ 6,024 | $ — | $ — |
| Certificates of deposit | 356 | — | 356 | — |
| Corporate debt securities | 27,833 | — | 27,833 | — |
| Government securities | 21,709 | — | 21,709 | — |
| Municipal securities | 1,956 | — | 1,956 | — |
| Commercial paper | 8,880 | — | 8,880 | — |
| Total cash equivalents and marketable securities | $ 66,758 | $ 6,024 | $ 60,734 | $ — |

| (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 June 30, 2015 and December 31, 2014:

| As of June 30, 2015 (in thousands): | Cost Basis | Unrealized Gain | Unrealized Loss | Fair Value |
|---|---|---|---|---|
| Money market funds | $ 6,024 | $ — | $ — | $ 6,024 |
| Certificates of deposit | 356 | — | — | 356 |
| Corporate debt securities | 27,853 | 1 | (21) | 27,833 |
| U.S. Government securities | 21,708 | 2 | (1) | 21,709 |
| Municipal securities | 1,955 | 1 | — | 1,956 |
| Commercial paper | 8,880 | — | — | 8,880 |
| | 66,776 | 4 | (22) | 66,758 |
| Less cash equivalents | 10,308 | — | — | 10,308 |
| Total marketable securities | $ 56,468 | $ 4 | $ (22) | $ 56,450 |

| 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 six months ended June 30, 2015 and 2014, respectively.

As of June 30, 2015, the weighted average maturity for the Company's available for sale securities was 4.1 months, with the longest maturity being May 2016.

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

| | In loss position for less than twelve months | |
|---|---|---|
| As of June 30, 2015 (in thousands): | Fair Value | Unrealized Loss |
| U.S. Government securities | $ 6,484 | $ (1) |
| Corporate debt securities | 24,225 | (21) |
| Total marketable securities | $ 30,709 | $ (22) |

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 | $ 375 |
| 2016 | 768 |
| 2017 | 260 |
| Thereafter | — |
| Total | $ 1,403 |

***Indemnification***

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, including business partners, contractors and parties performing its clinical trials. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party as a result of the Company's activities. The duration of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal. The Company maintains commercial general liability insurance and products liability insurance to offset certain of its potential liabilities under these indemnification provisions. Accordingly, the Company has not recognized any liabilities relating to these agreements as of June 30, 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 its expected uses and benefits;
- anticipated clinical developmental events for evofosfamide, including the timing of the commencement, conduct and completion of clinical trials for evofosfamide 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;
- our anticipated clinical development of tarloxotinib bromide or tarloxotinib (formerly referred to as TH-4000, PR610 or Hypoxin™) and the timing thereof, as well as its potential therapeutic benefit;
- 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 designed to be activated under severe tumor 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) licensed from the University of Auckland. We expect to initiate two Phase 2 proof-of-concept clinical trials of tarloxotinib later in the second half of 2015.

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 and 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. The primary efficacy analyses for the 406 trial and the MAESTRO trial require 434 deaths and 508 deaths to be reported, respectively. We will remain blinded to the data from both trials until the primary efficacy analyses are conducted. We currently expect to report top-line results for both trials around the end of 2015.

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. In December 2014, preliminary results from this portion of the trial were reported at December 2014 American Society of Hematology (ASH) 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. Enrollment in this arm of the trial is ongoing.

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 biopsy, 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 expect to initiate two Phase 2 proof-of-concept clinical trials of tarloxotinib later in the second half of 2015: one in patients with EGFR-positive, T790M-negative non-small cell lung cancer (NSCLC) and the other in patients with recurrent/metastatic head and neck squamous cell carcinoma or skin squamous cell carcinoma.

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 June 30, 2015 and December 31, 2014, we had cash, cash equivalents and marketable securities of $67.0 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 and tarloxotinib. 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 develop our recently licensed tarloxotinib product candidate, 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 six months ended both June 30, 2015 and June 30, 2014, we recognized $3.7 million and $7.4 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 $10.1 million for the three months ended June 30, 2015 compared to $8.7 million for the three months ended June 30, 2014, in each case net of the reimbursement for Merck KGaA's 70% share of total development expenses for evofosfamide. The $1.4 million increase in expenses was due primarily to an increase of $0.5 million in employee related expenses and a $1.2 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 $0.2 million in consulting expenses. Research and development expenses were $20.8 million for the six months ended June 30, 2015 compared to $18.3 million for the six months ended June 30, 2014. The $2.5 million increase in expenses was due primarily to an increase of $1.1 million in employee related expenses and a $1.7 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 $0.4 million in consulting expenses.

During the three and six months ended June 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 six months ended June 30, 2015, we were also engaged in preclinical evaluation of tarloxotinib as well as clinical activities designed to support the initiation of our two planned 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Evofosfamide | $ 7,700 | $ 7,177 | $ 16,294 | $ 15,409 |
| Tarloxotinib | 1,078 | — | 1,908 | — |
| Discovery Research | 1,363 | 1,487 | 2,619 | 2,908 |
| Total Research and Development Expenses | $ 10,141 | $ 8,664 | $ 20,821 | $ 18,317 |

Research and development expenses associated with our internally discovered compound evofosfamide were $7.7 million and $16.3 million for the three and six months ended June 30, 2015, respectively, and $7.2 million and $15.4 million for the three and six months ended June 30, 2014, respectively, in each case net of the reimbursement for Merck KGaA's 70% share of total development expenses for evofosfamide. The increase of $1.2 million and $1.6 million during the three and six months ended June 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 an increase in development costs for the MAESTRO trial partially offset by a decrease in development costs for the 415 and 406 trials. Evofosfamide continues to progress through the 406 trial, the MAESTRO trial, the 415 trial that was initiated in June 2014, and the various earlier stage trials.

Research and developments expenses associated with tarloxotinib bromide, which we licensed rights to September 2014, were $1.1 million and $1.9 million for the three and six months ended June 30, 2015, respectively, and were related to preclinical studies and clinical activities designed to support initiation of our two planned Phase 2 proof-of-concept clinical trials of tarloxotinib. Discovery research and development expenses were $1.4 million and $1.5 million for the three and six months ended June 30, 2015, respectively, compared to $1.5 million and $2.9 million for the three and six months ended June 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, start additional clinical trials of evofosfamide and tarloxotinib, 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 the anticipated commencement of new clinical trials for evofosfamide and tarloxotinib. 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 future clinical 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 planned 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 $2.5 million and $5.1 million for the three and six months ended June 30, 2015, respectively, compared to $2.5 million and $5.1 million for the three and six months ended June 30, 2014, respectively. We currently expect our general and administrative expenses to 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 six months ended June 30, 2015 was $39,000 and $72,000, respectively, compared to $30,000 and $70,000 of interest income for same periods in 2014.

***Other Income (Expense).*** Other income (expense) for the three months ended June 30, 2015 was non-cash income of $0.6 million compared to non-cash income of $6.7 million for the three months ended June 30, 2014. The non-cash income during the three months ended June 30, 2015 and 2014 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 six months ended June 30, 2015 was non-cash expense of $1.0 million compared to non-cash income of $8.1 million, for the six months ended June 30, 2014. The non-cash expense during the six months ended June 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 six months ended June 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 $67.0 million and $58.6 million at June 30, 2015 and December 31, 2014, respectively, available to fund operations.

In February 2015, we completed an underwritten public offering of 8,300,000 shares of our common stock and accompanying warrants to purchase up to 8,300,000 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 six months ended June 30, 2015 was $19.7 million compared to net cash used in operating activities of $6.5 million for the six months ended June 30, 2014. The increase of $13.2 million in cash used in operations was primarily attributable to a decrease of $12.5 million of cash received related to payments from the Merck KGaA collaboration during the six months ended June 30, 2015 compared to the same period in 2014.

Net cash used in investing activities for the six months ended June 30, 2015 was $6.6 million compared with net cash provided by investing activities of $5.3 million for the six months ended June 30, 2014. The $11.9 million increase in cash used in investing activities was due primarily to an increase in the purchase of marketable securities net of a decrease in proceeds from the sales and maturities of marketable securities.

Net cash provided by financing activities for the six months ended June 30, 2015 and 2014 was $28.5 million and $0.4 million, respectively. The $28.1 million increase in cash provided by financing activities was due to the $28.1 million net proceeds received from the completion of our underwritten public offering in February 2015.

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 products candidates or programs.

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

- the public equity market, including pursuant to our at market issuance sales agreement 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 outcomeof 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 Market Issuance Sales Agreement***

On August 1, 2014, we entered into an at market issuance sales agreement, or sales agreement, with MLV & Co. LLC, or MLV, 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 $30.0 million from time to time through MLV as our sales agent. Sales of our common stock through MLV, 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 MLV. Subject to the terms and conditions of the sales agreement, MLV 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 sales agreement. We will pay MLV 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 sales agreement. The number of shares we are able to sell under this arrangement will be limited in practice based on the trading volume of our common stock. We have not yet sold any common stock pursuant to the sales agreement.

***Obligations and Commitments***

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

During the six months ended June 30, 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 on our 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 six months ended June 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 June 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 June 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 June 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), which is our only product candidate currently in human clinical trials. 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 while we expect to initiate Phase 2 clinical development of tarloxotinib later in the second half of 2015, evofosfamide is our only product candidate currently in human clinical trials In addition, 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 resultsin either of the Phase 3 clinical trials or other clinical trials of evofosfamide could also result in Merck KGaA terminating our license andco-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, these preclinical studies may not accurately predict the results of our planned Phase 2 proof-of-concept clinical trials of tarloxotinib in patients with EGFR-positive, T790M-negative non-small cell lung cancer. 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, including the 406 trial, 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. 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 anyregulatory 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, while we expect to initiate Phase 2 clinical development of tarloxotinib later in the second half of 2015, evofosfamide is 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 plan to evaluate 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 head and neck cancer. 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 the planned 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 plan to evaluate 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 to comply 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 six months ended June 30, 2015, we had an operating loss of $18.6 million and a net loss of $19.5 million, including $1.0 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 market issuance sales agreement, or the sales agreement, with MLV & Co. LLC, or MLV;
- 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 June 30, 2015, we had 63 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 willneed 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 planned 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 planned Phase 2 proof-of-concept clinical trials, which could delay the commencement or completion of these planned clinical trials, could increase our costs and could negatively impact our planned 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 protect our rights or permit us to gain or keep our competitive advantage. For example:

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

Moreover, an issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing the same or related product candidates or could limit the length of the term of patent protection of our product candidates. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Patent term extensions may not be available for these patents. If we are not able to obtain adequate protection for, or defend, the intellectual property position of evofosfamide or any other potential future product candidates, then we may not be able to retain or attract collaborators to partner our development programs, including evofosfamide. Further, even if we can obtain protection for and defend the intellectual property position of evofosfamide or any potential future product candidates, we or any of our potential future collaborators still may not be able to exclude competitors from developing or marketing competing drugs. Should this occur, we, Merck KGaA and potential future collaborators may not generate any revenues or profits from evofosfamide 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 ratethat 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 alsomade 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. 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 MLV;
- 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 June 30, 2015, we had 71,334,779 outstanding shares of common stock, substantially all of which may be sold in the public market without restriction, subject to any affiliate restrictions. On August 1, 2014, we entered into the Sales Agreement with MLV, under which we may sell shares of our common stock from time to time through MLV, as our agent for the offer and sale of the shares, in an aggregate amount not to exceed $30 million. To the extent that we sell shares of our common stock pursuant to the Sales Agreement with MLV, 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 June 30, 2015, warrants to purchase 1,879,062 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 June 30, 2015, there were 10,151,236 shares of our common stock issuable upon the exercise of outstanding options having a weighted-average exercise price of $3.83 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**

None.

**ITEM 6. EXHIBITS**

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

| Exhibit Number | Description |
|---|---|
| 10.1 | Change of Control Severance Agreement by and between the Registrant and Nipun Davar, dated as of June 5, 2015. |
| 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: July 30, 2015

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

Date: July 30, 2015

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

**EXHIBIT INDEX**

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**Exhibit 10.1**

**THRESHOLD PHARMACEUTICALS, INC.**

**CHANGE OF CONTROL SEVERANCE AGREEMENT**

The Change of Control Severance Agreement (the "Agreement") is made and entered into effective as of June 5, 2015 (the "Effective Date"), by and between Nipun Davar (the "Employee") and Threshold Pharmaceuticals, Inc., a Delaware corporation (the "Company"). Certain capitalized terms used in this Agreement are defined in Section 1 below.

RECITALS

A. It is expected that the Company from time to time will consider the possibility of a Change of Control. The Board of Directors of the Company (the "Board") recognizes that such consideration can be a distraction to the Employee and can cause the Employee to consider alternative employment opportunities.

B. The Board believes that it is in the best interests of the Company and its stockholders to provide the Employee with an incentive to continue Employee's employment and to maximize the value of the Company upon a Change of Control for the benefit of its stockholders.

C. In order to provide the Employee with enhanced financial security and sufficient encouragement to remain with the Company notwithstanding the possibility of a Change of Control, the Board believes that it is imperative to provide the Employee with certain severance benefits upon the Employee's termination of employment following a Change of Control.

[D. The Company and Employee entered into a Change of Control and Severance Agreement dated January 6, 2015 (the "Prior Agreement"). The Board and the Employee agree that the Prior Agreement is superseded in its entirety by the terms of this Agreement and the Prior Agreement shall cease to have any further legal force or effect whatsoever following the Effective Date.]

AGREEMENT

In consideration of the mutual covenants herein contained and the continued employment of Employee by the Company, the parties agree as follows:

1. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) Cause. "Cause" shall mean (i) Employee's gross negligence or willful failure substantially to perform his or her duties and responsibilities to the Company or deliberate violation of a Company policy; (ii) Employee's commission of any act of fraud, embezzlement, dishonesty or any other willful misconduct that has caused or is reasonably expected to result in

material injury to the Company; (iii) unauthorized use or disclosure by Employee of any proprietary information or trade secrets of the Company or any other party to whom the Employee owes an obligation of nondisclosure as a result of his or her relationship with the Company; or (iv) Employee's willful breach of any of his or her obligations under any written agreement or covenant with the Company. The determination as to whether an Employee is being terminated for Cause shall be made in good faith by the Company and shall be final and binding on the Employee.

(b) Change of Control. "Change of Control" shall mean the occurrence of any of the following events:

(i) the approval by stockholders of the Company of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation;

(ii) the approval by the stockholders of the Company of a plan of complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; or

(iii) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) becoming the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities.

(c) Involuntary Termination. "Involuntary Termination" shall mean (i) without the Employee's express written consent, a material reduction of the Employee's duties, position or responsibilities relative to the Employee's duties, position or responsibilities in effect immediately prior to such reduction, or the removal of the Employee from such position, duties and responsibilities, unless the Employee is provided with comparable or greater duties, position and responsibilities; (ii) without the Employee's express written consent, a material reduction by the Company of the Employee's base salary as in effect immediately prior to such reduction; (iii) without the Employee's express written consent, the imposition of a requirement for the relocation of the Employee to a facility or a location more than fifty (50) miles from the Employee's current work location; (iv) any purported termination of the Employee's employment by the Company which is not effected for Cause or for which the grounds relied upon are not valid; or (v) the failure of the Company to obtain the assumption of this Agreement by any successors contemplated in Section 6 below. In order to be considered an Involuntary Termination with regards to parts (i)-(iii) and (v) of this Section 1(c), (1) the Employee's termination from employment must have occurred within six (6) months following the initial existence of the condition giving rise to the Involuntary Termination, (2) within thirty (30) days following the initial existence of the condition giving rise to the Involuntary Termination, the Employee must have provided the Company with notice of the existence of such condition

pursuant to Section 8(b), and (3) upon receipt of the notice of the condition from Employee, the Company failed to cure the condition within thirty (30) days.

(d) Termination Date. "Termination Date" shall mean the effective date of any notice of termination delivered by one party to the other hereunder.

2. Term of Agreement. This Agreement shall terminate on the date that all obligations of the parties hereto under this Agreement have been satisfied.

3. At-Will Employment. The Company and the Employee acknowledge that the Employee's employment is and shall continue to be at-will, as defined under applicable law. If the Employee's employment terminates for any reason, the Employee shall not be entitled to any payments, benefits, damages, awards or compensation other than as provided by this Agreement, or as may otherwise be established under the Company's then existing employee benefit plans or policies at the time of termination.

4. Severance Benefits.

(a) Termination Following a Change of Control. If the Employee's employment with the Company terminates as a result of an Involuntary Termination at any time within eighteen (18) months after a Change of Control, and the Employee signs and does not revoke the release of claims pursuant to Section 7 hereto, then subject to Section 4(d), Employee shall be entitled to the following severance benefits:

(1) Twelve (12) months of Employee's base salary and any applicable allowances as in effect as of the date of the termination or, if greater, as in effect immediately prior to the Change of Control, plus an amount equal to the full amount of Employee's target bonus for the calendar year of the date of termination plus a pro rata portion (based on the number of full weeks during such year) of the amount of such bonus, or, if no target bonus has been established, an amount equal to Employee's target bonus in the prior year plus a pro rata portion (based on the number of full weeks during such year) of the amount of such bonus, less applicable withholding, payable in a lump sum within sixty (60) days following the date of termination;

(2) unless provided otherwise in the applicable award agreement, the vesting of all equity awards granted by the Company to the Employee prior to the Change of Control shall accelerate and become fully vested to the extent such equity awards are outstanding and unvested at the time of such termination;

(3) the Employee shall be permitted to exercise all vested (including shares that vest as a result of this Agreement) stock options granted by the Company to the Employee prior to the Change of Control for a period ending on the earlier of (i) two (2) years following the Termination Date and (ii) the expiration of the term of the stock options specified in the applicable option agreements; and

(4) the same level of Company-paid health (i.e., medical, vision and dental) coverage and benefits for such coverage as in effect for the Employee (and any eligible dependents) on the day immediately preceding the Employee's Termination Date;

provided, however, that (i) the Employee constitutes a qualified beneficiary, as defined in Section 4980B(g)(1) of the Internal Revenue Code of 1986, as amended (the "Code"); and (ii) Employee elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), within the time period prescribed pursuant to COBRA. The Company shall continue to provide Employee with such Company-paid coverage on a monthly basis following the Termination Date until the earlier of (i) the date Employee (and his/her eligible dependents) is no longer eligible to receive continuation coverage pursuant to COBRA, or (ii) twelve (12) months from the Termination Date.

(b) Termination Apart from a Change of Control. If (but without duplication with the provisions set forth above in subsection 4(a)(1)), at any time on or after the Effective Date, the Employee's employment with the Company terminates as a result of an Involuntary Termination, and the Employee signs and does not revoke the release of claims pursuant to Section 7 hereto, then subject to Section 4(d), the Employee shall be entitled to severance benefits in the form of twelve (12) months of Employee's base salary as in effect as of the date of termination, less applicable withholding, payable in a lump sum within sixty (60) days following the date of termination.

(c) Accrued Wages and Vacation, Expenses. Without regard to the reason for, or the timing of, Employee's termination of employment: (i) the Company shall pay the Employee any unpaid base salary due for periods prior to the Termination Date; (ii) the Company shall pay the Employee all of the Employee's accrued and unused vacation through the Termination Date; and (iii) following submission of proper expense reports by the Employee, the Company shall reimburse the Employee for all expenses reasonably and necessarily incurred by the Employee in connection with the business of the Company prior to the Termination Date. With respect to parts (i) and (ii) of this Section 4(c), payments shall be made as soon as practicable, but no later than March 15th of the calendar year following Employee's termination of employment. Reimbursements made pursuant to part (iii) of this Section 4(c) shall be made as soon as practicable, but no later than December 31st of the year following the calendar year in which such expense was incurred.

(d) Section 409A. Notwithstanding anything to the contrary in this Agreement, if any benefit provided under this Agreement is subject to Section 409A of the Code and such benefit otherwise is payable in connection with the Employee's termination of employment, then the following will apply:

(i) such benefit will not be payable unless such termination constitutes a "separation from service" (as such term is defined in Treasury Regulations Section 1.409A-1(h) without regard to any alternative definition thereunder) ("Separation from Service");

(ii) if the Employee's Separation from Service occurs at a time during the calendar year when the release of claims described in Section 7 could become effective in the calendar year following the calendar year in which such Separation from Service occurs, then for purposes of such benefit, the release of claims will not be deemed effective any earlier than the latest permitted effective date set forth therein (which date, in all cases, will be in the subsequent calendar year); and

(iii) if the Employee is a "specified employee" (as determined in accordance with Section 409A of the Code and related Treasury guidance and regulations) as of the date of the Employee's Separation from Service, then, solely to the extent necessary to avoid the imposition of the adverse personal tax consequences under Section 409A of the Code, (A) the commencement of such benefit payments will be delayed until the earlier of (1) the date that is six (6) months and one (1) day after such Separation from Service and (2) the date of the Employee's death (such applicable date, the "Delayed Initial Payment Date"), and (B) the Company will (1) pay the Employee a lump sum amount equal to the sum of any benefit payments that the Employee otherwise would have received through the Delayed Initial Payment Date if the commencement of such benefit payments had not been delayed pursuant to this paragraph and (2) commence paying the balance, if any, of such benefit in accordance with the applicable payment schedule.

It is intended that each installment of any benefit payable under this Agreement be regarded as a separate "payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2)(i).

5. Limitation on Payments. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to the Employee (i) constitute "parachute payments" within the meaning of Section 280G of the Code, and (ii) would be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then Employee's benefits under this Agreement shall be either

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such benefits being subject to the Excise Tax,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Employee on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code.

Unless the Company and the Employee otherwise agree in writing, any determination required under this Section shall be made in writing by the Company's independent public accountants (the "Accountants"), whose determination shall be conclusive and binding upon the Employee and the Company for all purposes. For purposes of making the calculations required by this Section, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Section 280G and 4999 of the Code. The Company and the Employee shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section.

6. Successors.

(a) Company's Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the Company's obligations under this Agreement and agree expressly to perform the Company's obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which executes and delivers the assumption agreement described in this subsection (a) or which becomes bound by the terms of this Agreement by operation of law.

(b) Employee's Successors. Without the written consent of the Company, Employee shall not assign or transfer this Agreement or any right or obligation under this Agreement to any other person or entity. Notwithstanding the foregoing, the terms of this Agreement and all rights of Employee hereunder shall inure to the benefit of, and be enforceable by, Employee's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

7. Execution of Release Agreement upon Termination. As a condition of entering into this Agreement and receiving the benefits under Sections 4(a) and 4(b), the Employee agrees to execute and not revoke a general release of claims within forty-five (45) days following the termination of employment with the Company.

8. Notices.

(a) General. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of the Employee, mailed notices shall be addressed to Employee at the home address which Employee most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Chief Executive Officer.

(b) Notice of Termination. Any termination by the Company for Cause or by the Employee as a result of a voluntary resignation or an Involuntary Resignation shall be communicated by a notice of termination to the other party hereto given in accordance with this Section. Such notice shall indicate the specific termination provision in this Agreement relied upon, shall set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and shall specify the Termination Date (which shall be not more than 30 days after the giving of such notice, such period to be extended to the extent a 30 day cure period under Section 1(c) applies). Except for the notice required under Section 1(c), the failure by the Employee to provide notice under this Section 8(b) shall not waive any right of the Employee hereunder or preclude the Employee from asserting any fact or circumstance in enforcing his rights hereunder.

9. Arbitration.

(a) Any dispute or controversy arising out of, relating to, or in connection with this Agreement, or the interpretation, validity, construction, performance, breach, or termination thereof, shall be settled by binding arbitration to be held in Santa Clara, California, in accordance with the National Rules for the Resolution of Employment Disputes then in effect of the American Arbitration Association (the "Rules"). The arbitrator may grant injunctions or other relief in such dispute or controversy. The decision of the arbitrator shall be final, conclusive and binding on the parties to the arbitration. Judgment may be entered on the arbitrator's decision in any court having jurisdiction. The arbitrator may require one party to pay the costs and attorney fees of the prevailing party.

(b) The arbitrator(s) shall apply California law to the merits of any dispute or claim, without reference to conflicts of law rules. The arbitration proceedings shall be governed by federal arbitration law and by the Rules, without reference to state arbitration law. Employee hereby consents to the personal jurisdiction of the state and federal courts located in California for any action or proceeding arising from or relating to this Agreement or relating to any arbitration in which the parties are participants.

(c) Employee understands that nothing in this Section modifies Employee's at-will employment status. Either Employee or the Company can terminate the employment relationship at any time, with or without Cause.

(d) EMPLOYEE HAS READ AND UNDERSTANDS THIS SECTION, WHICH DISCUSSES ARBITRATION. EMPLOYEE UNDERSTANDS THAT SUBMITTING ANY CLAIMS ARISING OUT OF, RELATING TO, OR IN CONNECTION WITH THIS AGREEMENT, OR THE INTERPRETATION, VALIDITY, CONSTRUCTION, PERFORMANCE, BREACH OR TERMINATION THEREOF TO BINDING ARBITRATION, CONSTITUTES A WAIVER OF EMPLOYEE'S RIGHT TO A JURY TRIAL AND RELATES TO THE RESOLUTION OF ALL DISPUTES RELATING TO ALL ASPECTS OF THE EMPLOYER/EMPLOYEE RELATIONSHIP, INCLUDING BUT NOT LIMITED TO, THE FOLLOWING CLAIMS:

(i) ANY AND ALL CLAIMS FOR WRONGFUL DISCHARGE OF EMPLOYMENT; BREACH OF CONTRACT, BOTH EXPRESS AND IMPLIED; BREACH OF THE COVENANT OF GOOD FAITH AND FAIR DEALING, BOTH EXPRESS AND IMPLIED; NEGLIGENT OR INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS; NEGLIGENT OR INTENTIONAL MISREPRESENTATION; NEGLIGENT OR INTENTIONAL INTERFERENCE WITH CONTRACT OR PROSPECTIVE ECONOMIC ADVANTAGE; AND DEFAMATION.

(ii) ANY AND ALL CLAIMS FOR VIOLATION OF ANY FEDERAL STATE OR MUNICIPAL STATUTE, INCLUDING, BUT NOT LIMITED TO, TITLE VII OF THE CIVIL RIGHTS ACT OF 1964, THE CIVIL RIGHTS ACT OF 1991, 1 AGE DISCRIMINATION IN EMPLOYMENT ACT OF 1967, THE AMERICANS WITH DISABILITIES ACT OF 1990, THE FAIR LABOR STANDARDS ACT, THE CALIFORNIA FAIR EMPLOYMENT AND HOUSING ACT, AND LABOR CODE SECTION 20 1, *et seq*;

(iii) ANY AND ALL CLAIMS ARISING OUT OF ANY OTHER LAWS AND REGULATIONS RELATING TO EMPLOYMENT OR EMPLOYMENT DISCRIMINATION.

10. Miscellaneous Provisions.

(a) Effect of Statutory Benefits. To the extent that any severance benefits are required to be paid to the Employee upon termination of employment with the Company as a result of any requirement of law or any governmental entity in any applicable jurisdiction, the aggregate amount of severance benefits payable pursuant to Section 4 hereof shall be reduced by such amount.

(b) No Duty to Mitigate. The Employee shall not be required to mitigate the amount of any payment contemplated by this Agreement, nor shall any such payment be reduced by any earnings that the Employee may receive from any other source.

(c) Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by the Employee and by an authorized officer of the Company (other than the Employee). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(d) Integration. This Agreement and any outstanding stock option agreements and any restricted stock purchase agreements referenced herein represent the entire agreement and understanding between the parties as to the subject matter herein and supersede all prior or contemporaneous agreements, whether written or oral (including the Prior Agreement), with respect to this Agreement and any stock option agreement or any restricted stock purchase agreement, provided, that, for clarification purposes, this Agreement shall not affect any agreements between the Company and Employee regarding intellectual property matters or confidential information of the Company.

(e) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(f) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(g) Employment Taxes. All payments made pursuant to this Agreement shall be subject to withholding of applicable income and employment taxes.

(h) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY: Threshold Pharmaceuticals, Inc.

By: /s/ Harold E. Selick, Ph.d.

Title: Chief Executive Officer

EMPLOYEE: /s/ NIPUN DAVAR

Signature

NIPUN DAVAR

Printed Name

**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: July 30, 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: July 30, 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 June 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: July 30, 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 June 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: July 30, 2015

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