
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED June 30, 2016

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: 001-33415

OREXIGEN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

3344 North Torrey Pines Court, Suite 200, La Jolla, CA
(Address of Principal Executive Offices)

65-1178822
(I.R.S. Employer
Identification No.)

92037
(Zip Code)

(858) 875-8600
(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 registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer", "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 registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 1, 2016, the registrant had 14,586,771 shares of Common Stock (\$0.001 par value) outstanding.

[Table of Contents](#)

OREXIGEN THERAPEUTICS, INC.
TABLE OF CONTENTS

| | |
|---|----|
| <u>PART I. FINANCIAL INFORMATION</u> | 3 |
| <u>Item 1. Financial Statements</u> | 3 |
| <u>Consolidated Balance Sheets as of June 30, 2016 (Unaudited) and December 31, 2015</u> | 3 |
| <u>Unaudited Consolidated Statements of Operations for the three and six months ended June 30, 2016 and June 30, 2015</u> | 4 |
| <u>Unaudited Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2016 and June 30, 2015</u> | 5 |
| <u>Unaudited Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and June 30, 2015</u> | 6 |
| <u>Notes to Unaudited Consolidated Financial Statements</u> | 7 |
| <u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> | 22 |
| <u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u> | 30 |
| <u>Item 4. Controls and Procedures</u> | 31 |
| <u>PART II. OTHER INFORMATION</u> | 31 |
| <u>Item 1. Legal Proceedings</u> | 31 |
| <u>Item 1.A. Risk Factors</u> | 34 |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u> | 66 |
| <u>Item 3. Defaults Upon Senior Securities</u> | 66 |
| <u>Item 4. Mine Safety Disclosures</u> | 66 |
| <u>Item 5. Other Information</u> | 66 |
| <u>Item 6. Exhibits</u> | 67 |
| <u>SIGNATURES</u> | 68 |
| EXHIBIT 10.1 | |
| EXHIBIT 10.2 | |
| EXHIBIT 10.3 | |
| EXHIBIT 10.4 | |
| EXHIBIT 10.5 | |
| EXHIBIT 31.1 | |
| EXHIBIT 31.2 | |
| EXHIBIT 32.1 | |
| EXHIBIT 32.2 | |
| EXHIBIT 101 | |

[Table of Contents](#)**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS**

Orexigen Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and par value amounts)

| | <u>June 30,</u> <u>2016</u> | <u>December 31,</u> <u>2015</u> |
|--|--------------------------------|------------------------------------|
| | (Unaudited) | (See Note below) |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 78,173 | \$ 155,422 |
| Accounts receivable | 2,922 | 6,828 |
| Investment securities, available-for-sale | 20,983 | 58,589 |
| Restricted cash and investments | 165,203 | — |
| Inventory | 11,458 | 10,802 |
| Prepaid expenses and other current assets | 3,965 | 2,254 |
| Total current assets | 282,704 | 233,895 |
| Property and equipment, net | 1,377 | 1,284 |
| Prepaid purchase price—Contrave | 60,000 | — |
| Other long-term assets | 1,210 | 1,013 |
| Restricted cash | 138 | 138 |
| Total assets | <u>\$ 345,429</u> | <u>\$ 236,330</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 4,105 | \$ 6,485 |
| Accrued clinical trial expenses | 10,516 | 5,820 |
| Accrued expenses | 10,551 | 10,323 |
| Deferred revenue, current portion | 9,600 | 9,613 |
| Total current liabilities | 34,772 | 32,241 |
| Long-term convertible debt | 90,142 | 87,870 |
| Long-term convertible debt, at fair value | 116,300 | — |
| Warrant liability, at fair value | 33,100 | — |
| Deferred revenue, less current portion | 77,737 | 82,691 |
| Other long-term liabilities | 37 | 150 |
| Commitments and contingencies | | |
| Series Z preferred stock, \$.001 par value, 219,994 and no shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively | 3,343 | — |
| Stockholders' equity: | | |
| Preferred stock, \$.001 par value, 10,000,000 shares authorized at June 30, 2016 and December 31, 2015; 219,994 and no shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively | — | — |
| Common stock, \$.001 par value, 300,000,000 shares authorized at June 30, 2016 and December 31, 2015; 14,586,780 and 14,554,592 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively | 15 | 15 |
| Additional paid-in capital | 659,129 | 653,835 |
| Accumulated other comprehensive income (loss) | (881) | 215 |
| Accumulated deficit | (668,265) | (620,687) |
| Total stockholders' equity (deficit) | (10,002) | 33,378 |
| Total liabilities and stockholders' equity | <u>\$ 345,429</u> | <u>\$ 236,330</u> |

See accompanying notes.

Note: The Balance Sheet at December 31, 2015 has been derived from the audited financial statements at that date.

[Table of Contents](#)

Orexigen Therapeutics, Inc.
Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

| | Three Months Ended | | Six Months Ended | |
|---|--------------------|------------|------------------|------------|
| | June 30, | | June 30, | |
| | 2016 | 2015 | 2016 | 2015 |
| Revenues: | | | | |
| Collaborative agreement | \$ 2,403 | \$ 2,057 | \$ 4,794 | \$ 4,114 |
| Royalties | 2,453 | 3,137 | 5,095 | 5,439 |
| Net product sales | 2,935 | — | 2,935 | — |
| Total revenues | 7,791 | 5,194 | 12,824 | 9,553 |
| Cost of product sales | 1,784 | — | 1,784 | — |
| Operating expenses: | | | | |
| Research and development | 14,249 | 15,107 | 26,050 | 26,349 |
| Selling, general and administrative | 24,991 | 10,815 | 41,542 | 19,399 |
| Total operating expenses | 39,240 | 25,922 | 67,592 | 45,748 |
| Loss from operations | (33,233) | (20,728) | (56,552) | (36,195) |
| Other income (expense): | | | | |
| Interest income | 163 | 67 | 286 | 130 |
| Interest expense | (1,954) | (1,843) | (3,890) | (3,672) |
| Change in fair value of financial instruments | 11,600 | — | 11,600 | — |
| Foreign currency gain (loss), net | (1,806) | — | 978 | — |
| Total other income (expense) | 8,003 | (1,776) | 8,974 | (3,542) |
| Net loss | \$(25,230) | \$(22,504) | \$(47,578) | \$(39,737) |
| Basic and diluted net loss per share | \$ (1.73) | \$ (1.80) | \$ (3.27) | \$ (3.19) |
| Basic and diluted shares used in computing net loss per share | 14,566 | 12,519 | 14,561 | 12,454 |

See accompanying notes.

Orexigen Therapeutics, Inc.
Consolidated Statements of Comprehensive Loss
(In thousands)
(Unaudited)

| | Three Months Ended | | Six Months Ended | |
|---|---------------------------|-------------------|-------------------------|-------------------|
| | June 30, | | June 30, | |
| | 2016 | 2015 | 2016 | 2015 |
| Net loss | \$(25,230) | \$(22,504) | \$(47,578) | \$(39,737) |
| Other comprehensive gain (loss) | | | | |
| Foreign currency translation gain (loss) | 1,865 | — | (1,154) | — |
| Unrealized gain (loss) on investment securities | 20 | (6) | 58 | 36 |
| Other comprehensive gain (loss) | 1,885 | (6) | (1,096) | 36 |
| Comprehensive loss | <u>\$(23,345)</u> | <u>\$(22,510)</u> | <u>\$(48,674)</u> | <u>\$(39,701)</u> |

See accompanying notes.

[Table of Contents](#)

Orexigen Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

| | Six Months Ended | |
|---|------------------|------------------|
| | June 30, | |
| | 2016 | 2015 |
| Operating activities | | |
| Net loss | \$ (47,578) | \$ (39,737) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Amortization of premium on securities available-for-sale | 104 | 511 |
| Accretion of debt discount | 2,248 | 2,065 |
| Change in fair value of financial instruments | (11,600) | — |
| Depreciation | 194 | 103 |
| Stock-based compensation | 5,103 | 8,939 |
| Deferred revenue | (5,091) | (4,114) |
| Unrealized foreign currency gain | (473) | — |
| Other non-cash adjustments | 35 | 28 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 3,906 | (4,233) |
| Inventory | (596) | (3,711) |
| Prepaid expenses and other current assets | (1,712) | (553) |
| Other assets | (208) | (288) |
| Accounts payable and accrued expenses | 2,544 | 6,903 |
| Deferred rent and lease incentives | (113) | (96) |
| Net cash used in operating activities | (53,237) | (34,183) |
| Investing activities | | |
| Purchases of securities available-for-sale | (23,600) | (56,981) |
| Maturities of securities available-for-sale | 61,135 | 54,324 |
| Restricted cash and investments | (165,179) | — |
| Prepaid purchase price—Contrave | (60,000) | — |
| Purchase of property and equipment | (286) | (11) |
| Net cash used in investing activities | (187,930) | (2,668) |
| Financing activities | | |
| Proceeds from convertible debt issuance | 120,000 | — |
| Proceeds from issuance of warrants | 41,000 | — |
| Proceeds from issuance of Series Z Preferred | 3,343 | — |
| Proceeds from issuance of common stock | 139 | 4,193 |
| Net cash provided by financing activities | 164,482 | 4,193 |
| Effect of exchange rate changes on cash | (564) | — |
| Net decrease in cash and cash equivalents | (77,249) | (32,658) |
| Cash and cash equivalents at beginning of period | 155,422 | 104,243 |
| Cash and cash equivalents at end of period | <u>\$ 78,173</u> | <u>\$ 71,585</u> |

See accompanying notes.

OREXIGEN THERAPEUTICS, INC.
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. The Company and Basis of Presentation

Organization

Orexigen Therapeutics, Inc. (the “Company”), a Delaware corporation, is a biopharmaceutical company focused on the development of pharmaceutical product candidates for the treatment of obesity. The Company was incorporated in September 2002 and commenced operations in 2003.

The Company’s primary activities since incorporation have been organizational activities, including recruiting personnel, conducting research and development, including clinical trials, raising capital, and preparing for the marketing and commercialization of its sole product, Contrave, in the United States. Contrave was launched commercially in the United States by the Company’s former partner, Takeda Pharmaceutical Company Limited (“Takeda”), in October 2014. In addition, the Company has experienced losses since its inception, and as of June 30, 2016, had an accumulated deficit of \$668.3 million. The Company expects to continue to incur losses for at least the next several years. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company’s cost structure, and until that time, the Company may need to continue to raise additional equity or debt financing.

Basis of Presentation

The Company has prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying unaudited financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company’s interim financial information. The consolidated financial statements of the Company include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

The financial statements of the Company’s foreign subsidiary with a functional currency other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders’ equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income (loss) in stockholders’ equity. Foreign currency transaction gains and losses are included in the results of operations in other income and expense.

The balance sheet as of December 31, 2015 has been derived from the audited financial statements as of December 31, 2015 but does not include all information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. For more complete financial information, the accompanying unaudited consolidated financial statements and notes thereto should be read in conjunction with the audited financial statements for the year ended December 31, 2015 included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015.

Reverse Stock Split

In July 2016, the Orexigen Board of Directors and stockholders approved a 1-for-10 reverse stock split of all of the outstanding shares of Orexigen’s common stock. On the effective date (July 12, 2016) of the reverse stock split, every 10 shares of the Company’s issued and outstanding common stock, par value \$0.001, was consolidated into one outstanding share of common stock, par value \$0.001. The reverse stock split reduced the number of shares of the Company’s outstanding common stock from approximately 145.9 million to approximately 14.6 million. Proportional adjustments were made to the Company’s outstanding convertible debt, stock options, warrants, and equity incentive plan. The effect of this event has been reflected in all the share quantities and per share amounts in these financial statements. The shares of common stock authorized remained at 300 million shares and retained a par value of \$0.001.

2. Summary of Significant Accounting Policies

Research and Development Costs

All research and development costs are charged to expense as incurred and consist principally of costs related to clinical trials, license fees and salaries and related benefits. Clinical trial costs are a significant component of research and development expenses. These costs are accrued based on estimates of work performed, and require estimates of total costs incurred based on patients enrolled, progress of clinical studies and other events. Clinical trial costs are subject to revision as the trials progress and revisions are charged to expense in the period in which they become known.

Revenue Recognition

Prior to the revised multiple element and milestone method of revenue recognition guidance adopted by the Company on January 1, 2011, nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by the Company under the agreements were recognized as revenue upon the earlier of when payments were received or collection was assured, but were deferred if the Company had continuing performance obligations. If the Company had continuing involvement through contractual obligations under such agreements, such up-front fees were deferred and recognized over the period for which the Company continued to have a performance obligation.

Effective January 1, 2011, for multiple element agreements entered into or materially modified after December 31, 2010, the Company follows the provisions of Accounting Standards Update ("ASU") No. 2009-13. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. A delivered item is considered a separate unit of accounting when the delivered item has value to the partner on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace. Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor-specific objective evidence ("VSOE") of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement. Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of drug products, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, the Company's price to the partner is fixed or determinable, and collectability is reasonably assured.

Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have a material impact on the amount of revenue recognized in a given period.

The Company accounts for milestone payments under its agreements using the Milestone Method of accounting. The Company recognizes consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following three criteria: 1) the consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, 2) the consideration relates solely to past performance, and 3) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company. Any milestone payments that do not satisfy these revenue recognition criteria are recorded over the remaining life of the agreements with a cumulative catch up adjustment for the portion of the milestone earned from the inception of the agreement to the expected term of the agreement. The excess of the milestone paid and the amount recognized in the cumulative catch up adjustment is recorded as deferred revenue and recognized over the remaining expected term of the agreement.

[Table of Contents](#)

Royalties to be received based on sales of the Company's licensed products by partners are recognized as earned.

The Company recognizes product revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Specifically, net product revenue from the sale of Contrave/Mysimba is generally recognized upon transfer of title of the product to our third-party customers.

Inventory

Inventories are stated at the lower of cost (using a first-in, first-out basis) or market. Inventory costs including raw materials and finished goods that may be associated with its products prior to regulatory approval are charged to research and development expense prior to such approval on a country-specific basis.

Fair Value Option

The Company has elected the fair value option to account for its convertible notes that were issued during the quarter ended March 31, 2016 and records these convertible notes at fair value with changes in fair value recorded in the statement of operations. As a result of applying the fair value option, direct costs and fees related to the convertible notes were recognized in earnings as incurred and not deferred.

Preferred Stock

Preferred shares subject to mandatory redemption (if any) are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. At all other times, the Company classifies its preferred shares in stockholders' equity. Similar in nature to a redemption right, the Company's Series Z Preferred Stock features a contingent right to receive payment from the Company in the event of certain fundamental changes, some of which are not within the Company's control. Accordingly, the Series Z Preferred Stock is presented as a component of temporary equity.

Accounting for Warrants at Fair Value

The Company classifies as liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

The Company assessed the classification of warrants issued in 2016 and associated with the 2016 convertible notes as of the date of the offering and determined that such instruments met the criteria for liability classification. Accordingly, the Company classified the warrants issued in 2016 as a liability at their fair value and adjusts the instruments to fair value at each balance sheet date until the warrants are exercised or expired. Any change in the fair value of the warrants is recognized as "change in fair value of financial instruments" in the consolidated statements of operations.

Prepaid Purchase Price – Contrave

In March 2016, the Company entered into a separation agreement with Takeda which will result in our acquisition of the Contrave business held by Takeda on August 1, 2016. The Company will record this transaction as a business combination in the quarter ended September 30, 2016 (see Note 11 for further details). The Company accounted for the \$60 million paid to Takeda as a prepaid noncurrent asset, as control of the business has not transferred to the Company.

[Table of Contents](#)

Restricted Cash and Investments

Any cash that is legally restricted from use is recorded in restricted cash on the balance sheets. The convertible senior secured notes due 2020 as executed in March 2016 (See Note 10) requires the Company to maintain a minimum account balance which is considered to be restricted cash and investments. The required restricted cash and investment amounts are \$165.0 million, \$100.0 million and \$50.0 million until December 21, 2016, March 21, 2017 and June 21, 2017, respectively. The restricted cash and investments balance was \$165.3 million and \$138,000 on June 30, 2016 and December 31, 2015, respectively.

Recently Issued Accounting Standards

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASU 2014-09 defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. In March 2016, the FASB issued an amendment to clarify the implementation guidance around considerations of whether an entity is a principal or an agent, impacting whether an entity reports revenue on a gross or net basis. In April 2016, the FASB issued an amendment to clarify guidance on identifying performance obligations and the implementation guidance on licensing. In May 2016, the FASB issued amendments to certain aspects of the new revenue guidance (including transition, collectability, noncash consideration and the presentation of sales and other similar taxes) and provided certain practical expedients. The new standard will be effective for the Company starting in the first quarter of fiscal 2018; early adoption as of January 1, 2017 is permitted. The Company is in the process of evaluating the transition methods as well as the effects the adoption will have on its consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which simplifies the presentation of debt issuance costs by requiring debt issuance costs to be presented as a deduction from the corresponding debt liability, consistent with the presentation of debt discounts or premiums. Previous guidance generally required entities to present debt issue costs separately as deferred charges. The Company adopted the new guidance in the first quarter of 2016, and prior year amounts were reclassified to conform to the current year presentation. The adoption of this guidance resulted in the reclassification of approximately \$259,000 of unamortized debt issuance costs principally from other noncurrent assets to a reduction of long term debt on our consolidated balance sheet as of December 31, 2015. At June 30, 2016, debt issuance costs of approximately \$235,000 were netted against long term debt on our consolidated balance sheet under the new guidance.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and provide related footnote disclosures. ASU No. 2014-15 will be effective for the Company for the year ended December 31, 2016 and for interim reporting periods thereafter. The adoption of this new standard is not expected to have a significant impact on the consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Liabilities*. ASU No. 2016-01 requires several targeted changes including that equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) be measured at fair value with changes in fair value recognized in net income. In addition, the new guidance requires an entity that has elected the fair value option for a financial liability to present separately in other comprehensive income the portion of the total change in the fair value of the liability resulting from a change in the instrument-specific credit risk. The new guidance also changes certain disclosure requirements and other aspects of current U.S. GAAP. Amendments are generally to be applied as a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. ASU No. 2016-01 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is not permitted with the exception of the provision addressing instrument-specific credit risk related to financial liabilities recorded at fair value under the fair value option. We are currently in the process of evaluating the impact of adoption of ASU No. 2016-01 on the consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU No. 2016-2 requires an entity to recognize right-of-use assets and lease liabilities on its balance sheet for all leases and to disclose key information about leasing arrangements. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash

[Table of Contents](#)

flows arising from leases. ASU No. 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. Early adoption is permitted. The Company currently in the process of evaluating the impact of adoption of ASU No. 2016-02 on the consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, “*Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*” (“ASU 2016-09”). The amendment is to simplify several aspects of the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in ASU 2016-09 are effective for interim and annual reporting periods beginning after December 15, 2016. The Company is currently assessing the impact of ASU 2016-09 on the consolidated financial statements and related disclosures.

3. Net Loss per Share

Basic earnings per share (“EPS”) is calculated by dividing the net income or loss available to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net income or loss available to common stockholders by the weighted average number of common shares outstanding for the period and the weighted average number of dilutive common stock equivalents outstanding for the period determined using the treasury-stock method or if converted method.

For purposes of this calculation, options, warrants and shares underlying convertible notes are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

(In thousands, except per share amounts)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--|--------------------------------|-------------------|------------------------------|-------------------|
| | 2016 | 2015 | 2016 | 2015 |
| Numerator: | | | | |
| Net loss | <u>\$(25,230)</u> | <u>\$(22,504)</u> | <u>\$(47,578)</u> | <u>\$(39,737)</u> |
| Denominator: | | | | |
| Basic and diluted weighted average shares of common stock outstanding | <u>14,566</u> | <u>12,519</u> | <u>14,561</u> | <u>12,454</u> |
| Basic and diluted net loss per share | <u>\$ (1.73)</u> | <u>\$ (1.80)</u> | <u>\$ (3.27)</u> | <u>\$ (3.19)</u> |
| Potentially outstanding anti-dilutive securities not included in diluted net loss per share calculation include the following: | | | | |
| Shares underlying convertible senior notes | 1,404 | 1,404 | 1,404 | 1,404 |
| Common stock options outstanding | <u>2,289</u> | <u>1,914</u> | <u>2,289</u> | <u>1,914</u> |
| | <u>3,693</u> | <u>3,318</u> | <u>3,693</u> | <u>3,318</u> |

[Table of Contents](#)

4. Investment Securities, Available-for-Sale

The Company invests its excess cash in investment securities, including debt instruments of financial institutions, corporations with investment grade credit ratings and government agencies. Investment securities, available-for-sale, consisted of the following at June 30, 2016 and December 31, 2015 (in thousands):

June 30, 2016

| | Maturity in Years | Amortized Cost | Unrealized | | Fair Value |
|-----------------------------------|----------------------|-------------------|--------------|-------------|------------------|
| | | | Gains | Losses | |
| U.S. government agency securities | Less than 1 | 12,231 | 5 | — | 12,236 |
| U.S. Treasury securities | Less than 1 | 140,166 | 43 | — | 140,209 |
| Corporate debt securities | Less than 1 | 3,740 | 1 | — | 3,741 |
| Total investment securities | | <u>\$ 156,137</u> | <u>\$ 49</u> | <u>\$ —</u> | <u>\$156,186</u> |

December 31, 2015

| | Maturity in Years | Amortized Cost | Unrealized | | Fair Value |
|-----------------------------------|----------------------|------------------|-------------|----------------|------------------|
| | | | Gains | Losses | |
| U.S. government agency securities | Less than 1 | \$ 36,748 | \$ 7 | \$ (12) | \$ 36,743 |
| Corporate debt securities | Less than 1 | 9,803 | — | (2) | 9,801 |
| U.S. Treasury securities | Less than 1 | 12,046 | — | (1) | 12,045 |
| Total investment securities | | <u>\$ 58,597</u> | <u>\$ 7</u> | <u>\$ (15)</u> | <u>\$ 58,589</u> |

A portion of the investments at June 30, 2016 are restricted investments as described in Note 2. Gross realized gains and losses on available-for-sale securities were immaterial during the three and six months ended June 30, 2016 and 2015.

5. Fair Value Measurements

The fair values of the Company's financial instruments are estimated and classified using a hierarchical disclosure framework based upon the level of subjectivity of the inputs used in measuring assets and liabilities. The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2016, and indicates the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. The Company classifies money market funds as Level 1 assets. Fair values determined by Level 2 inputs utilize inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets and liabilities in active markets, and inputs other than quoted prices that are observable for the asset or liability, such as interest rates and yield curves that are observable at commonly quoted intervals. The Company classifies commercial paper holdings, U.S. Treasury securities, U.S. government agency securities and asset-backed security holdings as Level 2 assets. Level 3 inputs are unobservable inputs for the assets or liabilities, and include situations where there is little, if any, market activity for the asset or liability. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

Table of Contents

Assets and liabilities measured at fair value on a recurring basis at June 30, 2016 are shown below (in thousands):

| Description | Balance as of June 30, 2016 | Fair Value Measurement at Reporting Date Using | | |
|--|--------------------------------|--|---|---|
| | | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Assets: | | | | |
| Money market funds | \$ 87,149 | \$ 87,149 | \$ — | \$ — |
| U.S. government agency securities | 147,440 | — | 147,440 | — |
| U.S. Treasury securities | 5,006 | — | 5,006 | — |
| Corporate debt securities | 3,740 | — | 3,740 | — |
| Total assets measured at fair value | <u>\$ 243,335</u> | <u>\$ 87,149</u> | <u>\$ 156,186</u> | <u>\$ —</u> |
| Liabilities: | | | | |
| Convertible debt | \$ 116,300 | \$ — | \$ — | \$ 116,300 |
| Warrants | 33,100 | — | — | 33,100 |
| Total liabilities measured at fair value | <u>\$ 149,400</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 149,400</u> |

There were no transfers between Levels 1, 2 or 3 during the three and six months ended June 30, 2016 and June 30, 2015.

The following table presents additional information about Level 3 liabilities measured at fair value. Both observable and unobservable inputs may be used to determine the fair value of positions that the Company has classified within the Level 3 category. As a result, the unrealized gains and losses for liabilities within the Level 3 category may include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs. There was no change in the fair values of the convertible debt or warrant liabilities for the three months ended March 31, 2016.

Changes in Level 3 liabilities measured at fair value for the three months ended June 30, 2016 (in thousands):

| | |
|--|------------------|
| Convertible Debt—March 31, 2016 | \$120,000 |
| Change in fair value of convertible debt (recognized in earnings) | (3,700) |
| Convertible debt at fair value – June 30, 2016 | <u>\$116,300</u> |
| Warrant Liabilities – March 31, 2016 | \$ 41,000 |
| Change in fair value of warrant liability (recognized in earnings) | (7,900) |
| Fair value of warrant liability—June 30, 2016 | <u>\$ 33,100</u> |

In March 2016, the Company issued \$165.0 million in aggregate principal amount of 0.0% convertible senior notes, which included the principal amount of the convertible note, a conversion feature, warrant coverage, and preferred shares.

To measure the fair value of the principal amount, the Company used an income approach, discounting the principal amount due under the convertible note by market interest rates by potential scenario. To measure the fair value of the conversion feature of the convertible note, a Black-Scholes option pricing model was utilized. The Black-Scholes option pricing model utilized the following assumptions: (i) expected term; (ii) common stock price; (iii) risk-free interest rate; and (iv) expected volatility. Assumptions used in the estimates represent what market participants would use in pricing the liability components, including market interest rates, credit standing, yield curves, volatilities, and risk-free rates, all of which are defined as Level 2 observable inputs. The estimated implied interest rates were applied to the principal amount of the convertible note by scenario and were weighted based on the probability of each scenario occurring. The estimated volatilities and the risk-free rates were incorporated into the Black-Scholes option pricing models for the conversion feature of the convertible note by scenario and were weighted based on the probability of each scenario occurring. Scenarios and probabilities were based on Company management estimates and were incorporated into the determination of the fair values of the principal amount and the conversion feature of the convertible note.

[Table of Contents](#)

To measure the fair value of the warrant coverage component, a Black-Scholes option pricing model was utilized. The Black-Scholes option pricing model utilized the following assumptions: (i) expected term; (ii) common stock price; (iii) risk-free interest rate; and (iv) expected volatility. Assumptions used in the estimates represent what market participants would use in pricing the component, including volatilities and risk-free rates, which are defined as Level 2 observable inputs. The estimated volatilities and the risk-free rates were incorporated into the Black-Scholes option pricing models for the warrants by scenario and were weighted based on the probability of each scenario occurring. Scenarios and probabilities were based on Company management estimates and were incorporated into the determination of the fair value of the warrant coverage.

The fair values of the principal amount of the convertible note, the conversion feature of the convertible note and the warrant coverage were impacted by certain unobservable inputs, most significantly with regards to the discount rates, probabilities of certain scenarios occurring, expected volatility, share price performance, and expected scenario timing. Significant changes to these inputs in isolation could result in a significantly different fair value measurement.

6. Inventory

Inventory consists of the following (in thousands):

| | June 30, 2016 | December 31, 2015 |
|-----------------|------------------|----------------------|
| Raw materials | \$ 7,817 | \$ 8,619 |
| Work in process | 571 | 708 |
| Finished goods | 3,070 | 1,475 |
| | <u>\$11,458</u> | <u>\$ 10,802</u> |

7. Property and Equipment

Property and equipment consist of the following (in thousands):

| | Useful Life In Years | June 30, 2016 | December 31, 2015 |
|--|-------------------------|------------------|----------------------|
| Furniture and fixtures | 5 | \$ 1,202 | \$ 1,202 |
| Computer equipment and software | 3 to 5 | 1,180 | 553 |
| Leasehold improvements | 5 | 644 | 644 |
| Manufacturing equipment | 5 | 663 | 664 |
| Asset under construction | | 98 | 437 |
| | | 3,787 | 3,500 |
| Less accumulated depreciation and amortization | | (2,410) | (2,216) |
| | | <u>\$ 1,377</u> | <u>\$ 1,284</u> |

8. Accrued Expenses

Accrued expenses consist of the following (in thousands):

| | June 30, 2016 | December 31, 2015 |
|--|------------------|----------------------|
| Accrued compensation related expenses | \$ 3,397 | \$ 4,115 |
| Inventory received, not invoiced | 1,089 | 2,032 |
| Accrued income taxes | — | 1,346 |
| Accrued marketing and market research expenses | 3,669 | 559 |
| Accrued research and development expenses | 788 | 889 |
| Accrued interest on convertible notes | 263 | 264 |
| Accrued legal and professional expenses | 859 | 353 |
| Other accrued expenses | 486 | 765 |
| | <u>\$10,551</u> | <u>\$ 10,323</u> |

[Table of Contents](#)

9. Stock-Based Compensation

Total stock-based compensation expense recognized during the three and six months ended June 30, 2016 and 2015 was comprised of the following (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|-------------------------------------|--------------------------------|-----------------|------------------------------|----------------|
| | 2016 | 2015 | 2016 | 2015 |
| Cost of goods sold | \$ 51 | \$ — | \$ 51 | \$ — |
| Selling, general and administrative | \$ 1,652 | \$ 3,618 | \$3,474 | \$6,580 |
| Research and development | 608 | 1,213 | 1,578 | 2,359 |
| | <u>\$ 2,311</u> | <u>\$ 4,831</u> | <u>\$5,103</u> | <u>\$8,939</u> |

The fair value of each option award is estimated on the date of grant using the Black-Scholes option valuation model. The following weighted-average assumptions were utilized for the calculations during each period:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--------------------------|--------------------------------|-------|------------------------------|-------|
| | 2016 | 2015 | 2016 | 2015 |
| Expected life (in years) | 5.8 | 5.6 | 5.8 | 5.6 |
| Expected volatility | 94.7% | 93.9% | 94.7% | 93.9% |
| Risk-free interest rate | 1.4% | 1.9% | 1.5% | 1.5% |
| Expected dividend yield | — | — | — | — |

The Company granted an aggregate of 340,000 performance-vesting stock units (PSUs) to certain employees during the three months ended March 31, 2016. These PSUs are subject to vesting in 20% installments over five years from the date of grant but will only be earned during such five-year period if pre-determined share price hurdles with respect to the price of the Company's common stock are attained. The expense associated with these awards is being recognized over the anticipated service period.

10. Convertible Debt

0% Convertible Senior Secured Notes due 2020

On March 21, 2016, the Company closed an offering (the "Offering") of \$165.0 million aggregate principal amount of 0% Convertible Senior Secured Notes due 2020 (the "2016 Notes") and related warrants ("Warrants") to purchase up to 21,999,999 shares of the Company's common stock, par value \$0.001 per share ("Common Stock"), and 219,994 shares of Series Z Non-Convertible Non-Voting Preferred Stock, par value \$0.001 per share (the "Series Z Preferred Stock" and, together with the 2016 Notes, Warrants and Common Stock underlying the 2016 Notes and Warrants, the "Securities") to qualified institutional buyers and accredited investors (the "Purchasers") pursuant to a securities purchase agreement, dated March 15, 2016 (the "Securities Purchase Agreement"), by and among the Company and the Purchasers. The Offering was led by funds managed by The Baupost Group, L.L.C. (collectively, "Baupost"), which, prior to the Offering, was the holder of approximately 18.1% of the Company's outstanding Common Stock.

The 2016 Notes will mature on July 1, 2020, unless earlier repurchased, redeemed or converted in accordance with the Indenture. The 2016 Notes shall only be convertible (without regard into shares of Common Stock of the Company at the Conversion Rate. In the event of a change of control transaction at any time, the 2016 Notes will be convertible for a period beginning on the closing of such change of control transaction and ending 35 Trading Days after the closing of such transaction.

The Conversion Rate was initially 1,333.33 shares of Common Stock for each \$1,000 principal amount of 2016 Notes, which represented an initial conversion price of \$0.75 per share of Common Stock. Following the reverse stock split of our common stock in July 2016, the Conversion Rate is 133.333 shares of Common Stock for each \$1,000 principal amount of 2016 Notes, which represents a conversion price of \$7.50 per shares of Common Stock. The Conversion Rate and the corresponding conversion price will be subject to further adjustment for certain events, but will not be adjusted for accrued and unpaid interest.

[Table of Contents](#)

If one or more Events of Default occurs then unless the principal of all of the 2016 Notes shall have already become due and payable, either the Trustee or the holders of at least 25% in aggregate principal amount of the 2016 Notes then outstanding, by notice in writing to the Company (and to the Trustee if given by holders), may declare 100% of the principal of, and accrued and unpaid interest, if any, on, all the 2016 Notes to be due and payable immediately, and upon any such declaration the same will become and will automatically be immediately due and payable. If an Event of Default resulting from a voluntary or involuntary liquidation, reorganization, or other relief occurs and is continuing, 100% of the principal of, and accrued and unpaid interest, if any, on, all 2016 Notes shall become and shall automatically be immediately due and payable.

Upon the occurrence of certain fundamental changes or adverse events related to the regulatory approval for, commercialization of, and net sales of Contrace, as described in the Indenture, holders of the 2016 Notes will, at their option, have the right to require the Company to repurchase for cash all or a portion of their 2016 Notes at a repurchase price equal to 100% of the aggregate principal amount of 2016 Notes. The 2016 Notes were not redeemable by the Company, in whole or in part, prior to the receipt of Stockholder Approval, which the Company obtained at its 2016 annual meeting of stockholders in July 2016. From and after the receipt of Stockholder Approval, the 2016 Notes will not be redeemable, in whole or in part, without the consent of the holders of not less than 70% in aggregate principal amount of the 2016 Notes at the time outstanding.

In March 2016, the Company entered into a Security Agreement by and among the Company, the guarantors party thereto from time to time and U.S. Bank National Association, as the collateral agent, pursuant to which the Company granted a first-priority security interest in substantially all of the Company's current and future assets, subject to customary exclusions, to secure the Company's obligations under the Indenture. The security interests shall be released once less than 25% of the original principal amount of 2016 Notes issued on the date of the Indenture remains outstanding.

The Purchasers received Warrants exercisable for a number of shares of Common Stock equal to the aggregate principal amount of the 2016 Notes acquired by the Purchasers, multiplied by the Conversion Rate. The exercise price of the Warrants was initially \$1.50 per share (the "Exercise Price"), which was adjusted to \$15.00 per share following the reverse stock split of the Common Stock, and the Warrants expire on September 21, 2026. From and after the date that the Company obtains Stockholder Approval, the Warrants became only exercisable for a number of shares of Common Stock of the Company at the Exercise Price. In the event of a change of control transaction at any time, the Warrants will be exercisable for a period beginning on closing of such change of control transaction and ending 35 days after such transaction. Given the cash settlement features described above the warrants were classified as liabilities and measured at fair value of \$33.1 million as of June 30, 2016.

Due to the complexity and number of embedded features within the convertible note and as permitted under accounting guidance, the Company elected to account for the convertible notes and all the embedded features (collectively, the "hybrid instrument") under the fair value option. The Company recognizes the convertible debt at fair value rather than at historical cost with changes in fair value recorded in the consolidated statements of operations. Direct costs and fees incurred to issue the convertible notes were recognized in earnings as incurred and not deferred. On the initial measurement date of March 21, 2016, the fair value of the hybrid instrument was estimated at \$120.0 million, which was \$45.0 million lower than the principal amount of \$165.0 million. Upfront costs and fees related to items for which the fair value option is elected was \$5.3 million and was recorded as a component of selling, general and administrative expense for the six months ended June 30, 2016.

In connection with the Offering the Company issued 219,994 shares of Series Z Non-Convertible Non-Voting Preferred Stock, par value \$0.001 per share (the "Series Z Preferred Stock").

The Series Z Preferred Stock is not convertible and does not pay or accrete dividends. The Series Z Preferred Stock is entitled to a liquidation preference upon a Fundamental Change, which includes a change of control. Upon a Fundamental Change, the Company must pay each holder an amount equal to the lesser of (i) the amount by which \$975 exceeds the amount received by holders of each 1,000 shares of Common Stock (which reflects an adjustment for the reverse stock split and is subject to further adjustment for future stock splits, dividends, etc.) and (ii) \$225; provided however that, if \$975 does not exceed the amount received by holders of each 100 shares of Common Stock (which reflects an adjustment for the reverse stock split and is subject to further adjustment for future stock splits, dividends, etc.), then the Fundamental Change Amount will be \$0.

[Table of Contents](#)

The Series Z Preferred Stock expires on the earlier to occur of (a) December 31, 2020 or (b) upon receipt of the consent of the holders of at least seventy percent (70%) of the outstanding shares of Series Z Preferred Stock, voting as a separate class. Expiration requires no cash outlay by the Company. The Series Z Preferred Stock is classified outside of permanent equity, since all of the contingent events requiring payment are not solely within the Company's control. The gross proceeds received on March 21, 2016, in the Offering, net of fees paid directly to the note holders, were allocated to the initial fair value of the Warrants and Notes with the residual amount of approximately \$3.3 million allocated to the Series Z Preferred Stock.

2.75% Convertible Senior Notes due 2020

In December 2013, the Company issued \$115.0 million in aggregate principal amount of 2.75% convertible senior notes due 2020 ("2013 Notes") in an offering to qualified institutional buyers conducted in accordance with Rule 144A under the Securities Act of 1933, as amended. Debt issuance costs of approximately \$488,000 were primarily comprised of legal, accounting and other professional fees, the majority of which were recorded as a reduction to the 2013 Notes on the consolidated balance sheet and are being amortized to interest expense over the seven-year term of the 2013 Notes.

The Company has the option to settle the 2013 Notes through payment or delivery, as the case may be, of cash, shares of the Company's common stock or a combination thereof, at the Company's election. The conversion rate for the 2013 Notes was initially 122.1225 shares per \$1,000 principal amount, which is equivalent to an initial conversion price of approximately \$8.19 per share of common stock, and is subject to adjustment under the terms of the 2013 Notes. As a result of the reverse stock split of our Common Stock, the conversion rate for the 2013 Note is currently 12.21225 shares per \$1,000 principal amount, which is equivalent to a conversion price of approximately \$81.88 per share of common stock, and is subject to further adjustment under the terms of the 2013 Notes.

The 2013 Notes will mature on December 1, 2020, unless earlier repurchased or converted in accordance with their terms prior to such date. Prior to the close of business on the business day immediately preceding September 1, 2020, holders may convert all or a portion of their 2013 Notes only under the following circumstances: (1) during any fiscal quarter commencing after March 31, 2014, if, for at least 20 trading days (whether or not consecutive) during the 30 consecutive trading day period ending on the last trading day of the immediately preceding fiscal quarter, the last reported sale price of the Company's common stock on such trading day is greater than or equal to 130% of the applicable conversion price on such trading day; (2) during the five consecutive business day period immediately following any ten consecutive trading day period (the "measurement period") in which, for each trading day of that measurement period, the trading price per \$1,000 principal amount of notes for such trading day was less than 98% of the product of the last reported sale price of the Company's common stock on such trading day and the applicable conversion rate on such trading day, or (3) upon the occurrence of specified corporate transactions. On and after September 1, 2020 until the close of business on the business day immediately preceding the maturity date, holders may convert all or a portion of their 2013 Notes at any time, regardless of the foregoing circumstances. Holders of the Notes will have the right to require the Company to repurchase all or some of their Notes at 100% of their principal amount, plus any accrued and unpaid interest, upon the occurrence of certain events.

The Company pays 2.75% interest per annum on the principal amount of the 2013 Notes semi-annually in arrears in cash on June 1 and December 1 of each year. If a designated event, as defined in the indenture for the 2013 Notes, including, but not limited to, a change in control, certain mergers or liquidation, occurs prior to the maturity date, subject to certain limitations, holders of the Notes may require the Company to repurchase all or a portion of their 2013 Notes for cash at a repurchase price equal to 100% of the principal amount of the 2013 Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the repurchase date.

The Company accounts separately for the liability and equity components of the 2013 Notes in accordance with authoritative guidance for convertible debt instruments that may be settled in cash upon conversion. The guidance requires the carrying amount of the liability component to be estimated by measuring the fair value of a similar liability that does not have an associated conversion feature. Because the Company has no outstanding non-convertible public debt, the Company determined that senior, unsecured corporate bonds traded on the market represent a similar liability to the 2013 Notes without the conversion option. The Company estimated the implied interest rate of its 2013 Notes to be 8.69%, assuming no conversion option. Assumptions used in the estimate represent what market participants would use in pricing the liability component, including market interest rates, credit standing, and yield curves, all of which are defined as Level 2 observable inputs. The estimated implied interest rate was applied to the 2013 Notes, which resulted in a fair value of the liability component of \$79.7 million upon issuance, calculated as the present value of implied future payments based on the \$115.0 million in aggregate principal amount. The \$31.3 million difference between the cash proceeds and the estimated fair value of the liability component was recorded in additional paid-in capital as the 2013 Notes were not considered redeemable.

Table of Contents

A summary of the liability and equity components of the 2013 Notes is as follows at June 30, 2016 and December 31, 2015 (in thousands):

| | June 30, 2016 | December 31, 2015 |
|--|------------------|----------------------|
| Principal amount of senior convertible notes outstanding | \$ 115,000 | \$ 115,000 |
| Unamortized discount of liability component | (24,623) | (26,871) |
| Unamortized debt issuance costs | (235) | (259) |
| Long term convertible debt | \$ 90,142 | \$ 87,870 |
| Carrying value of equity component, net of issuance costs | \$ 31,178 | \$ 31,178 |
| Remaining amortization period of discount on the liability component | 4.5 years | 5.0 years |

11. Technology, License and Distribution Agreements

Takeda Pharmaceutical Company Limited

In September 2010, the Company entered into a collaboration agreement with Takeda to develop and commercialize Contrave (formerly referred to as NB32) in the United States, Canada and Mexico. Effective in September 2013, the Company and Takeda entered into an amendment to the collaboration agreement pursuant to which Takeda assumed from the Company the responsibility to package Contrave for commercial sale in the United States, Canada and Mexico. Under the terms of the original collaboration agreement, the Company received from Takeda a nonrefundable upfront cash payment of \$50.0 million and additional payments totaling \$100.0 million that were achieved between the execution of the collaboration agreement and the first commercial sale of Contrave in the United States. The Company was eligible to receive additional payments of over \$1.0 billion upon achieving certain anniversary, regulatory/development and sales-based milestones. The Company was also eligible to receive tiered royalty payments ranging from a minimum of 20% to a maximum of 35%, subject to customary reductions, on increasing levels of net sales in the United States.

In July 2015, the Company entered into an amended and restated collaboration agreement with Takeda (the "Restated Collaboration Agreement") which amends and restates the original agreement that the parties entered into in September 2010. The Restated Collaboration Agreement is substantially the same as the prior agreement subject to the following key changes:

- (a) The territory covered by the collaboration is revised to only include the United States, returning all rights for the countries of Mexico and Canada to the Company.
- (b) The responsibilities for the costs of development activities for Contrave from and after August 1, 2015 have been restructured.
 - (i) The Company is responsible for the cost of the randomized, double-blind, placebo-controlled cardiovascular outcomes clinical trial (the "CVOT") to be conducted by Takeda up to the currently-projected total cost of such CVOT, above which the parties will generally share the costs of such CVOT equally, with certain exceptions.
 - (ii) Takeda will be responsible for 100% of remaining costs for the terminated Light Study.
 - (iii) Takeda and the Company will be responsible for 75% and 25% of expenses, respectively, of any other post-approval development costs, including all other post-marketing requirement studies other than the CVOT.
- (c) The Company will now be eligible to receive up to an additional \$105 million of potential milestone payments upon achievement of a combination of factors related to superiority claims reflected in approved labeling for Contrave, a lack of generic competition and net sales.

The termination provisions of the Restated Agreement were not changed from the prior agreement. In addition to the Restated Collaboration Agreement, the parties also simultaneously agreed to a mutual release to, among other things, any claims or potential claims related to the prior dispute among the parties.

The upfront payment of \$50.0 million was determined not to have standalone value and was deferred and is being recognized over the estimated term of the agreement of 14.5 years. In addition to the upfront payment, the Company earned milestones of \$30.0 million for the FDA approval of Contrave and for delivery of launch supplies to Takeda in 2014. This milestone payment was determined to meet the definition of a substantive milestone and was recognized at

[Table of Contents](#)

the time the milestone was earned. Also, in October 2014, the Company earned and was paid a \$70.0 million milestone for the shipment of Contrave, by Takeda, to pharmacy wholesalers in preparation for the commercial launch. This milestone payment was determined to not meet the definition of a substantive milestone. As a result, the Company recognized \$20.8 million in 2014 and deferred \$49.2 million which was to be recognized over the remaining estimated life of the agreement.

In March 2016, the Company entered into a separation agreement with Takeda (the "Separation Agreement"), which will terminate the Restated Collaboration Agreement between the Company and Takeda, and the manufacturing services agreement between the Company and Takeda in September 2016. We anticipate terminating the Restated Collaboration Agreement, effective as of August 1, 2016. The Separation Agreement provides for the transfer of certain rights and assets to the Company and provided for the transition of activities under the collaboration agreement from Takeda to the Company during the transition period. In connection with the Separation Agreement, the Company made a \$60.0 million prepayment for the acquisition of the Contrave business and will pay an additional \$15.0 million at the end of the transition period assuming Takeda meets its obligations under the Separation Agreement. The Company may also be obligated to pay Takeda milestone payments of \$10 million, \$20 million, \$30 million and \$50 million, based on the achievement of annual Contrave net sales milestones of \$200 million, \$300 million \$400 million and \$600 million, respectively, in any year following the end of the transition period. Each such milestone payment shall be payable only once but more than one may be payable with respect to net sales in a single year. The Separation Agreement is not terminable by the parties. The acquisition date for a business is the date on which the Company obtains control of the acquiree, which is anticipated to occur on August 1, 2016.

As of June 30, 2016, the Company accounted for the purchase consideration of \$60.0 million as a prepaid noncurrent asset. The acquisition may result in the recognition of a loss or gain resulting from the settlement of the preexisting collaboration relationship, including recognition of any off-market component of the existing agreement. Proceeds paid to Takeda to acquire the business will be adjusted to reflect the settlement of the pre-existing collaboration relationship and write off of the remaining deferred revenue.

For the six months ended June 30, 2016, the Company recognized revenues under The Restated Collaboration Agreement of approximately \$9.7 million, including approximately \$5.1 million in royalties earned for the sale of Contrave by Takeda and approximately \$4.6 million in continued recognition of the up front and non-substantive milestone payments. At June 30, 2016, deferred revenue under this agreement totaled \$81.0 million.

12. Litigation

In May 2013, the Company received a shareholder demand alleging that certain option grants to the President and Chief Executive Officer, Michael A. Narachi, the Chief Business Officer and acting-Chief Financial Officer, Joseph P. Hagan, and the Senior Vice President, General Counsel and Secretary, Heather D. Turner, in 2011 were granted in excess of the 1,500,000 share limit set forth in Section 3.3 of the Orexigen Therapeutics, Inc. 2007 Equity Incentive Award Plan, or Plan, as to the number of shares of the Company's common stock with respect to which one or more stock awards may be granted to any one eligible participant during any of the Company's fiscal years. The Company refers to this limit as the 162(m) Award Limit. The Company's board of directors established a demand review committee composed of independent directors to conduct an investigation with respect to the shareholder demand and to make recommendations to the board of directors. The demand review committee engaged independent counsel as part of its investigation and evaluated (1) the terms of the Plan, (2) the initial issuance procedures for the option grants to Mr. Narachi, Mr. Hagan and Ms. Turner during 2011, (3) the authority available to the compensation committee of the board of directors under its charter and the Plan, (4) the expectations of the award recipients and (5) the intent of the board of directors and the compensation committee regarding the availability of an exemption from the deductibility limitations of Section 162(m) of the Internal Revenue Code for such option grants. Following its investigation, the demand review committee determined that the 162(m) Award Limit first became effective as of June 2, 2011, and that, therefore, awards granted under the Plan prior to June 2, 2011, did not count toward the 162(m) Award Limit. The demand review committee determined that the awards granted to Mr. Hagan between June 2, 2011 and December 31, 2011 did not exceed the 162(m) Award Limit. The demand review committee further determined that the options granted to Mr. Narachi and Ms. Turner, including the portion of such awards in excess of the 162(m) Award Limit, were validly approved under the Plan, although the portion of those awards in excess of the 162(m) Award Limit does not qualify as performance-based compensation under Section 162(m). In September 2013, the compensation committee amended the Plan, with the approval of the Company's board of directors, to take the following actions: (1) to clarify that the 162(m) Award Limit only applies to awards or the portion thereof intended to qualify as performance-based compensation under Section 162(m); and (2) to confirm that the compensation committee has the

[Table of Contents](#)

authority to make awards in excess of the 162(m) Award Limit, which board action the Company refers to as the Plan Amendment. The Plan Amendment is deemed effective as of June 10, 2011, consistent with the authority of the compensation committee as administrator of the Plan as of that date. Any grants under the Plan in excess of the 162(m) Award Limit are not intended to qualify as performance-based compensation under Section 162(m).

On December 9, 2013, the same shareholder who made a demand on the board in May 2013 filed a derivative lawsuit purportedly on behalf of the Company against certain of the officers and current and former members of the board of directors in the United States District Court, for the Southern District of California, captioned *Turgeman v. Narachi, et al.* The lawsuit asserts claims for breach of fiduciary duty, waste and unjust enrichment based on, among other things, the alleged grant of stock options to certain officers in excess of the 162(m) Award Limit, repricing stock options allegedly in violation of the Company's equity incentive plan, the board of directors' conduct in responding to the May 2013 shareholder demand, and making allegedly false and misleading statements. The lawsuit seeks, among other things, declaratory relief, corporate governance reforms, rescission of certain stock option awards, rescission of the Plan Amendment, injunctive relief, damages, restitution, disgorgement and attorney's fees. On July 23, 2014, the Company and the individual defendants filed a motion to dismiss the *Turgeman* complaint. On March 9, 2015, the court granted the motion to dismiss with thirty days leave to amend. An amended complaint was filed on April 8, 2015. The amended complaint asserts the same derivative claims as the original complaint and asserts a putative claim on behalf of plaintiff and the Company's shareholders for breach of contract for alleged violations of the 2007 Equity Incentive Plan. On May 8, 2015, the Company and the individual defendants filed a motion to dismiss the amended complaint. The court has not yet ruled on the motion.

On March 10, 2015, a purported class action lawsuit was filed against the Company and certain of the Company's officers in the United States District Court, for the Southern District of California, captioned *Colley v. Orexigen, et al.* The following day, two additional putative class action lawsuits were filed in the same court, captioned *Stefanko v. Orexigen, et al.*, and *Yantz v. Orexigen, et al.*, asserting substantially similar claims. On June 22, 2015, the court consolidated the lawsuits and appointed a lead plaintiff. On August 20, 2015, the lead plaintiff filed a consolidated complaint. The consolidated complaint purports to assert claims on behalf of a class of purchasers of the Company's stock between March 3, 2015 and May 12, 2015. It alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by purportedly making false and misleading statements regarding the interim results and termination of the Light Study. The consolidated complaint seeks an unspecified amount of damages, attorneys' fees and equitable or injunctive relief. On October 5, 2015, defendants filed a motion to dismiss the consolidated complaint. On May 19, 2016, the District Court granted the motion to dismiss, dismissing portions of the consolidated complaint with prejudice and portions without prejudice. The Court granted lead plaintiff 30 days to file an amended complaint with respect to those portions not dismissed with prejudice. On June 16, 2016, lead plaintiff filed a notice of intent not to file an amended complaint but to proceed directly to an appeal of the Court's decision dismissing the consolidated complaint. As a result, the court entered judgment dismissing the consolidated complaint with prejudice on June 27, 2016. Lead plaintiff has not yet filed a Notice of Appeal. Although management believes that any appeal would lack merit and intends to defend against it vigorously, there are uncertainties inherent in any litigation and the Company cannot predict the outcome. At this time, the Company is unable to estimate possible losses or ranges of losses that may result from such legal proceedings, and it has not accrued any amounts in connection with such legal proceedings other than ongoing attorney's fees.

On June 3, 2016, plaintiff Ben Wilkin, a shareholder who had previously made a shareholder demand to inspect certain books and records of the Company, filed a derivative lawsuit purportedly on behalf of the Company against certain of the Company's current and former officers and members of the board of directors in the Delaware Chancery Court, captioned *Wilkin v. Narachi, et al.* The lawsuit asserts claims for breach of fiduciary duty and waste of corporate assets based on essentially the same set of facts underlying the *Colley*, *Stefanko* and *Yantz* consolidated class action. The lawsuit seeks, among other things, damages, corporate governance reforms, injunctive relief, restitution, disgorgement and attorney's fees. Management believes that the claims lack merit and intends to defend against them vigorously. The Company is unable to estimate possible losses or ranges of losses that may result from this lawsuit and has not accrued any amounts in connection with this suit.

It is possible that additional securities class action litigation may be brought against the Company following stock price declines related to the release of information regarding Contrave or clinical trial results, including the Light Study or related to the matters alleged in the May 2013 shareholder demand and/or the Plan Amendment. Any adverse determination in such litigation could subject the Company to significant liabilities.

In April 2015, the Company and Takeda received a Paragraph IV certification notice letter regarding an abbreviated new drug application, or ANDA, submitted to the FDA by Actavis Laboratories FL, Inc., or Actavis, requesting approval to market, sell, and use a generic version of Contrave. In its notice letter, Actavis alleges that U.S. Patent Nos. 7,375,111; 7,462,626; 8,088,786; 8,318,788; 8,722,085; 8,815,889; and 8,916,195, which are listed in the

[Table of Contents](#)

FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, for Contrave, are invalid, unenforceable and/or will not be infringed by Actavis' manufacture, use or sale of the product described in its ANDA. In June 2015, the Company and Takeda filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Actavis and certain of its affiliates related to the ANDA previously filed by Actavis and described above. The lawsuit claims infringement of the seven patents that were the subject of Actavis' notice letter, as described above. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, as a result of having filed a patent infringement lawsuit within 45 days of receipt of Actavis' notice letter, FDA approval of the ANDA will be stayed until the earlier of (i) 30 months from the date of receipt of the notice letter or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. In July 2015, Actavis filed an answer, affirmative defenses and counterclaim to the Company's and Takeda's complaint, and the Company and Takeda filed an answer to Actavis' counterclaim in August 2015. Moreover, in July 2015, the court ordered a stipulation between the Company, Takeda and Actavis in which we and Takeda agreed to dismiss all defendants except Actavis without prejudice, and Actavis agreed that the related Actavis entities will be bound to judgments and orders of the court against Actavis and will be subject to discovery as if they were parties. In September 2015, the court entered a scheduling order, setting a claim construction hearing for May 2016 and a three-day bench trial to begin in June 2017. After reviewing Actavis' ANDA, the Company and Takeda subsequently dropped U.S. Patent Nos. 8,088,786, 8,318,788, 8,722,085 and 8,916,195 from the lawsuit. In April 2016, the Company and Takeda filed an amended complaint against Actavis asserting newly issued U.S. Patent No. 9,125,868. In June 2016, in response to the May 2016 claim construction hearing, the court adopted the Company's proposed constructions for the majority of the disputed claim terms. In August 2016, in connection with the end of the transition period associated with the separation agreement entered into between the Company and Takeda, we anticipated that Takeda will transfer responsibility for management of this patent infringement lawsuit to the Company. Although the Company plans to vigorously enforce Contrave intellectual property rights, there are uncertainties inherent in any litigation and we cannot predict the outcome.

13. Subsequent event

On August 1, 2016, the transition period under the Separation Agreement between the Company and Takeda terminated and the Company reacquired all commercial rights to Contrave in the United States. The Company made an initial payment of \$60 million to Takeda in March 2016 and will pay an additional \$15 million to Takeda in January 2017 (the "January 2017 Payment") provided that Takeda substantially performs its obligations under the Separation Agreement and related agreements, including certain specified activities. The source of funds for the Initial Payment and the January 2017 Payment was, and will be, from the Company's cash on hand. The Company may also be obligated to pay Takeda milestone payments of \$10 million, \$20 million, \$30 million and \$50 million, based on the achievement of annual Contrave net sales milestones of \$200 million, \$300 million \$400 million and \$600 million, respectively, in any future year.

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

This report contains certain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act, and is subject to the safe harbor provisions created by that statute. Forward-looking statements are based on our management's current beliefs, expectations and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions. Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "hopes," "may," "will," "plans," "intends," "indicates," "suggests," "assuming," "designed," "estimates," "could," "should," "would," "continue," "seeks," "aims," "projects," "predicts," "pro forma," "anticipates," "potential," "probability" or other similar expressions that are intended to identify forward-looking statements.

These statements include but are not limited to statements regarding: the potential for Contrave®/Mysimba™ to achieve commercial success globally; the potential to obtain marketing authorizations outside the United States, the European Union and South Korea or commercialization partner(s) for Contrave; the benefit risk profile for Contrave; the potential for past Contrave clinical trials to predict the outcome of future Contrave clinical trials; and the potential to demonstrate the real world weight loss potential of Contrave with a commercially available comprehensive lifestyle intervention program. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Actual results may differ materially from those expressed or implied in this report by the forward-looking statements due to the risk and uncertainties inherent in our business, including the ability to obtain partnerships and marketing authorizations globally; competition in the global obesity market, particularly from existing therapies; our ability to carry out the commercial launch of Contrave in the United States; our ability to obtain and maintain global intellectual property protection for Contrave and Mysimba; the potential that of the data/results from past clinical trials may not be predictive of results from future clinical trials; the therapeutic and commercial value of Contrave and Mysimba; our ability to maintain sufficient capital to fund our operations for the foreseeable future; estimates of the capacity of manufacturing and other facilities to support Contrave; and the other risks and uncertainties discussed below under Part II, Item 1A, "Risk Factors."

Given these risks and uncertainties, we urge you not to place undue reliance on these forward-looking statements, which speak 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. The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2015. We hereby qualify our forward-looking statements by these cautionary statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, whether as a result of new information, future events, or for any other reason.

Overview

Background

We are a biopharmaceutical company focused on the treatment of obesity. Our sole product, Contrave, is approved in the United States by the U.S. Food and Drug Administration, or FDA, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index, or BMI, of 30 kg/m² or greater (obese), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition. Contrave is a combination of generic drug components, each of which has already received regulatory approval for other indications and been commercialized in the United States and in a majority of the member countries of the European Union.

On September 10, 2014, the FDA notified us that it had approved our NDA for Contrave extended-release. We are now focused on the commercialization of Contrave. Our former collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda, commercially launched Contrave in the United States in October 2014. As part of the approval of Contrave by the FDA, we and Takeda agreed to several post-marketing requirements, including studies to assess the safety and efficacy of Contrave for weight management in obese pediatric patients. We are also required to conduct a new randomized double-blind, placebo-controlled study to evaluate the effects of long-term treatment with Contrave on the incidence of major adverse cardiovascular, or CV, events in overweight and obese subjects with CV disease or multiple CV risk factors, as well as a group of short-term trials including a thorough QT study, single-dose pharmacokinetic studies in renal and hepatic impairment, and a drug-drug interaction study.

[Table of Contents](#)

In March 2016, we and Takeda entered into a separation agreement, which will terminate our collaboration agreement at the end of September 2016. We anticipate that we will terminate our collaboration with Takeda on August 1, 2016 and we will be solely responsible for developing and commercializing Contrave within the United States and the rest of the world and will be responsible for the functions previously the responsibility of Takeda, including management and oversight of certain ongoing and planned post-marketing clinical trials of Contrave.

In March 2015, the European Commission granted centralized marketing authorization for Contrave (under the name Mysimba™) (naltrexone HCl / bupropion HCl prolonged release) as an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥18 years) with an initial Body Mass Index of ≥30 kg/m² (obese), or ≥27 kg/m² to <30 kg/m² (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidemia, or controlled hypertension). This authorization applies to all 28 European Union member states.

In May 2016, our commercialization partner, Kwang Dong Pharmaceutical Company, Ltd., obtained regulatory approval for Contrave in South Korea. Kwang Dong expects to begin marketing Contrave in the second half of 2016.

In March 2016, the Company closed an offering (the “Offering”) of \$165.0 million aggregate principal amount of 0% Convertible Senior Secured Notes due 2020 (the “2016 Notes”) and related warrants (“Warrants”) to purchase up to 21,999,999 shares of the Company’s common stock, par value \$0.001 per share (“Common Stock”), and 219,994 shares of Series Z Non-Convertible Non-Voting Preferred Stock, par value \$0.001 per share (the “Series Z Preferred Stock”) and, together with the 2016 Notes, Warrants and Common Stock underlying the 2016 Notes and Warrants, the “Securities”) to qualified institutional buyers and accredited investors (the “Purchasers”) pursuant to a securities purchase agreement, dated March 15, 2016 (the “Securities Purchase Agreement”), by and among the Company and the Purchasers. The Offering was led by funds managed by The Baupost Group, L.L.C., which, prior to the Offering, was the holder of approximately 18.1% of the Company’s outstanding Common Stock.

Our primary activities since incorporation have been organizational activities, including recruiting personnel, conducting research and development, including clinical trials, and raising capital. Since entering into a separate agreement with Takeda, our organizational activities have been updated to include the build out of a sales and marketing team for the anticipated takeover of commercial sales of Contrave in the United States. We have incurred significant net losses since our inception. As of June 30, 2016, we had an accumulated deficit of \$668.3 million. These losses have resulted principally from costs incurred in connection with research and development activities, primarily costs of clinical trial activities associated with our current product and product candidates, performing manufacturing-related activities, and selling, general and administrative expenses. We expect to continue to incur losses for the next several years. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure, and until that time, we may need to continue to raise additional equity or debt financing.

Revenues

We generated approximately \$12.8 million in revenue for the six months ended June 30, 2016, resulting primarily from the sublicensing of technology and amounts earned under our collaboration agreement with Takeda. In September 2010, we entered into a collaboration agreement with Takeda to develop and commercialize Contrave in the United States, Canada and Mexico. Under the collaboration agreement, we received an upfront, nonrefundable cash payment of \$50.0 million from Takeda and this amount is being recognized ratably over the estimated life of the agreement. In September 2014, we also recognized two regulatory/development milestones, consisting of \$20.0 million due to us upon regulatory approval in the United States and \$10.0 million due to us upon the delivery of launch supplies to Takeda as these payments were determined to meet the definition of a substantive milestone. In October 2014, we earned and were paid a \$70.0 million milestone from Takeda for the shipment of Contrave to pharmacy wholesalers in preparation for the commercial launch. This milestone payment was determined to not meet the definition of a substantive milestone. As a result, we recognized \$20.8 million in 2014 with \$49.2 million deferred which will be recognized over the remaining estimated life of the agreement. For the six months ended June 30, 2016, we recognized revenues under this agreement of \$9.9 million, including approximately \$5.1 million in royalties earned for the sale of Contrave by Takeda and approximately \$4.8 million in amortization of deferred revenue. Takeda accounted for 77% of our revenue for six months ended June 30, 2016. At June 30, 2016, deferred revenue under this agreement totaled \$81.0 million. In addition to the revenue generated from our collaboration agreement with Takeda, we recorded our 1st sale of Contrave to our Korean Distributor for approximately \$2.9 million for the six months ended June 30, 2016.

[Table of Contents](#)

Other than the amortization of the upfront payment of \$50.0 million and regulatory/development milestones totaling \$100.0 million from Takeda, our ability to generate revenue in the near term will depend solely on the success of Takeda sales of Contrave in the U.S. during the transition period associated with the separation agreement and our sales of Contrave following the end of the transition period. Pursuant to an amended and restated collaboration we entered into with Takeda in July 2015, we are eligible to receive tiered royalty payments ranging from a minimum of 20% to a maximum of 35%, on increasing levels of net sales of Contrave in the United States during the remainder of the transition period. Given the early stage of commercialization, it is difficult to predict the amount of future sales of Contrave or the related revenues we will generate. Future sales of Contrave will depend on, among other factors, the availability and use of Contrave, Takeda's ability to market and sell Contrave during the transition period, our ability to continue to market and sell Contrave following the end of the transition period, and coverage and reimbursement by third-party payors.

In the quarter ended June 30, 2016, we recorded net product sales of approximately \$2.9 million of Contrave to our commercialization partner, Kwang Dong Pharmaceutical Company, Ltd., or Kwang Dong, in South Korea. The Company recognizes product revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Specifically, net product revenue from the sale of Contrave/Mysimba is generally recognized upon transfer of title of the product to our third party customers.

Research and Development Expenses

The majority of our operating expenses to date have been incurred in research and development activities. Our research and development expenses consisted primarily of costs associated with clinical trials managed by contract research organizations, or CROs, product development efforts, raw materials, inventory, and manufacturing-related expenses. License fees, salaries and related employee benefits for certain personnel, and costs associated with certain non-clinical activities such as regulatory expenses, are also included in this amount. Our most significant costs to date are expenses incurred in connection with the clinical trials for Contrave. The clinical trial expenses included payments to vendors such as CROs, investigators, suppliers of clinical drug materials and related consultants. Following FDA approval of Contrave in September 2014, the responsibility for the continuation of the Light Study was transferred to our former partner, Takeda. Upon transfer of this responsibility, we began to pay the clinical trial expenses associated with the Light Study directly to Takeda who then made direct payments to such vendors. We charge all research and development expenses to operations as incurred because the underlying technology associated with these expenditures relates to our research and development efforts and has no alternative future uses.

Our internal research and development resources are not directly tied to any individual research project and are primarily deployed across our Contrave and other programs. We have developed Contrave in parallel with other projects and, due to the fact that we use shared resources across projects, we do not maintain information regarding our internal costs incurred for our research and development programs on a program-specific basis. We use external service providers to manage our clinical trials, to manufacture the product supplies used in these trials and for formulations development, consulting and other activities.

The following table summarizes our research and development expenses for the three and six months ended June 30, 2016 and 2015. Costs that are not attributable to a specific research program are included in the "Other" category (in thousands):

| | Three Months Ended | | Six Months Ended | |
|--|--------------------|-----------------|------------------|-----------------|
| | June 30, | June 30, | June 30, | June 30, |
| | 2016 | 2015 | 2016 | 2015 |
| Costs of external service providers: | | | | |
| Obesity | \$10,633 | \$11,050 | \$18,438 | \$18,558 |
| Other | 145 | 110 | 207 | 179 |
| Subtotal | 10,778 | 11,160 | 18,645 | 18,737 |
| Internal costs | 2,863 | 2,734 | 5,827 | 5,253 |
| Stock-based compensation | 608 | 1,213 | 1,578 | 2,359 |
| Total research and development expenses | \$14,249 | \$15,107 | \$26,050 | \$26,349 |

At this time, due to the risks inherent in the drug development process, we are unable to estimate with any certainty the costs we will incur for the post-marketing requirements of Contrave and any additional clinical trials required for post-marketing requirements of Contrave, under the name Mysimba, by the EMA. Future development expenses will depend on the conduct of the new CVOT and any other additional clinical trials for Contrave, if any, our financial resources and ongoing assessments as to Contrave's commercial potential. Clinical development timelines, the probability of success and development costs can differ materially from expectations. The lengthy process of completing our clinical trials, and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing our clinical trials, or in obtaining regulatory approvals, could cause a delay in the commencement of product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

[Table of Contents](#)

Selling, General and Administrative

Our selling, general and administrative expenses consist primarily of salaries and related costs for personnel in executive, commercial and internal support functions, as well as professional fees for legal, consulting and accounting services. In addition, selling, general and administrative expenses include our outsourced sales representatives and other sales and marketing costs necessary for commercializing Contrave. We anticipate selling, general and administrative expenses to increase substantially as we establish our sales and marketing capabilities in the United States

Interest and Other (Expense), Income net

Other Income (Expense) consists principally of interest expense incurred on the 2020 Notes, offset by our change in the fair value of our financial instruments on our 2016 convertible debt and warrant liability, income earned on marketable securities and foreign currency gains and losses. A portion of our business is conducted outside of the U.S. through our Irish foreign subsidiary. The foreign subsidiary keeps its accounting records in its functional currency, the Euro.

Income Taxes

At December 31, 2015, we have federal, state and foreign net operating loss carryforwards of approximately \$380.2 million, \$409.9 million and \$14.2 million, respectively, not considering the IRC Section 382 annual limitation discussed below. The federal loss carryforwards begin to expire in 2024, unless previously utilized. At December 31, 2015, we have federal and state research and development tax credit carryforwards of \$20.0 million and \$6.1 million, respectively. The federal research and development tax credit carryforwards begin to expire in 2024 unless previously utilized. The state research and development tax credits and foreign net operating losses carry forward indefinitely. The California net operating loss carryforwards are scheduled to begin to expire starting in 2016. Approximately \$12.2 million of the net operating loss carryforwards relates to excess tax deductions for stock compensation, the income tax benefit of which will be recorded as additional paid in capital if and when realized.

Additionally, the utilization of the net operating loss and research and development tax credit carryforwards is subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state tax provisions due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes limit the amount of the net operating loss and research and development tax credit carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percent points over a three-year period. The Company has completed an ownership change analysis in accordance with Section 382 from inception through December 31, 2015. As a result of the analysis, it was determined that the Company experienced several ownership changes during this period with the last one occurring in December 2014. The analysis to determine the limitation of NOLs and federal credits as a result of the ownership changes has not been finalized. Based on the preliminary analysis of the limitation of our net operating losses and federal credits, deferred tax assets for net operating losses of \$189.8 million and \$182.6 million for federal and state, respectively, and federal research and development credits of \$12.0 million have been removed from the deferred tax asset schedule. A corresponding decrease to the valuation allowance has also been recorded. Due to the existence of the valuation allowance, future changes in the deferred tax assets related to these tax attributes will not impact the effective tax rate.

During 2015, we expanded our operations internationally. We fully funded our Irish subsidiary with equity and debt and transferred the rights to exploit our intellectual property in markets outside of North America to our Irish subsidiary in exchange for a note. We also entered into a cost sharing arrangement, an intercompany services agreement and other related agreements with our Irish subsidiary which enable it to function as our foreign trading company.

[Table of Contents](#)

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations are based upon our financial statements, which are prepared in accordance with accounting principles that are generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, related disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to accounting for research and development expenses and stock-based compensation costs. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

The significant changes in the six months ended June 30, 2016 to the items that we disclosed as our critical accounting policies and estimates in Note 2 to our audited financial statements in our Annual Report on Form 10-K for the year ended December 31, 2015 are disclosed as follows;

Fair Value Option

The Company has elected the fair value option to account for its convertible notes that were issued during the quarter ended March 31, 2016 and records these convertible notes at fair value with changes in fair value recorded in the statement of operations. As a result of applying the fair value option, direct costs and fees related to the convertible notes were recognized in earnings as incurred and not deferred.

Preferred Stock

Preferred shares subject to mandatory redemption (if any) are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. At all other times, the Company classifies its preferred shares in stockholders' equity. Similar in nature to a redemption right, the Company's Series Z Preferred Stock features a contingent right to receive payment from the Company in the event of certain fundamental changes, some of which are not within the Company's control as of June 30, 2016. Accordingly, the Series Z Preferred Stock is presented as a component of temporary equity.

Accounting for Warrants at Fair Value

The Company classifies as liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

The Company assessed the classification of warrants issued in 2016 and associated with the 2016 convertible notes as of the date of the offering and determined that such instruments met the criteria for liability classification. Accordingly, the Company classified the warrants issued in 2016 as a liability at their fair value and adjusts the instruments to fair value at each balance sheet date until the warrants are exercised or expired. Any change in the fair value of the warrants is recognized as "change in the fair value of warrant liabilities" in the consolidated statements of operations

Results of Operations

Comparison of three months ended June 30, 2016 to three months ended June 30, 2015

Revenues. Revenues for the three months ended June 30, 2016 and 2015 were \$7.8 million and \$5.2 million, respectively, and primarily represent revenues recognized under our collaboration agreement with Takeda. \$2.5 million and \$3.1 million of revenues for the three months ended June 30, 2016 and 2015, respectively, are royalty revenues for the sales of Contrave by Takeda. We recorded net product sales of approximately \$2.9 million of Contrave to our commercialization partner, Kwang Dong in South Korea.

Cost of Sales. Cost of sales was approximately \$1.8 million for the three months ended June 30, 2016 as the Company recorded its first product sale outside the United States to our commercialization partner, Kwang Dong in South Korea.

[Table of Contents](#)

Research and Development Expenses. Research and development expenses decreased to \$14.2 million for the three months ended June 30, 2016 as compared to \$15.1 million for the comparable period during 2015. This decrease of approximately \$900,000 was due primarily to a decrease in expenses in connection with our Contrave CVOT, related proprietary product formulation work and consulting activities.

Selling, General and Administrative Expenses. Sales, general and administrative expenses increased to \$25.0 million for the three months ended June 30, 2016 from \$10.8 million for the comparable period during 2015. Specifically, sales and marketing costs were \$15.9 million and \$1.8 million for the three months ended June 30, 2016 and 2015, respectively. General and administrative costs were \$9.1 million and \$9.0 million for the three months ended June 30, 2016 and 2015, respectively. This overall increase of approximately \$14.2 million was due primarily to an increase in sales and marketing department costs of \$14.1 million as we establish sales, marketing and distribution capabilities in order to commercialize Contrave. This increase in sales and marketing department costs included an increase of \$4.0 million in contract sales expenses, an increase in salaries and personnel related costs of \$2.4 million, an increase in professional fees of \$2.1 million and an increase in marketing meeting/training related expenses of \$1.4 million.

Interest Income. Interest income increased to \$163,000 for the three months ended June 30, 2016 from \$67,000 in 2015. This increase of approximately \$96,000 was primarily due to an increase in average investment balances and higher interest rates as compared to 2015.

Interest Expense. Interest expense increased to \$2.0 million for the three months ended June 30, 2016 from \$1.8 million in 2015.

Change in Fair Value of Financial Instruments. The change in fair value of financial instruments was \$11.6 million for the three months ended June 30, 2016 reflecting the change in fair value of the convertible debt and warrant liability.

Foreign Currency Gain (Loss), net. Foreign currency loss, net increased to \$1.8 million for the three months ended June 30, 2016. This increase was primarily due to the fluctuation in the Euro.

Comparison of six months ended June 30, 2016 to six months ended June 30, 2015

Revenues. Revenues for the six months ended June 30, 2016 and 2015 were \$12.8 million and \$9.6 million, respectively, and primarily represent revenues recognized under our collaboration agreement with Takeda. \$5.1 million and \$5.4 million of revenues for the six months ended June 30, 2016 and 2015, respectively, are royalty revenues for the sales of Contrave by Takeda. We recorded net product sales of approximately \$2.9 million of Contrave to our commercialization partner, Kwang Dong in South Korea.

Cost of Sales. Cost of sales was approximately \$1.8 million for the six months ended June 30, 2016, as the Company recorded its first product sale outside the United States to our commercialization partner, Kwang Dong in South Korea.

Research and Development Expenses. Research and development expenses decreased to \$26.1 million for the six months ended June 30, 2016 from \$26.3 million for the comparable period during 2015. This decrease was due primarily to a \$1.3 million decrease in expenses in connection with our Contrave CVOT, related proprietary product formulation work and consulting activities and a decrease in stock-based compensation expense of \$780,000. These decreases were partially offset by an increase in salaries and personnel related costs of \$656,000, an increase in manufacturing related activities of \$590,000, and increase in consulting activities of \$378,000.

Selling, General and Administrative Expenses. Sales, general and administrative expenses increased to \$41.5 million for the six months ended June 30, 2016 from \$19.4 million for the comparable period during 2015. Specifically, sales and marketing costs were \$20.1 million and \$3.3 million for the six months ended June 30, 2016 and 2015, respectively. General and administrative costs were \$21.4 million and \$16.1 million for the six months ended June 30, 2016 and 2015, respectively. This overall increase of approximately \$22.1 million was due primarily to an increase in sales and marketing department costs of \$16.8 million as we establish sales, marketing and distribution capabilities in order to commercialize Contrave. This increase in sales and marketing department costs included an increase of \$4.0 million in contract sales expenses, an increase in professional fees of \$4.0 million, an increase in salaries and personnel related costs of \$3.1 million, an increase in marketing meeting/training related expenses of \$1.4 million and an increase in market research expenses of \$1.2 million.

[Table of Contents](#)

The general and administrative department expenses increased by approximately \$5.3 million including an increase in legal and other fees related to the March 2016 debt offering of \$6.1 million, an increase in salaries and personnel related costs of \$1.2 million, and an increase of professional and consulting costs of \$465,000. These increases were partially offset by a decrease in stock-based compensation expense of \$2.8 million.

Interest Income. Interest income increased to \$286,000 for the six months ended June 30, 2016 from \$130,000 in 2015. This increase of approximately \$156,000 was primarily due to an increase in average investment balances and higher interest rates as compared to 2015.

Interest Expense. Interest expense increased to \$3.9 million for the six months ended June 30, 2016 from \$3.7 million in 2015.

Change in Fair Value of Financial Instruments. The change in fair value of financial instruments was \$11.6 million for the six months ended June 30, 2016 reflecting the change in fair value of the convertible debt and warrant liability.

Foreign Currency Gain (Loss) net. Foreign currency gain net increased to approximately \$978,000 for the six months ended June 30, 2016. This increase was primarily due to the fluctuation in the Euro.

Liquidity and Capital Resources

Since inception, our operations have been financed primarily through the sale of equity and convertible debt securities. Through June 30, 2016, we received net proceeds of approximately \$798.5 million from the issuance of equity and convertible debt securities as follows:

- from September 12, 2002 to December 31, 2006, we issued and sold a total of 105,357 shares of common stock for aggregate net proceeds of \$14,801;
- in March 2004, we issued and sold a total of 932,204 shares of Series A redeemable convertible preferred stock for aggregate net proceeds of \$9.2 million and the conversion of promissory notes and interest thereon totaling \$1.7 million;
- from April 2005 to May 2005, we issued and sold 1,483,051 shares of Series B redeemable convertible preferred stock for aggregate net proceeds of \$34.9 million;
- in November 2006, we issued and sold a total of 877,193 shares of Series C convertible preferred stock for aggregate net proceeds of \$29.9 million;
- in May 2007, we issued and sold a total of 805,000 shares of common stock for aggregate net proceeds of \$87.9 million;
- in January and February 2008, we issued and sold a total of 732,644 shares of common stock for aggregate net proceeds of \$74.9 million;
- in July 2009, we issued and sold a total of 1,150,000 shares of common stock for aggregate net proceeds of \$81.6 million;
- in December 2011, we issued and sold a total of 564,617 shares of common stock and common stock warrants to purchase up to 5,646,173 shares for aggregate net proceeds of \$86.9 million;
- in October 2012, we issued and sold a total of 1,100,000 shares of common stock for aggregate net proceeds of \$56.5 million; and
- in December 2013, we issued the 2013 Notes for aggregate net proceeds of \$110.5 million; and
- in September 2015, we issued and sold a total of 2.0 million shares of common stock and common stock warrants to purchase 500,000 shares of our common stock for aggregate net proceeds of \$59.8 million; and
- in March 2016, we issued the 2016 Notes, warrants to purchase up to 21,999,999 shares of common stock and 219,994 shares of Series Z Preferred Stock for aggregate net proceeds of \$164.5 million.

[Table of Contents](#)

As of June 30, 2016, we had \$78.2 million in cash and cash equivalents, \$21.0 million in investment securities, available-for-sale and restricted investments of \$165.2 million. As of June 30, 2016, our holdings primarily consisted of treasury-backed money market funds, treasuries and other instruments that are insured, guaranteed or supported by the U.S. federal government, and corporate debt obligations. We maintain established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity. The Company also had \$165.2 million in restricted cash and investments as of June 30, 2016 as required by our 2016 financing agreements. The required restricted cash and investments amounts are \$165.0 million, \$100.0 million and \$50.0 million until December 21, 2016, March 21, 2017 and June 21, 2017, respectively.

Net cash used in operating activities was \$53.2 million and \$34.2 million for the six months ended June 30, 2016 and 2015, respectively. Net cash used in each of these periods was primarily a result of external research and development expenses, clinical trial costs, sales and marketing costs, personnel-related costs, third-party supplier expenses and professional fees.

Net cash used in investing activities was \$187.9 million and \$2.7 million for the six months ended June 30, 2016 and 2015, respectively. In 2016, restricted cash and investments increased by \$165.2 million as required by the issuance of the 2016 Notes. In the first quarter of 2016, we made a \$60.0 million prepayment to Takeda for the acquisition of the Contrave business. Also, these amounts are the result of the net purchases and maturities of investment securities.

Net cash provided by financing activities was \$164.4 million and \$4.2 million for the six months ended June 30, 2016 and 2015, respectively. In the first quarter of 2016, we received approximately \$164.3 million net proceeds from the issuance of convertible debt, warrants and preferred stock. The net cash provided by financing activities in 2016 and 2015 also included proceeds from the issuance of common stock due to exercises of stock options.

We cannot be certain if, when or to what extent we will receive cash inflows from the commercialization of our product candidates beyond the milestones and royalties related to Contrave.

We have a license agreement for the rights to develop and commercialize Contrave. Pursuant to this agreement, we obtained exclusive and non-exclusive licenses to the patent rights and know-how for selected indications and territories. Pursuant to our agreement with Oregon Health & Science University, we issued 7,631 shares of our common stock in December 2003 and paid an upfront fee of \$65,000. We are also obligated to pay royalties on any net sales of the applicable licensed product(s), including Contrave. Our royalty payable to OHSU at June 30, 2016 for Contrave sales was approximately \$255,000.

Our future capital uses and requirements depend on numerous factors. These factors include but are not limited to the following:

- the successful commercialization of Contrave;
- the scope and cost of the post-marketing requirements for Contrave in the U.S. and Mysimba in the E.U.;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish with respect to Contrave;
- the costs of establishing sales, marketing and distribution capabilities in order to commercialize Contrave;
- the costs involved in enforcing or defending patent claims or other intellectual property rights;
- the costs and timing of additional regulatory approvals for Contrave, if at all; and
- the extent to which we in-license, acquire or invest in other indications, products, technologies and businesses.

Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents and investment securities, available-for-sale, and anticipated product revenue, will be sufficient to meet our projected operating requirements through the next 12 months.

[Table of Contents](#)

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources, proceeds of potential offerings of our equity securities, debt, potential milestone payments under our existing collaboration agreement, receivables or royalty financings and potential future corporate collaborations and licensing arrangements. However, we cannot be sure that our existing cash and investment resources and future product revenue will be adequate, that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our development programs and/or our pre-commercialization and commercialization activities, relinquish some or even all rights to product candidates or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders' We cannot be certain if, when or to what extent we will receive cash inflows from the commercialization of our product candidates beyond the sales, milestones and royalties related to Contrave. As a result of the termination of our collaboration with Takeda, we are solely responsible for developing and commercializing Contrave within the United States and the rest of the world and are responsible for the functions previously the responsibility of Takeda, including management and oversight of certain ongoing and planned post-marketing clinical trials of Contrave, including the new CVOT. We will incur substantial costs as we establish sales, marketing and distribution capabilities in order to commercialize Contrave. We will incur substantial additional development expenses to pay for the new CVOT for Contrave.

Any turbulence in the U.S. and international markets and economies may adversely affect our ability to access the capital markets and obtain additional financing on terms acceptable to us, or at all.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities as defined in Regulation S-K 303(a)(4)(ii).

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our cash and cash equivalents and investment securities, available-for-sale, as of June 30, 2016 consisted primarily of money market funds, certificate of deposits, U.S. government agency securities and corporate debt obligations. We do not have any auction rate securities on our balance sheet, as they are not permitted by our investment policy. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable debt securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment will probably decline. To minimize this risk, we intend to continue to maintain our portfolio of cash equivalents and short-term investments in a variety of securities including commercial paper, money market funds and government and non-government debt securities, all with various maturities. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

Our cash is invested in accordance with an investment policy approved by our board of directors which specifies the categories, allocations, and ratings of securities we may consider for investment. We do not believe our cash, cash equivalents and investment securities have significant risk of default or illiquidity. We made this determination based on discussions with our investment advisors and a review of our holdings. While we believe our cash, cash equivalents and investment securities are well diversified and do not contain excessive risk, we cannot provide assurance that in the future our investments will not be subject to adverse changes in market value.

In addition, domestic and international equity markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue and the markets continue to remain volatile, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary and our stock price may further decline. In addition, we maintain significant amounts of cash and cash equivalents that are not federally insured. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, we carried out an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a — 15(e) and 15d — 15(e) under the Exchange Act) as of June 30, 2016. Based on such evaluation, our management has concluded as of June 30, 2016, our disclosure controls and procedures are effective.

Changes in Internal Control over Financial Reporting

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In May 2013, the Company received a shareholder demand alleging that certain option grants to the President and Chief Executive Officer, Michael A. Narachi, the Chief Business Officer and acting-Chief Financial Officer, Joseph P. Hagan, and the Senior Vice President, General Counsel and Secretary, Heather D. Turner, in 2011 were granted in excess of the 1,500,000 share limit set forth in Section 3.3 of the Orexigen Therapeutics, Inc. 2007 Equity Incentive Award Plan, or Plan, as to the number of shares of the Company's common stock with respect to which one or more stock awards may be granted to any one eligible participant during any of the Company's fiscal years. The Company refers to this limit as the 162(m) Award Limit. The Company's board of directors established a demand review committee composed of independent directors to conduct an investigation with respect to the shareholder demand and to make recommendations to the board of directors. The demand review committee engaged independent counsel as part of its investigation and evaluated (1) the terms of the Plan, (2) the initial issuance procedures for the option grants to Mr. Narachi, Mr. Hagan and Ms. Turner during 2011, (3) the authority available to the compensation committee of the board of directors under its charter and the Plan, (4) the expectations of the award recipients and (5) the intent of the board of directors and the compensation committee regarding the availability of an exemption from the deductibility limitations of Section 162(m) of the Internal Revenue Code for such option grants. Following its investigation, the demand review committee determined that the 162(m) Award Limit first became effective as of June 2, 2011, and that, therefore, awards granted under the Plan prior to June 2, 2011, did not count toward the 162(m) Award Limit. The demand review committee determined that the awards granted to Mr. Hagan between June 2, 2011 and December 31, 2011 did not exceed the 162(m) Award Limit. The demand review committee further determined that the options granted to Mr. Narachi and Ms. Turner, including the portion of such awards in excess of the 162(m) Award Limit, were validly approved under the Plan, although the portion of those awards in excess of the 162(m) Award Limit does not qualify as performance-based compensation under Section 162(m). In September 2013, the compensation committee amended the Plan, with the approval of the Company's board of directors, to take the following actions: (1) to clarify that the 162(m) Award Limit only applies to awards or the portion thereof intended to qualify as performance-based compensation under Section 162(m); and (2) to confirm that the compensation committee has the authority to make awards in excess of the 162(m) Award Limit, which board action the Company refers to as the Plan Amendment. The Plan Amendment is deemed effective as of June 10, 2011, consistent with the authority of the compensation committee as administrator of the Plan as of that date. Any grants under the Plan in excess of the 162(m) Award Limit are not intended to qualify as performance-based compensation under Section 162(m).

[Table of Contents](#)

On December 9, 2013, the same shareholder who made a demand on the board in May 2013 filed a derivative lawsuit purportedly on behalf of the Company against certain of the officers and current and former members of the board of directors in the United States District Court, for the Southern District of California, captioned *Turgeman v. Narachi, et al.* The lawsuit asserts claims for breach of fiduciary duty, waste and unjust enrichment based on, among other things, the alleged grant of stock options to certain officers in excess of the 162(m) Award Limit, repricing stock options allegedly in violation of the Company's equity incentive plan, the board of directors' conduct in responding to the May 2013 shareholder demand, and making allegedly false and misleading statements. The lawsuit seeks, among other things, declaratory relief, corporate governance reforms, rescission of certain stock option awards, rescission of the Plan Amendment, injunctive relief, damages, restitution, disgorgement and attorney's fees. On July 23, 2014, the Company and the individual defendants filed a motion to dismiss the *Turgeman* complaint. On March 9, 2015, the court granted the motion to dismiss with thirty days leave to amend. An amended complaint was filed on April 8, 2015. The amended complaint asserts the same derivative claims as the original complaint and asserts a putative claim on behalf of plaintiff and the Company's shareholders for breach of contract for alleged violations of the 2007 Equity Incentive Plan. On May 8, 2015, the Company and the individual defendants filed a motion to dismiss the amended complaint. The court has not yet ruled on the motion.

On March 10, 2015, a purported class action lawsuit was filed against the Company and certain of the Company's officers in the United States District Court, for the Southern District of California, captioned *Colley v. Orexigen, et al.* The following day, two additional putative class action lawsuits were filed in the same court, captioned *Stefanko v. Orexigen, et al.*, and *Yantz v. Orexigen, et al.*, asserting substantially similar claims. On June 22, 2015, the court consolidated the lawsuits and appointed a lead plaintiff. On August 20, 2015, the lead plaintiff filed a consolidated complaint. The consolidated complaint purports to assert claims on behalf of a class of purchasers of the Company's stock between March 3, 2015 and May 12, 2015. It alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by purportedly making false and misleading statements regarding the interim results and termination of the Light Study. The consolidated complaint seeks an unspecified amount of damages, attorneys' fees and equitable or injunctive relief. On October 5, 2015, defendants filed a motion to dismiss the consolidated complaint. On May 19, 2016, the District Court granted the motion to dismiss, dismissing portions of the consolidated complaint with prejudice and portions without prejudice. The Court granted lead plaintiff 30 days to file an amended complaint with respect to those portions not dismissed with prejudice. On June 16, 2016, lead plaintiff filed a notice of intent not to file an amended complaint but to proceed directly to an appeal of the Court's decision dismissing the consolidated complaint. As a result, the court entered judgment dismissing the consolidated complaint with prejudice on June 27, 2016. Lead plaintiff has not yet filed a Notice of Appeal. Although management believes that any appeal would lack merit and intends to defend against it vigorously, there are uncertainties inherent in any litigation and the Company cannot predict the outcome. As this time, the Company is unable to estimate possible losses or ranges of losses that may result from such legal proceedings, and it has not accrued any amounts in connection with such legal proceedings other than ongoing attorney's fees.

On June 3, 2016, plaintiff Ben Wilkin, a shareholder who had previously made a shareholder demand to inspect certain books and records of the Company, filed a derivative lawsuit purportedly on behalf of the Company against certain of the Company's current and former officers and members of the board of directors in the Delaware Chancery Court, captioned *Wilkin v. Narachi, et al.* The lawsuit asserts claims for breach of fiduciary duty and waste of corporate assets based on essentially the same set of facts underlying the *Colley*, *Stefanko* and *Yantz* consolidated class action. The lawsuit seeks, among other things, damages, corporate governance reforms, injunctive relief, restitution, disgorgement and attorney's fees. Management believes that the claims lack merit and intends to defend against them vigorously.

It is possible that additional securities class action litigation may be brought against the Company following stock price declines related to the release of information regarding Contrave or clinical trial results, including the Light Study or related to the matters alleged in the May 2013 shareholder demand and/or the Plan Amendment. Any adverse determination in such litigation could subject the Company to significant liabilities.

In April 2015, the Company and Takeda received a Paragraph IV certification notice letter regarding an abbreviated new drug application, or ANDA, submitted to the FDA by Actavis Laboratories FL, Inc., or Actavis, requesting approval to market, sell, and use a generic version of Contrave. In its notice letter, Actavis alleges that U.S. Patent Nos. 7,375,111; 7,462,626; 8,088,786; 8,318,788; 8,722,085; 8,815,889; and 8,916,195, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, for Contrave, are invalid, unenforceable and/or will not be infringed by Actavis' manufacture, use or sale of the product described in its ANDA. In June 2015, the Company and Takeda filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Actavis and certain of its affiliates related to the ANDA previously filed by Actavis and described above. The lawsuit claims infringement of the seven patents that were the subject of Actavis' notice letter,

[Table of Contents](#)

as described above. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, as a result of having filed a patent infringement lawsuit within 45 days of receipt of Actavis' notice letter, FDA approval of the ANDA will be stayed until the earlier of (i) 30 months from the date of receipt of the notice letter or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. In July 2015, Actavis filed an answer, affirmative defenses and counterclaim to the Company's and Takeda's complaint, and the Company and Takeda filed an answer to Actavis' counterclaim in August 2015. Moreover, in July 2015, the court ordered a stipulation between the Company, Takeda and Actavis in which we and Takeda agreed to dismiss all defendants except Actavis without prejudice, and Actavis agreed that the related Actavis entities will be bound to judgments and orders of the court against Actavis and will be subject to discovery as if they were parties. In September 2015, the court entered a scheduling order, setting a claim construction hearing for May 2016 and a three-day bench trial to begin in June 2017. After reviewing Actavis' ANDA, the Company and Takeda subsequently dropped U.S. Patent Nos. 8,088,786, 8,318,788, 8,722,085 and 8,916,195 from the lawsuit. In April 2016, the Company and Takeda filed an amended complaint against Actavis asserting newly issued U.S. Patent No. 9,125,868. In June 2016, in response to the May 2016 claim construction hearing, the court adopted the Company's proposed constructions for the majority of the disputed claim terms. In August 2016, in connection with the end of the transition period associated with the separation agreement entered into between the Company and Takeda, Takeda transferred the responsibility for management of this patent infringement lawsuit to the Company. Although the Company plans to vigorously enforce Contrave intellectual property rights, there are uncertainties inherent in any litigation and we cannot predict the outcome.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the factors described when evaluating our business. We have marked with an asterisk () those risk factors that reflect substantive changes from the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2015.*

Risks Related to Our Business and Industry

****Our success for the foreseeable future is dependent solely on the success of our approved product, Contrave® (naltrexone HCl and bupropion HCl) extended release, or ER, tablets.***

To date the majority of our resources have been focused on the research and development of Contrave. In September 2014, the U.S. Food and Drug Administration, or the FDA, approved our New Drug Application, or NDA, for Contrave extended-release tablets as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index, or BMI, of 30 kg/m² or greater (obese), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition. In March 2015, the European Commission, or the EC, granted a centralized marketing authorization for Contrave (under the name Mysimba®) that is valid in all 28 European Union member states, as well as Norway, Ireland and Lichtenstein, for Mysimba to be placed on the market. We are now focused on the commercialization of Contrave in the United States. Our former collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda, commercially launched Contrave in the United States in October 2014. In addition, in May 2016, our commercialization partner, Kwang Dong Pharmaceutical Company, Ltd., obtained regulatory approval for Contrave in South Korea. Kwang Dong expects to begin marketing Contrave in the second half of 2016. We are currently advancing plans for the commercial launch of Mysimba in certain markets in Central and Eastern Europe and Turkey with our partner, Valeant Pharmaceuticals, while in parallel continuing partnering discussions for the rights to Contrave and Mysimba in other markets in the European Union and other territories outside the United States, our ability to generate revenue for the foreseeable future will depend primarily on the commercial success of Contrave in the United States.

****If Contrave does not achieve broad market acceptance, the revenues that we generate from its sales will be limited.***

The commercial success of Contrave or any other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by both the medical community and patient population. Coverage and reimbursement of our product by third-party payors, including government payors, generally is also necessary for optimal commercial success. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the timing of market introduction of our products as well as competitive products;
- the relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in a product's FDA-approved labeling, including, the "black box" warning(s) and pregnancy precautions associated with the active pharmaceutical ingredients, or APIs, in Contrave and included in Contrave's product label;
- availability of alternative treatments and the potential or perceived advantages or disadvantages of such treatments, including, in the case of Contrave, a number of competitive products approved for the treatment of weight loss or expected to be commercially launched in the near future;
- pricing, discounts and cost effectiveness;
- our Risk Evaluation and Mitigation Strategy, or REMS, if any are imposed;

[Table of Contents](#)

- the effectiveness of our, our contract sales organization's, and our collaborators' sales and marketing strategies;
- the effectiveness of our ability to distribute our products to our customers, including our ability to negotiate the terms of our agreements with third party distributors that are consistent with, or as favorable as, terms that were negotiated when we had a large pharmaceutical partner;
- our and our partners' ability to obtain sufficient third-party coverage or reimbursement; and
- the willingness of patients to pay out of pocket in the absence of third-party coverage.

If Contrave does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from our product, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product may require significant resources and may never be successful.

****We have limited sales and marketing experience and resources.***

To date, the marketing of Contrave has been focused on large markets traditionally served by general and family practitioners and internists. General physicians number in the several hundred thousand in the United States and hundreds of thousands outside the United States. Traditional pharmaceutical companies employ groups of sales representatives numbering in the thousands to call on this large generalist physician population. In order to effectively promote to these physician groups, we entered into an amended and restated collaboration agreement with Takeda in July 2015 to further develop and commercialize Contrave in the United States. However, following the end of a transition period on August 1, 2016, we will assume full responsibility for the continued development and commercialization of Contrave in the United States. We have never, as an organization, commercialized a product and there is no guarantee that we will be able to do so successfully. Included in our strategy in the United States is the establishment of a specialty sales force to continue the commercialization of Contrave. While we have established our commercial team and have hired our U.S. sales force, we will need to further develop the team in order to successfully market and sell Contrave in the United States which will require significant time and resources and our ability to market and sell our product and generate revenues from Contrave may be delayed or limited. Our sales organization is currently contracted through a contract sales force. Although the new contract sales force consists of sales professionals with experience in the pharmaceutical industry, including many with experience selling weight management products, we cannot assure you that their sales efforts will be effective or produce the results we expect. We will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. Further, we may face difficulties or delays in obtaining the required licenses and permits to sell Contrave in individual states and jurisdictions. If our commercialization of Contrave in the United States is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our Company could be harmed.

****If we do not enter into additional collaboration, distribution or co-promotion arrangements, we may not be able to effectively market and sell Contrave/Mysimba outside the United States and our ability to generate revenues may be delayed or limited.***

We have entered into an agreement with a contract sales organization to sell Contrave in the United States. We have a distribution agreement with Valeant Pharmaceuticals for the sale of Contrave in certain Central and Eastern European countries and Turkey and we have an agreement with Kwang Dong Pharmaceutical Company, Ltd. for commercialization of Contrave in South Korea. In order to expand the market opportunity for Contrave we must either establish additional sales and marketing collaborations, additional distribution or co-promotion arrangements or continue to expend significant resources to develop our own sales and marketing presence. We may not be able to enter into additional collaboration, distribution or co-promotion arrangements on acceptable terms, if at all. If we are unable to enter into additional collaboration, distribution or co-promotion arrangements for Contrave/Mysimba in additional geographies and we must develop our own sales and marketing presence to address the physicians in these geographic areas, we will require additional capital and our ability to market and sell our product and generate revenues from our product may be delayed or limited. Even if we do enter into additional collaboration, distribution or co-promotion arrangements with third parties, we will be reliant on such third parties to successfully develop and/or commercialize

[Table of Contents](#)

our product in these areas. These third parties may fail to develop or effectively commercialize our product because they cannot obtain the necessary regulatory approvals, decide to pursue a competitive potential product that may be developed outside of the collaboration or fail to devote the resources necessary to realize the full commercial potential of our product, especially in light of the resources being devoted by our competitors' collaboration and co-promotion partners. Any such failures would negatively affect our ability to generate revenues from sales of Contrave/Mysimba outside the United States.

We also face competition in our search for collaborators, co-promoters and distributors. If our competitors are able to establish collaboration, distribution or co-promotion arrangements with pharmaceutical companies who have substantially greater resources than we have, our ability to successfully commercialize Contrave/Mysimba outside the United States will be limited and as a result our competitors may be more successful in marketing and selling their products in these geographic areas.

****We currently rely on our former collaboration partner, Takeda, for a number of services related to the commercialization and development of Contrave.***

Following the end of a transition period on August 1, 2016, we will assume full responsibility for the continued development and commercialization of Contrave in the United States. However, we continue to rely on Takeda for a number of services pursuant to a transition services agreement, which services we expect to completely transition to us over the next many months. The full transition of these services requires us to expand our organization and our capabilities and will require additional time and resources and we cannot assure you that our efforts to complete the transition of all services will be completed successfully.

In addition, pursuant to our separation agreement, Takeda remains responsible for the conduct and completion of certain post-marketing studies for Contrave. We are reliant on Takeda for execution of these studies. Nevertheless, as the IND holder, we are responsible for ensuring that these studies are conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on Takeda does not relieve us of our regulatory responsibilities. Except for remedies available to us under our agreements with Takeda, we cannot control whether or not it devotes sufficient time and resources to these studies. If Takeda does not successfully carry out its responsibilities or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our post-marketing development of Contrave may be delayed.

****Even though Contrave received regulatory approval from the FDA and the EC, it will still be subject to ongoing and continued regulatory review and post-marketing requirements in these countries and elsewhere, which may result in significant expense and limit our ability to commercialize this product.***

Even though U.S. regulatory approval has been obtained for Contrave, the FDA has imposed restrictions on its indicated uses and marketing and has imposed ongoing requirements for post-marketing studies and other activities. For example, the approved use of Contrave is limited as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of 30 kg/m² or greater (obese), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related co-morbid condition. The label also contains a "boxed" warning regarding the potential for suicidal thoughts and behaviors and neuropsychiatric reactions as a side effect of the drug. We are also required to conduct a number of post-marketing studies including a series of studies in obese pediatric patients to evaluate the safety and efficacy of Contrave for weight management in pediatric populations and a group of short-term trials, including a thorough QT study, single-dose pharmacokinetic studies in renal and hepatic impairment, and a drug-drug interaction study. Finally, although FDA approval of Contrave was based in part on 25% interim analysis data from the Light Study, which was terminated in May 2015 and which evaluated the CV safety of Contrave, the FDA determined that the Light Study would not satisfy a post-marketing requirement related to CV outcomes. As a result, the FDA is requiring us to conduct a new placebo-controlled CVOT, with a pre-specified goal to exclude a hazard ratio of 1.4, with the upper bound of the 95% confidence interval. A CVOT, which we refer as the CONVENE trial, was initiated by Takeda in February 2016, with the final study results originally expected to be available by January 2022. However, following the termination of our collaboration with Takeda, we determined that the transfer of the recently-initiated, multi-year CONVENE trial to us from Takeda would have involved substantial complexity due to the scope, size and nature of the trial. After a careful assessment, we determined that the transfer of current clinical trial operations and systems may result in a significant interruption to study conduct and possibly data integrity. As a result, Takeda terminated the CONVENE trial in April 2016. We notified the clinical trial sites and the FDA of the decision to terminate the CONVENE trial and we expect to finalize a revised protocol and plans to start a new CVOT under our IND after conferring with the FDA. We cannot assure you that a new CVOT will satisfy the

[Table of Contents](#)

FDA's post-marketing requirements related to CV outcomes or that the FDA will not require us to conduct additional studies during or after the new CVOT. Any issues relating to these restrictions or post-marketing requirements (including any additional studies which the FDA may require or a delay in conducting the post-marketing required studies) could have an adverse impact on our ability to achieve market acceptance of or continue marketing Contrave in the United States and to generate revenue from its sale in the United States. To the extent that Contrave is approved for sale in other countries in addition to the United States, the European Union and South Korea, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

Contrave will also be subject to ongoing requirements established by the FDA and other regulatory authorities in the European Union and elsewhere governing the manufacturing, labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information, including, among other things, information related to the stability and consistency and reliability of the quality of Contrave (e.g. strength, purity and potency). These requirements include, among other things, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMP, regulations and good clinical practice, or GCP, requirements for any clinical trials that we conduct post-approval.

Approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. Later discovery of previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or failure to comply with regulatory requirements, may result in, among other things, restrictions on that product or on us or a partner, including:

- withdrawal of the product from the market or voluntary or mandatory product recalls;
- warning letters or untitled letters;
- civil or criminal penalties, including fines;
- withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- restrictions on operations, including restrictions on the marketing or manufacturing of the product or the imposition of costly new manufacturing requirements; or
- seizure or detention, or refusal to permit the import or export of products.

In addition, the policies of the FDA and other regulatory authorities in the European Union and elsewhere may change and additional government regulations may be enacted that could impact the marketing of Contrave/Mysimba. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained in the United States and Europe, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

****Our clinical trials, including the CVOT and other post-marketing required studies, may fail to demonstrate acceptable levels of safety or efficacy of Contrave, which could prevent or significantly delay Contrave's regulatory approval in countries outside the United States, the European Union and South Korea and may adversely impact our ability to maintain regulatory approval in the United States and the European Union.***

Contrave is prone to the risks of failure inherent in drug development, even following approval from the FDA. Even though U.S. and European Union regulatory approvals have been obtained for Contrave/Mysimba, the FDA has imposed ongoing requirements for post-marketing studies. Any issues relating to these post-marketing requirements (including any additional studies which the FDA may require or a delay in conducting the post-marketing required studies and issues relating to the safety or efficacy of Contrave) could have an adverse impact on our ability to receive regulatory approval outside the United States, to achieve market acceptance of or continue marketing Contrave in the United States and to generate revenue from its sale in the United States. To the extent that Contrave is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

[Table of Contents](#)

Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in adequate and well-controlled clinical trials, and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidate is safe and effective for use for that target indication.

In addition, we may need to complete additional preclinical testing of any product candidate to evaluate safety and toxicity and the FDA may require us to conduct additional clinical trials. The results from the preclinical and clinical trials that we have completed for Contrave may not be replicated in future trials, or we may be unable to demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for Contrave (outside the United States, the European Union and South Korea) and maintain approval for Contrave in the geographies in which we have approval today. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, including post-marketing clinical trials, even after promising results in earlier trials. If Contrave is not shown to be safe and effective in clinical trials, our clinical development program could be delayed or terminated. Any delays could also result in the need for additional financing, and our failure to adequately demonstrate the efficacy and safety of any other product candidates that we may develop, in-license or acquire would prevent receipt or maintenance of regulatory approval and, ultimately, the commercialization of that product candidate.

We expect intense competition in the obesity marketplace for Contrave and new products may emerge that provide different or better therapeutic alternatives for obesity and weight loss.

Contrave competes with well-established prescription drugs for the treatment of obesity, including Xenical® (orlistat), marketed by Genentech, Inc. Orlistat has also been launched by GlaxoSmithKline in over-the-counter form under the brand name alli®, which represents additional competition and potential negative pricing pressure. Orlistat is marketed by a pharmaceutical company with substantially greater resources than we have. In addition, a number of generic pharmaceutical products are prescribed for obesity, including phentermine, phendimetrazine, benzphetamine and diethylpropion. Some of these generic drugs, and others, are prescribed in combinations that have shown anecdotal evidence of efficacy. These products are sold at much lower prices than Contrave. The availability of a large number of branded prescription products, including drugs that are prescribed off-label, generic products and over-the-counter products could limit the demand for, and the price we or our partners are able to charge for Contrave and any future products. Vivus, Inc. commercially launched its combination product, phentermine/topiramate, in the United States under the name Qsymia in September 2012. Eisai Inc., the collaboration partner of Arena Pharmaceuticals, Inc., or Arena, commercially launched lorcaserin in the United States under the name Belviq in June 2013. Vivus, Arena and Eisai may already have built a significant competitive advantage as Contrave did not become commercially available in the United States until October 2014. Moreover, Novo Nordisk's product, Saxenda, received FDA and European Commission approval and commercially launched in the United States in April 2015, with launches in additional markets planned in the future. These products represent additional competition and potential negative pricing pressure with respect to Contrave. Further, if safety concerns about these products' use arise after their launch, such concerns may materially and adversely affect the commercialization of Contrave.

Currently, there are a number of drug products in development for obesity which could become competitors against our product. These include products being developed by AstraZeneca, Athersys, Inc., Johnson & Johnson, Norgine BV, A/S, and Novo Nordisk.

There are also surgical approaches to treat severe obesity that are becoming increasingly accepted and could become competitors against our product. Two of the most well established surgical procedures are gastric bypass surgery and adjustable gastric banding. In addition, other potential approaches which utilize various implantable devices or surgical tools are in development, including an endoscopic approach for treating obesity. Some of these approaches are in late stage development and may be approved for marketing. Companies such as Allergan, Inc., Boston Scientific, Covidien Ltd., EnteroMedics, Inc., GI Dynamics, Inc., Johnson & Johnson and Medtronic, Inc. are all active in this space and may have substantially greater resources than we have.

New developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the nutritional, pharmaceutical and medical technology industries at a rapid pace. These developments may render our product less competitive. Some of our potential competitors are large pharmaceutical or device firms and have substantially greater resources than we have. These resources could be directed toward the obesity market and include:

- research and development resources, including personnel and technology;

[Table of Contents](#)

- regulatory experience;
- drug development and clinical trial experience;
- experience and expertise in exploitation of intellectual property rights; and
- capital resources.

As a result of these factors, our competitors may more rapidly develop products than we did or may do in the future or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product. Our competitors may also develop drugs or surgical approaches that are more effective, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. In addition, our competitors may be more effective in commercializing their products. We currently outsource our manufacturing and therefore rely on third parties for that competitive expertise. There can be no assurance that we will be able to develop or contract for these capabilities on acceptable economic terms, or at all.

****We and our partners are subject to uncertainty relating to reimbursement policies which, if not favorable to Contrave, could hinder or prevent Contrave's commercial success.***

Our ability and our partners' ability to commercialize our approved product successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors establish favorable coverage and reimbursement levels for our product and related treatments. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We cannot provide any assurances that we or our partners will be able to obtain adequate third-party coverage or reimbursement for our product in whole or in part.

The obesity therapy market, in particular, continues to be marked by limited coverage and reimbursement from health insurers and other payors, who have historically viewed obesity as a lifestyle issue. For example, state Medicaid programs, administered by individual states for qualifying low-income individuals, are permitted to exclude coverage for weight loss drugs. In addition, weight loss drugs are excluded from coverage under the Medicare Part D prescription drug program for eligible seniors and disabled individuals. Medicare is a federal governmental third-party payor whose policies often are emulated or adopted by other payors. Although the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program, has removed longstanding policy language that obesity itself cannot be considered an illness, the agency interprets the Part D exclusion of weight loss drugs as applying to novel obesity therapies. However, CMS has since issued a national policy covering bariatric surgery for co-morbid conditions associated with obesity, and extended coverage under the Medicare program for intensive behavioral therapy for beneficiaries with obesity. The benefit provides for screening for obesity and counseling for eligible beneficiaries by primary care providers in physician's offices. Although third-party payors' willingness to cover and reimburse obesity-related products and services appears to be changing, as exemplified by Medicare changes, we may continue to face a poor coverage and reimbursement environment.

Currently, Contrave as well as our competitors' drug products have limited third-party payor coverage. This means that individuals prescribed such drug products often either have significant out-of-pocket costs or pay for the products entirely by themselves. If Contrave does not receive adequate coverage or reimbursement, or if patients are unwilling to pay out of pocket for Contrave, the market acceptance and commercial success of Contrave may be limited.

Our failure to successfully acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our corporate strategy, we may acquire, in-license, develop and/or market additional products and product candidates. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products,

[Table of Contents](#)

businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we may acquire will be commercialized profitably or achieve market acceptance.

****Delays in the commencement, the transfer and delivery of clinical trial information, the transition of clinical trials or completion of clinical trials or the requirement to conduct additional clinical trials could result in increased costs to us and delay or limit our ability to continue development programs, maintain or receive additional regulatory approvals and/or generate revenues.***

Delays in the commencement, the transfer and delivery of clinical trial information, the transition of clinical trials, including the transition of post-marketing studies from Takeda to us, or completion of clinical trials could significantly affect our product development costs or adversely impact our ability to maintain or receive additional regulatory approvals. We do not know whether clinical trials will begin on time or whether clinical trials will be completed on schedule, if at all. The commencement, transfer and delivery of clinical trial information, the transition of clinical trials and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory approval to commence a clinical trial, including regulatory approval of the design of a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- manufacturing sufficient quantities of a product for use in clinical trials;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;

Table of Contents

- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the treatment of obesity or similar indications and the restrictions imposed by the design and length of a clinical trial;
- retaining patients who have initiated a clinical trial, but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up;
- the status of our collaborative relationship with Takeda with respect to the post-marketing requirements which are being completed by Takeda during the transition period; and
- timely collection, review and analysis of our clinical trial data.

A clinical trial may be suspended or terminated by us, a development partner, the FDA (or an equivalent regulatory authority outside the United States), the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- lack of adequate funding or other resources to continue the clinical trial;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; and
- logistical and operational challenges inherent in complex clinical trials.

Additionally, changes in regulatory requirements and guidance for developing products for weight management may occur and we may need to initiate new clinical trials or change protocols of existing clinical trials to account for these changes. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion or termination of clinical trials, may also ultimately lead to the termination of a development program and/or the denial of regulatory approval of a product candidate, including the denial of an NDA or regulatory approval outside the United States.

****Contrace may cause undesirable side effects that could delay or prevent commercialization, limit the commercial profile of an approved label, result in significant negative consequences following marketing approval or delay or prevent regulatory approval.***

Undesirable side effects caused by our product could cause regulatory authorities to withdraw or limit their approval of the product or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Contrace has been evaluated in four completed Phase III clinical trials, which we refer to collectively as the Contrace Obesity Research, or COR, program. Across the entire COR program, seven patients experienced serious adverse events that were attributed by investigators as possibly related or related to Contrace treatment. These consisted of cholecystitis (gallbladder inflammation) (2), seizure (2), palpitations (1), paresthesia (1) and vertigo (1). The most frequently observed treatment-emergent adverse events were nausea, constipation, headache, vomiting, dizziness, insomnia, dry mouth and diarrhea. Nausea was the leading adverse event resulting in discontinuation; however, for the majority of patients experiencing nausea, it was mild to moderate, transient and manageable. In the Light Study 50% interim analysis, which interim analysis was completed in connection with the termination of the Light Study in 2015 and was designed only as an early and preliminary assessment of safety to support regulatory approvals of Contrace, there were no unexpected new safety signals observed. Serious adverse events and adverse events leading to discontinuation were generally consistent with the overall safety profile established in the COR program. However, a larger number of CV events are required to determine the effect of Contrace on CV outcomes and these safety conclusions may change in connection with the required post-marketing CVOT.

The safety data we have disclosed to date represents our interpretation of the data at the time of disclosure and it is subject to our further review and analysis. Serious adverse events have been reported to the FDA (and an equivalent applicable regulatory authority) and study investigators as required in accordance with current guidelines and standards. Serious adverse events that are not characterized by clinical investigators as possibly related to our study drug or adverse events that occur in small numbers may not be disclosed to the public until such time the various

[Table of Contents](#)

documents submitted to the FDA as part of the approval process are made public. We are unable to determine if the subsequent disclosure of adverse events will have an adverse effect on our stock price. In addition, our interpretation of the safety data from our clinical trials is contingent upon the review and ultimate approval of the FDA. The FDA may not agree with our methods of analysis or our interpretation of the results.

In addition, the constituent drugs of our product each has its own side effect profile that is included in the respective current product label. Contrave's label includes the side effect profiles of each of its constituent drugs, including a "boxed" warning regarding the potential for suicidal thoughts and behaviors and neuropsychiatric reactions as a side effect of the drug. Moreover, patients may experience side effects that are indicated in the constituent drugs' labels, as was the case with the side effects experienced by patients in our clinical trials of Contrave. In addition, while the constituent drugs that make up Contrave have post-marketing safety records and while we have tested these constituent drugs in combination in our clinical trials of Contrave to date, the safety of the combined use of the constituents of Contrave is not yet fully known, and any future trials may produce side effects not observed to date. Any of the side effects of Contrave, or its individual constituent drugs, could limit the commercial profile of the approved label.

Further, if we or others, including our partners, identify undesirable side effects caused by the recently launched Contrave, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as an additional "boxed" warning with Contrave or an additional contraindication;
- we may be required to change the way the product is distributed or administered, to conduct additional clinical trials or to change the labeling of the product;
- we or our partners may decide to remove the products from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product; and
- our reputation may suffer.

Any of these events could prevent us and our partners from achieving or maintaining market acceptance of Contrave or any other affected product candidate and could substantially increase the costs of commercializing Contrave and significantly impact our ability and our partners' ability to successfully commercialize Contrave and generate revenues.

****We rely primarily on third parties to assist us in the conduct of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to commercialize our product within our expected timeframes or at all.***

We expect to use a CRO to assist us with monitoring, oversight and statistical support for the post-marketing requirements for Contrave/Mysimba, including the CVOT. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of our clinical trials and the subsequent collection, review and analysis of data. These third parties, including CROs and investigators, are not our employees, and we have limited ability to control the amount or timing of resources that they devote to our programs. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and that our regulatory filings are consistent with regulatory requirements. Our reliance on CROs does not relieve us of our regulatory responsibilities. We and our CROs that assist us with our clinical studies are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and regulatory authorities may not accept the clinical data in support of our marketing applications or in connection with our post-marketing commitments. We cannot assure you that upon inspection by a given regulatory authority, such authority will determine that any clinical trial complied with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP regulations. If our CROs, consultants or independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard or fails to

[Table of Contents](#)

comply with regulatory requirements, it may adversely impact the commercialization of our product. In addition, the execution of clinical trials, the subsequent compilation, review and analysis of the data produced and the preparation of regulatory applications requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties provide the necessary resources and communicate and coordinate with one another. If these third parties are unable to provide the necessary resources or coordinate and communicate with one another, our clinical trials may be delayed or the completion and analysis of the data and the related regulatory applications may be delayed or compromised. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. If these third parties also contract to provide services for our competitors, it could adversely affect our business.

****If the contract manufacturers upon whom we rely fail to produce our product in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we and our partners may face delays in the development and commercialization of Contrace.***

We do not currently possess nor do we plan to implement manufacturing or packaging processes internally. We currently utilize the services of contract manufacturers to manufacture and package our clinical and commercial supplies. These supplies include the formulations of our product's APIs from our API suppliers, the tablets combining those components and the materials used to package these tablets for commercial use and use in clinical trials. If the contract manufacturers upon whom we rely fail to produce our product in the volumes required on a timely basis, we may face delays in the continued development and commercialization of Contrace.

In March 2010, we entered into a long-term manufacturing services agreement, or manufacturing agreement, with Patheon Pharmaceuticals and Patheon Inc., which we collectively refer to as Patheon, pursuant to which Patheon has agreed to manufacture commercial quantities of our Contrace tablet products. Under the terms of the manufacturing agreement, as amended by the parties in November 2013, we are required to purchase from Patheon a certain percentage of our requirements for Contrace tablet products intended for commercial sale, provided certain terms and conditions are met. The initial term of the manufacturing agreement commenced in March 2010 and shall continue in effect until December 31, 2019. Upon expiration of the initial term, the agreement will be automatically renewed for additional two year terms. Patheon may terminate the manufacturing agreement at any time upon specified prior written notice to us. We may also terminate the manufacturing agreement with specified prior written notice to Patheon, subject to our payment of certain termination amounts. Either party may terminate the manufacturing agreement effective immediately upon written notice to the other in the event that (a) the other party dissolves, or is declared insolvent or bankrupt by a court of competent jurisdiction, (b) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction, or (c) the manufacturing agreement is assigned for the benefit of creditors. We may terminate the manufacturing agreement upon specified prior written notice if any governmental or regulatory authority, including, but not limited to, the FDA, takes any action, or raises any objection, that prevents us from importing, exporting, purchasing or selling Contrace tablet products. We are also required to give specified advance notice if we intend to no longer order commercial supplies of Contrace tablet products pursuant to the manufacturing agreement due to the product's discontinuance in the market. Patheon may terminate the manufacturing agreement upon specified prior written notice to us if we assign any of our rights under the manufacturing agreement to an assignee that, in the opinion of Patheon acting reasonably, is (a) not a credit worthy substitute for us, or (b) a competitor of Patheon. Moreover, either party may terminate the manufacturing agreement upon written notice to the other party where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under the manufacturing agreement within a specified period of time following receipt of a written notice of the breach, subject to specified terms and conditions.

If we change to other manufacturers in the future, the FDA and comparable foreign regulators must approve these manufacturers' facilities and processes prior to use, which would require new clinical studies, testing and compliance inspections, and the new manufacturers would have to be educated in or demonstrate successful technology transfer of the processes necessary for the production of our product.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up for commercial production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel and production capacity, equipment failures as well as compliance with strictly enforced federal, state and foreign regulations, which include product requirements established by the FDA or other regulatory agencies and stability requirements in other foreign countries that our current product candidate formulations may not be able to meet. If our manufacturers were to encounter any of these difficulties in the United States or in other foreign countries or otherwise fail to comply with their obligations to us, or if we do not

[Table of Contents](#)

accurately forecast our demand, our ability to support the commercial sale of Contrave or to provide product to patients in our clinical trials would be jeopardized. Moreover, our API suppliers acquire the raw materials necessary to make Contrave API from a limited number of sources. Naltrexone, in particular, comes from a very limited number of sources. Any delay or disruption in the availability of these raw materials or a change in raw material suppliers could result in production disruptions, delays or high costs with consequent adverse effects on us. Any delay or interruption in our ability to meet commercial demand for Contrave will result in the loss of potential revenues. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining a clinical trial program and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

In addition, all manufacturers of our products must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements may be revised from time to time and include, among other things, quality control, quality assurance and the generation and maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. While we are ultimately responsible for ensuring that our contract manufacturers operate in accordance with cGMP requirements and have implemented a quality oversight program, we have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval and/or commercialization, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize Contrave or obtain regulatory approval for or successfully complete any required clinical trials, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in the sale of Contrave or any of its clinical trials, entail higher costs or result in our or our partners being unable to effectively commercialize Contrave. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis, pursuant to provided specifications and at commercially reasonable prices, we and our partners may be unable to meet demand for Contrave and would lose potential revenues. Now that we have sole responsibility for the commercialization of Contrave in the United States, in the future we may not be able to negotiate terms that are consistent with, or as favorable as, terms that were negotiated when we had a large pharmaceutical company as our collaboration partner. To the extent that Contrave is approved for sale in other geographies in addition to the United States, Europe and South Korea, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those geographies.

****There are labeled adverse side effects to the individual use of bupropion and naltrexone.***

A key constituent of Contrave is bupropion, which has been approved by the FDA for the treatment of depression and to assist smoking cessation. The FDA has directed manufacturers of all antidepressant drugs to include in their product labels a "boxed" warning and expanded warning statements regarding an increased risk of suicidal thinking and behavior in children and adolescents being treated with these drugs. The package insert for bupropion includes such a "boxed" warning statement. In December 2006, the FDA held an advisory committee meeting regarding suicidal thinking and behavior in adults being treated with antidepressant drugs. The advisory committee recommended that the "boxed" warning be extended to cover adults up to their mid-20s. The package insert for Contrave includes a "boxed" warning regarding the potential for suicidal thoughts and behaviors and neuropsychiatric reactions as a side effect of the drug. To the extent that any additional warnings or labeling changes related to suicidal thinking and behavior in adults are required, we expect that any such additional warnings or other labeling changes will also be required on labeling for Contrave. In July 2009, the FDA issued a news release announcing that it was requiring manufacturers to put a "boxed" warning on the prescribing information for smoking cessation drugs including Zyban®, which is a branded form of bupropion. The warning highlights the risk of serious mental health events including changes in behavior, depressed mood, hostility, and suicidal thoughts. Although Contrave is not intended to be promoted for or used in the treatment of major depression or smoking cessation, a similar warning is included in the labeling for Contrave, particularly because it is likely that there will be obese patients who smoke or depressed obese patients who will use Contrave.

The FDA has also directed manufacturers of antidepressant drugs to create Medication Guides to be distributed to patients regarding the risk of suicidal thinking and behavior in children and adolescents. Although we have not included children or adolescents in the Contrave clinical trials, the FDA required us to create a Medication Guide for Contrave. These warnings and other requirements may have the effect of limiting the market acceptance by targeted physicians and patients of Contrave.

The other constituent of Contrave, naltrexone, has been approved by the FDA for the treatment of alcohol and opioid dependence. The FDA has directed the manufacturers of naltrexone for these indications to include in their product labels a "boxed" warning and expanded warnings statements regarding hepatotoxicity, or liver toxicity. A similar warning statement is included in the labeling for Contrave.

[Table of Contents](#)

Each of the constituent drugs included in the Contrave combination has in its package insert a “Category C” pregnancy precaution. This means that animal studies have shown that each of these constituent drugs has the potential to cause birth defects and that there have been no adequate and well-controlled studies of the constituent drugs in pregnant women, but that the FDA has determined that the benefits from the use of such drugs in pregnant women may be acceptable despite the potential risks. In addition, although Contrave is not known to be teratogenic, it appears from a recent FDA action, in which the FDA stated that weight loss offers no potential benefit to a pregnant woman and may result in fetal harm, that the FDA is likely to classify all weight loss pharmaceutical products as Category X. Contrave, the obesity therapeutics approved by the FDA in 2012 and orlistat all have Category X pregnancy precautions.

Any of these known side effects and any associated warning statements or classification or categorization of risk may limit the commercial profile of the approved label for Contrave and prevent us from achieving or maintaining market acceptance of Contrave.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and we may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or “off-label” uses, resulting in damage to our reputation and business.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about approved drugs, such as Contrave. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product’s approved labeling, also known as “off-label” promotion. Physicians may nevertheless use our product for their patients in a manner that is inconsistent with the approved label, as the FDA does not restrict or regulate a physician’s choice of treatment within the practice of medicine. If the FDA determines that our promotional materials or training or the statements made by our sales representatives constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, which could have an adverse impact on our reputation and financial results. Moreover, in the European Union, direct-to-consumer advertising for a prescription only medicine is expressly prohibited by law.

****If the suppliers upon whom we rely for API fail to produce such ingredients in the volumes that we or our partners require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we or our partners may face delays in the further development or commercialization of Contrave.***

We do not manufacture any of our API nor do we plan to develop any capacity to do so. Instead, we rely on suppliers of API to provide component materials to our other contract manufacturers, who produce finished pharmaceutical products incorporating the API. The failure or inability of our API suppliers to satisfy our API requirements on a timely basis could limit or halt our ability to sell Contrave in the United States, the European Union or elsewhere that we have or may receive regulatory approval for sale.

Although naltrexone itself is not addictive, synthesis of naltrexone is a multi-step process with a natural opiate starting material that has the potential for abuse and is therefore regulated as a controlled substance under the federal Controlled Substances Act or applicable foreign equivalents. As such, manufacturers of naltrexone API must be registered with the Drug Enforcement Administration, or DEA, or applicable foreign equivalents. Manufacturers making naltrexone also must obtain annual quotas from the DEA for the opiate starting material. Because of the DEA-related requirements and modest current demand for naltrexone API, there currently exist a limited number of manufacturers of this API. Therefore, API costs for naltrexone are greater than for the other constituents of our product. Demand for Contrave may require amounts of naltrexone greater than the currently available worldwide supply or our or our partners’ current forecasts for the supply to us of Contrave or its components. Any lack of sufficient quantities of naltrexone would limit our ability to continue to commercialize Contrave in the United States and complete any additional required clinical trials and would limit our ability to commercialize Contrave/Mysimba outside the United States and Europe. Although we are evaluating additional possible manufacturers to supplement our current naltrexone manufacturing capacity, including those in the United States and Europe, we may not be successful in accessing additional manufacturing supply of naltrexone API or other necessary components of our product at the appropriate quantities, quality or price.

In May 2015, we entered into a supply agreement with Mallinckrodt, effective January 2015, pursuant to which Mallinckrodt manufactures commercial supplies of naltrexone for use in Contrave. Pursuant to the terms of the supply agreement, we will pay certain fixed prices for such naltrexone, which prices may be adjusted, subject to specified

[Table of Contents](#)

limitations. We are required to purchase from Mallinckrodt a specified percentage of our requirements for naltrexone in our drug products containing naltrexone which are intended for commercial sale, provided that certain terms and conditions are met. The initial term of the supply agreement commenced in January 2015 and will continue in effect through December 2018. This initial term may only be renewed with the express written agreement of both parties. Either party may terminate the supply agreement effective immediately upon written notice to the other in the event that (a) the other party dissolves, or is declared insolvent or bankrupt by a court of competent jurisdiction, (b) a voluntary or involuntary (if not dismissed within a specified number of days) petition of bankruptcy is filed in any court of competent jurisdiction by or against the other party, or (c) the supply agreement is assigned by the other party for the benefit of creditors. Either party may terminate the supply agreement upon 90 days' written notice to the other party of a failure by that party to perform or observe any material covenant, condition or agreement to be performed or observed by it under the supply agreement, unless such breach has been cured within the 90 day notice period, *provided that* Mallinckrodt can only cure a breach for failure to timely supply ordered quantities of naltrexone up to one time per year, and *provided further that*, if we breach the agreement by failing to pay an invoice, the notice and cure periods referred to in this sentence shall only be 30 days. We may terminate the supply agreement upon 60 days' prior written notice to Mallinckrodt in the event that, (a) any regulatory agency takes any action, or raises any objection that prevents us from importing, exporting, purchasing or selling naltrexone or any of its drug product containing naltrexone, (b) our drug product containing naltrexone fails during clinical trials and we withdraw the NDA, or (c) we determine, in our sole discretion, to no longer pursue the development and/or commercialization of any of our drug products containing naltrexone.

Other than our agreement with Mallinckrodt, we have no other material, long-term commitments or supply agreements with any of our other API suppliers. Although we may seek to establish additional long-term supply commitments in the future, we may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions. We may not be able to enter into additional long-term agreements on commercially reasonable terms, or at all. Consequently, we and our partners may not be able to successfully commercialize Contrave if we are unable to secure long-term supply commitments for its API components. Further, now that we have sole responsibility for the commercialization of Contrave in the United States, in the future we may not be able to negotiate terms that are consistent with, or as favorable as, terms that were negotiated when we had a large pharmaceutical company as our collaboration partner.

In addition, our API suppliers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and must maintain and comply with their respective DMFs on file with the FDA. These requirements include, among other things, quality control, quality assurance and the generation and maintenance of records and documentation. Suppliers of our API may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. While we are ultimately responsible for ensuring that our contract manufacturers operate in accordance with cGMP requirements and have implemented a quality oversight program, we have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our suppliers' failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize Contrave, and we may be held liable for an injuries sustained as a result. Any of these factors could cause a delay of clinical trials or commercialization of Contrave, entail higher costs or result in our and our partners being unable to effectively commercialize our product. Furthermore, if our suppliers fail to deliver the required commercial quantities of API on a timely basis, pursuant to the required specifications set forth in their respective DMF and at commercially reasonable prices, and we are unable to timely secure and qualify additional suppliers with applicable regulatory authorities, we and our partners may not be able to successfully commercialize Contrave and/or we and our partners may be unable to meet demand for our product and would lose potential revenues. To the extent that Contrave is approved for sale in other countries in addition to the United States and Europe, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

****Contrave is a combination of generically-available pharmaceutical products, and our success is dependent on our ability and our partners' ability to compete against off-label generic substitutes and demonstrate the advantages of our proprietary combination products.***

Off-label use occurs when physicians prescribe a drug that is approved by the FDA for one indication for a different, unapproved indication. We believe that a practitioner seeking safe and effective therapy is not likely to prescribe such off-label generics in place of Contrave because the dosage strengths, pharmacokinetic profiles and titration regimens recommended for Contrave are not available using existing generic preparations of immediate release, or IR, naltrexone and bupropion ER, and there are no oral generic ER formulations of naltrexone. However, a physician could seek to prescribe off-label generics in place of Contrave. Such off-label prescriptions could significantly diminish the market potential of our product and significantly impact our ability to generate revenues.

[Table of Contents](#)

With regard to off-label substitution at the pharmacy level, we expect to rely on the novel dose ratios and novel pharmacokinetic properties of our product, as well as the differences in its approved indications, to provide sufficient distinction such that generic preparations are not considered therapeutic equivalents by the FDA. State pharmacy laws in many instances only permit pharmacists to substitute generic products for branded products if the products are therapeutic equivalents. Therefore, the lack of therapeutic equivalency should limit generic substitution by pharmacies and/or pharmacy benefit managers. However, we cannot be certain that pharmacists and/or pharmacy benefit managers will not seek prescriber authorization to substitute generics in place of Contrave, which could significantly diminish their market potential and significantly impact our ability and our partners' ability to successfully commercialize our product and generate revenues.

In addition, although we believe the current market prices for the generic forms of naltrexone make generic substitution by physicians, pharmacists or pharmacy benefit managers unlikely, should the prices of the generic forms decline, the motivation for generic substitution may become stronger. Wide scale generic substitution by physicians and at the pharmacy level could have substantial negative consequences to our business.

Our development and commercialization strategy depends upon access to findings of safety and effectiveness based on data not developed by us but which the FDA may reference in reviewing our U.S. marketing applications. In territories outside the United States, we must either negotiate access to these safety and effectiveness findings or develop them ourselves.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This statutory provision expressly allows the FDA to rely, for purposes of approving an NDA, on findings of safety and effectiveness based on data not developed by the filer of the NDA. Under these guidelines, we were able to move directly into Phase II clinical trials for Contrave, because our NDA for Contrave relied, in part, upon the FDA's findings of safety and effectiveness for the previously-approved products that are incorporated into Contrave. Similar legislation for active substances with well-established medicinal use exists in the European Union under article 10a of European Directive 2001/83/EC, which allows for reference to scientific literature if active substances have been approved for at least ten years with recognized efficacy and an acceptable level of safety. There also are alleviations under article 10b of European Directive 2001/83/EC of the obligation to provide scientific references relating to individual active substances in combination products if such individual active substances have been previously authorized in the European Union, although not the obligation to provide results of new pre-clinical tests or new clinical trials relating to such combination products, which could provide an alternative pathway in Europe. In territories where data are not freely available, we may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds to generate our own data. We may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety and manufacturing dossiers. In addition, even though we have taken advantage of Section 505(b)(2) for approval of Contrave, the FDA may also require us to perform additional studies or measurements to support changes from the previously-approved products incorporated into our product.

To the extent that a Section 505(b)(2) application relies on the FDA's finding of safety and effectiveness of a previously-approved drug, the applicant is required to make certifications to the FDA with respect to any patents listed for the approved product in the FDA's publication called "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." Specifically, the applicant must certify when the application is submitted that: (1) there is no relevant patent information listed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the manufacture, use, or sale of the new product. A certification that the new product will not infringe the already approved product's Orange Book listed patents or that such patents are invalid is called a paragraph IV certification. If the 505(b)(2) applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA holder and patent owner. We have made paragraph IV certifications that Contrave does not infringe the bupropion ER formulation patents listed in the Orange Book, and have sent the appropriate notice to the patent holder and NDA holder.

[Table of Contents](#)

****We have received three year Hatch Waxman exclusivity in the U.S. for Contrave, but have already received patent certifications and are engaged in litigation that may permit the FDA to approve an ANDA to Contrave as early as September 2017.***

We have obtained three years of Hatch-Waxman marketing exclusivity for Contrave from the date of approval by the FDA on September 10, 2014. Under this form of exclusivity, the FDA is precluded from approving a 505(b)(2) NDA or ANDA for the same drug product for the protected indication (for example, a product that incorporates the change or innovation represented by our product) for a period of three years, although the FDA may accept and commence review of such applications. In April 2015, we and Takeda received notification of a Paragraph IV certification for certain patents for Contrave which are listed in the FDA's Orange Book. The certification resulted from the filing by Actavis Laboratories FL, Inc. of an ANDA challenging such patents for Contrave. In June 2015, we and Takeda filed a lawsuit in the U.S. District Court for the District of Delaware against Actavis Laboratories FL, Inc. and certain of its affiliates, which we refer to collectively as Actavis, on the basis that Actavis' proposed generic products infringe certain patents for Contrave. In accordance with the Hatch-Waxman Act, as a result of having filed a lawsuit within 45 days of the Paragraph IV certification notice, FDA approval of the ANDA will be stayed until the earlier of (i) 30 months from Takeda's receipt of the notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. In July 2015, Actavis filed an answer, affirmative defenses and counterclaim to our complaint, and in August 2015, we and Takeda filed an answer to Actavis' counterclaims. Moreover, in July 2015, the court ordered a stipulation between us, Takeda and Actavis in which we and Takeda agreed to dismiss all defendants except Actavis without prejudice, and Actavis agreed that the related Actavis entities will be bound to judgments and orders of the court against Actavis and will be subject to discovery as if they were parties. In September 2015, the court entered a scheduling order, setting a claim construction hearing for May 2016 and a three-day bench trial to begin in June 2017. After reviewing Actavis' ANDA, we and Takeda subsequently dropped U.S. Patent Nos. 8,088,786, 8,318,788, 8,722,085 and 8,916,195 from the lawsuit. In April 2016, we and Takeda filed an amended complaint against Actavis asserting newly issued U.S. Patent No. 9,125,868. In June 2016, in response to the May 2016 claim construction hearing, the court adopted our proposed constructions for the majority of the disputed claim terms. In August 2016, in connection with the end of the transition period associated with the separation agreement entered into between us and Takeda, Takeda transferred to us the responsibility for management of this patent infringement lawsuit. Although we plan to vigorously enforce Contrave intellectual property rights, there are uncertainties inherent in any litigation and we cannot predict the outcome. However, the Hatch-Waxman marketing exclusivity might not prevent the FDA from approving a 505(b)(1) NDA that relies on its own clinical data. Further, if another company obtains approval for an identical product candidate for the same new indication we are studying before we do, our approval of the new indication could be blocked until the other company's Hatch-Waxman marketing exclusivity expires, unless we conduct additional studies in support of a 505(b)(1) NDA.

****We may never receive approval or commercialize our products outside of the United States and the European Union.***

In order to market any products outside of the United States and the European Union, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety, efficacy and manufacturing. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. In August 2015, we entered into a distributorship agreement with Kwang Dong Pharmaceutical Company, Ltd., or Kwang Dong, through our wholly owned subsidiary. Kwang Dong began marketing Contrave in South Korea in June 2016.

Failure to obtain regulatory approval for Contrave in other countries outside of the United States, the European Union and South Korea, or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that Contrave may not be approved for all indications requested, which could limit the uses of Contrave and have an adverse effect on their commercial potential or require costly, post-marketing follow-up studies.

A variety of risks associated with operating our business and marketing our product internationally could materially adversely affect our business.

In addition to our U.S. operations, we have a subsidiary in Ireland and may establish additional international business entities in the future. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for Contrave and any future products;

Table of Contents

- compliance with Irish laws and the maintenance of our Irish tax residency for our Irish subsidiary, which may make certain corporate actions more cumbersome, costly and time-consuming;
- difficulties in staffing and managing foreign operations;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- changes in diplomatic and trade relationships.

Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K.'s Bribery Act 2010, or the U.K. Bribery Act. The FCPA and similar anti-corruption laws generally prohibit the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or decision, secure any other improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls. The U.K. Bribery Act prohibits giving, offering, or promising bribes to any person, including non-U.K. government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the U.K. Bribery Act, companies which carry on a business or part of a business in the U.K. may be held liable for bribes given, offered or promised to any person, including non-U.K. government officials and private persons, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability is strict, with no element of a corrupt state of mind, but a defense of having in place adequate procedures designed to prevent bribery is available. Furthermore, under the U.K. Bribery Act there is no exception for facilitation payments. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government and the purchasers of pharmaceuticals are government entities; therefore, any dealings with these prescribers and purchasers may be subject to regulation under the FCPA. Recently the SEC and the U.S. Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd–Frank Wall Street Reform and Consumer Protection Act, private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We are engaged in ongoing efforts that are designed to ensure our compliance with these laws, including due diligence, training, policies, procedures and internal controls. However, there is no certainty that all employees and third-party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third-party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

[Table of Contents](#)

We face potential product liability exposure, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product in clinical trials and the sale of our product expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health-care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product.

Although we have commercial product liability insurance, which includes coverage for our ongoing and future clinical trials we perform, our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Healthcare reform measures could hinder or prevent our product's commercial success.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems to contain healthcare costs and improve quality. While reform proposals often involve expanding coverage to more individuals, healthcare reform may also involve increased government price controls, additional regulatory mandates and other measures designed to lower medical and pharmaceutical costs. Within the United States, the pharmaceutical industry has been a particular focus of healthcare reform both federally and at the state level.

For example, in March 2010, the President signed into law one of the most significant health reform measures in decades. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, substantially changes the way healthcare is financed by both governmental and private insurers, including several payment reforms that establish payments to hospitals and physicians based in part on quality measures, subjects biologic products to potential competition by lower-cost "biosimilars," and significantly impacts the pharmaceutical and medical device industries. The PPACA includes, among other things, the following measures:

- annual, non-deductible fees on any entity that manufactures or imports certain prescription branded drugs and biologics;
- increased Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs and expanded rebates owed by manufacturers to include rebates on Medicaid managed care utilization;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical research;
- requirements for manufacturers to discount drug prices to eligible patients in the coverage gap by 50% at the pharmacy level and for mail order services in order for their outpatient drugs to be covered under Medicare Part D;

[Table of Contents](#)

- an extension of eligibility criteria for Medicaid programs;
- an increase in the number of entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a licensure framework for follow-on biologic products.

The PPACA provisions on comparative clinical effectiveness research extend the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included \$1.1 billion in funding to study the comparative effectiveness of healthcare treatments and strategies. This stimulus funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA also appropriates additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of healthcare, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies.

In addition, the PPACA provides for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement, including obesity reduction and obesity-related services that are available to Medicaid enrollees. The PPACA also provides funding for projects designed to reduce childhood obesity.

Other legislative changes have also been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals.

In the European Union and some other international markets, governments or payors have adopted local policy to contain costs for provisions of health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries have announced or implemented measures to reduce health care costs to constrain their overall level of government expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possibly retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases, and greater importation of drugs from lower-cost countries to higher-cost countries. If our product is approved in these markets, these measures may negatively impact our revenues. In addition, certain countries set prices by reference to the prices in other countries where approved products are marketed. Thus, our inability to secure adequate prices for our products, if approved, in a particular country may not only limit the marketing of these products within that country, but may also adversely affect our ability to obtain acceptable prices in other markets. This may create the opportunity for third party cross border trade or influence our decision to sell or not to sell a product, if approved, thus adversely affecting our revenues.

We cannot predict what effect the PPACA or other healthcare reform or cost control initiatives that may be adopted in the future will have on our business. Further, there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law, and we expect there will be additional challenges and amendments to the Health Care Reform Law in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- our ability to set a price we believe is fair for our approved product;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital.

[Table of Contents](#)

****We may not be able to manage our business effectively if we are unable to attract and retain key personnel.***

We may not be able to attract or retain qualified management, commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California area. Our retention efforts may be particularly challenging in light of the difficult regulatory climate for obesity drugs and the recent departures among our senior management team. Our industry has experienced a high rate of turnover of management personnel in recent years. As our business continues to grow, and we transition from primarily a drug development company to a commercial product organization, we expect to experience changes in our executive team, including potential departures and the addition of new executives with commercialization expertise or other necessary skill sets. We may also experience some departures from our current executive team as individuals transition to new experiences and/or retirement. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the successful development and commercialization of Contrave/Mysimba, our ability to raise additional capital and our ability to implement our overall business strategy.

We are highly dependent on the development, regulatory, commercial and financial expertise of our senior management, particularly Michael A. Narachi, our President and Chief Executive Officer and Thomas Cannell, our Chief Operating Officer and President of Global Commercial Products. Although we have employment agreements with each of our executive officers, these agreements are terminable at will at any time with or without notice and, therefore, we may not be able to retain their services as expected. If we lose any members of our senior management team, including Messrs. Narachi and Cannell, we may not be able to find suitable replacements, and our business may be harmed as a result. We are not aware of any key personnel who has plans to retire or leave our company in the immediate future. In addition to the competition for personnel, the San Diego area in particular is characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

In addition, we have scientific and clinical advisors who assist us in formulating our product development and clinical and regulatory strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

If we fail to comply with healthcare laws and regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a manufacturer of pharmaceuticals, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights, among other topics, may be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business, without limitation. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute (as amended by the PPACA, which modified the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation), which prohibits, among other things, persons and entities from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws, including the civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent, and which may apply to entities like us which promote pharmaceutical products and provide coding and billing advice to customers, and under the PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

[Table of Contents](#)

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, and their implementing regulations, which imposes certain requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information;
- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Additionally, the compliance environment is changing, with more states mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states requiring reporting to state governments of gifts, compensation, and other remuneration to physicians. The PPACA also imposes annual reporting and disclosure requirements on certain device and drug manufacturers for which payment is available for their products under Medicare, Medicaid, or the Children’s Health Insurance Program, for any “transfer of value” made or distributed to physicians and teaching hospitals. Such information is now publicly available in a searchable format. In addition, device and drug manufacturers are also required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Manufacturers were required to begin collecting requisite information on August 1, 2013, with the first reports due in 2014. Failure to submit requisite information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Further, under the PPACA, pharmaceutical manufacturers and distributors must provide the U.S. Department of Health and Human Services with an annual report on the drug samples they provide to physicians. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different compliance and/or reporting requirements, increases the possibility that a pharmaceutical company may run afoul of one or more laws.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, imprisonment, contractual damages, reputational harm, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers’ activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and other hazardous compounds. We and our manufacturers are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage. If we are subject to any liability as a result of our third-party manufacturers’ activities involving hazardous materials, our business and financial condition may be adversely affected.

[Table of Contents](#)

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for, could result in delays in our regulatory efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product could be delayed.

Risks Related to Intellectual Property

****Our market opportunity for Contrave may be limited by the relatively small number of issued U.S. patents and foreign patents that we own or in-license. In addition, although we have additional U.S. and international patent applications pending which seek further protection of our product, these applications may not issue on a timely basis or at all.***

Contrave is currently protected by U.S. patent number 7,375,111, which we refer to as the Weber/Cowley composition patent, and U.S. patent number 7,462,626, which we refer to as the Weber/Cowley methods patent. Provided maintenance fees are paid, the Weber/Cowley composition patent is expected to expire in March 2025, and the Weber/Cowley methods patent is expected to expire in July 2024. Collectively, we refer to the Weber/Cowley composition patent and the Weber/Cowley methods patent as the Weber/Cowley patents. We own the Weber/Cowley patents, but they are subject to our license agreement with Oregon Health & Science University, or OHSU. The Weber/Cowley patents cover the current composition of Contrave and methods of administering it to treat obesity. We and/or our licensors have filed a number of international counterparts to the Weber/Cowley patents in foreign countries. A European counterpart application to the Weber/Cowley patent has issued in the European Patent Office, or EPO, as EP1617832B1, and provides protection for Contrave in the various EPO countries in which the patent has been registered. Several international counterparts to the Weber/Cowley patents have also issued in other foreign jurisdictions. However, we cannot provide assurance that other pending international counterparts will issue on a timely basis or at all. There is also no assurance that the currently pending claims in those foreign countries will not be rejected, that any such rejections and any future rejections will ultimately be overcome, nor that any claims that may issue will be sufficiently broad to protect Contrave in those foreign countries. Furthermore, we cannot be certain that the scope of any issued foreign patent will be consistent with the currently pending claims, as there is a significant likelihood that the scope of the currently pending claims will be modified. If a competitor is willing to challenge the scope or validity of the Weber/Cowley patents, the competitor could file an NDA seeking approval for three years after the date we obtained approval from the FDA of the NDA for Contrave. For example, in April 2015, we and Takeda received notification of a Paragraph IV certification for certain patents for Contrave which are listed in the FDA's Orange Book. The certification resulted from the filing by Actavis of an ANDA challenging such patents for Contrave. In June 2015, we and Takeda filed a lawsuit in the U.S. District Court for the District of Delaware against Actavis on the basis that Actavis' proposed generic products infringe certain patents for Contrave. In accordance with the Hatch-Waxman Act, as a result of having filed a lawsuit within 45 days of the Paragraph IV certification notice, FDA approval of the ANDA will be stayed until the earlier of (i) 30 months from Takeda's receipt of the notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. In July 2015, Actavis filed an answer, affirmative defenses and counterclaim to our complaint, and in August 2015, we and Takeda filed an answer to Actavis' counterclaims. Moreover, in July 2015, the court ordered a stipulation between us, Takeda and Actavis in which we and Takeda agreed to dismiss all defendants except Actavis without prejudice, and Actavis agreed that the related Actavis entities will be bound to judgments and orders of the court against Actavis and will be subject to discovery as if they were parties. In September 2015, the court entered a scheduling order, setting a claim construction hearing for May 2016 and a three-day bench trial to begin in June 2017. After reviewing Actavis' ANDA, we and Takeda subsequently dropped U.S. Patent Nos. 8,088,786, 8,318,788, 8,722,085 and 8,916,195 from the lawsuit. In April 2016, we and Takeda filed an amended complaint against Actavis asserting newly issued U.S. Patent No. 9,125,868. In June 2016, in response to the May 2016 claim construction hearing, the court adopted the Company's proposed constructions for the majority of the disputed claim terms. In August 2016, in connection with the end of the transition period associated with the separation agreement entered into between us and Takeda, Takeda transferred to us the responsibility for management of this patent infringement lawsuit. Although we plan to vigorously enforce Contrave intellectual property rights, there are uncertainties inherent in any litigation and we cannot predict the outcome.

We have also filed patent applications, directed to various treatment and formulation aspects of Contrave, in the United States and certain foreign countries under the Patent Cooperation Treaty, or PCT. Use of our proprietary tri-layer Contrave tablet for weight loss is protected in the United States by U.S. patent numbers 8,088,786 and 8,318,788, which are expected to expire in February 2029 and November 2027, respectively. Corresponding patents

[Table of Contents](#)

have issued in several foreign countries, for example, in the European Patent Office as EP2089005 B1. In addition, the dose escalation schedule of Contrave is protected by U.S. patent numbers 8,722,085 and 9,125,868, which are expected to expire in November 2027. U.S. patent number 8,815,889, directed to methods of treating insulin resistance using Contrave, including in obese patients, is expected to expire in July 2024. Corresponding patents have issued in several foreign countries, for example, in the European Patent Office as EP2135603 B1. Use of our proprietary sustained-release formulation of Contrave for weight loss is protected by U.S. patent numbers 8,916,195 and 9,107,837 which are expected to expire in February 2030 and June 2027, respectively. U.S. patent numbers 8,969,371 and 9,119,850, which are expected to expire in July 2034, protect the use of Contrave for treating overweight or obesity in select patient populations that are at increased risk of a major adverse cardiovascular event. U.S. patent number 9,248,123, which is expected to expire in January 2032, protects the use of Contrave for treating overweight or obesity in select patient populations with major depressive disorder. The PCT is an international treaty providing a unified procedure under which the initial filing of a single patent application can provide an effective filing date in each participating country in which appropriate steps are subsequently taken. Such steps have been taken in various foreign countries, including Europe and Japan, with respect to a number of our PCT filings. Thus, we now have issued patents and pending patent applications in those foreign countries, along with our previous filings in the United States and certain non-PCT countries. These filings seek to provide further protection for Contrave in the United States and overseas; however, we cannot provide assurance that the claims in the other patent applications will issue in their current form or at all.

We may face additional competition outside of the United States as a result of a lack of patent enforcement in foreign countries and off-label use of other dosage forms of the generic components in our product.

While we have filed patent applications in many countries outside the United States, and have obtained some patent coverage for Contrave in certain foreign countries, we do not currently have widespread patent protection for Contrave outside the United States and have no protection in many foreign jurisdictions. Even if international patent applications ultimately issue or receive approval, it is likely that the scope of protection provided by such patents will be different from, and possibly less than, the scope provided by our corresponding U.S. patents. The success of our international market opportunity is dependent upon the enforcement of patent rights in various other countries. A number of countries in which we have filed or intend to file patent applications have a history of weak enforcement and/or compulsory licensing of intellectual property rights. Even if we have patents issued in these jurisdictions, there can be no assurance that our patent rights will be sufficient to prevent generic competition or unauthorized use. We may face competition from the off-label use of other dosage forms of the generic components in our product. In addition, others may attempt to commercialize our product combination in the countries of the European Union, Canada, Mexico, Japan or other markets, in some of which, we do not have patent protection for our product. Due to the lack of patent protection for these combinations in some territories outside the United States and the potential for correspondingly lower prices for the drugs in those markets, it is possible that patients will seek to acquire the generic IR component of our product (naltrexone IR) in those other territories. The off-label use of the generic IR component in the United States or the importation of the generic IR component from foreign markets could adversely affect the commercial potential for our product and adversely affect our overall business and financial results.

We have in-licensed all or a portion of the rights to Contrave from third parties. If we default on any of our material obligations under those licenses, we could lose rights to our product.

We have in-licensed and otherwise contracted for rights to our product, and we may enter into similar licenses in the future to supplement our product pipeline. Under the relevant agreements, we are subject to commercialization, development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. Loss of any of these licenses or the exclusive rights provided therein could harm our financial condition and operating results.

****Restrictions on our patent rights relating to Contrave may limit our and our partners' ability to prevent third parties from competing against us.***

Our success will depend on our and our partners' abilities to obtain and maintain patent protection for Contrave, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. Composition of matter patents on APIs are generally considered to be the strongest form of intellectual property protection for pharmaceutical products as they apply without regard to any method of use. Entirely new individual chemical compounds, often referred to as new chemical entities, are typically entitled to composition of matter coverage. Current law also allows novel and unobvious combinations of old compounds to receive composition of matter coverage for the combination. However, we cannot be certain that the current law will remain the same, or that our product will be considered novel and unobvious by the PTO and courts.

[Table of Contents](#)

In addition to composition of matter patents and patent applications, we also have issued and filed method of use patents and patent applications. This type of patent protects the use of Contrave only for the specified method. However, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if these competitors do not actively promote their product for our targeted indication, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Although we believe we and our licensors have conducted appropriate prior art searches relating to our key patents and patent applications, there is no assurance that all of the potentially relevant prior art has been found. Moreover, because the constituents of our combination product have been on the market as separate monotherapeutic products for many years, it is possible that these monotherapies have previously been used off-label in such a manner that such prior usage would affect the validity of our method of use patents.

Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we and the inventors of the issued patents and applications that we in-licensed were the first to conceive inventions covered by the patents and pending patent applications or that we and those inventors were the first to file patent applications for such inventions.

We also rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants, some of whom assist with the development of other obesity drugs. We and our partners also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

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

Our commercial success depends upon our and our partners’ abilities to develop, manufacture, market and sell our product and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product and/or proprietary technologies may give rise to claims of infringement of the patent rights of others. There may be issued patents of third parties of which we are currently unaware that may be infringed by our product or proprietary technologies. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us or our partners, which may later result in issued patents that Contrave or proprietary technologies may infringe.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product and/or proprietary technologies infringe their intellectual property rights. If one of these patents is found to cover Contrave, proprietary technologies or their uses, we or our partners could be enjoined by a court and required to pay damages and could be unable to commercialize our product or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us or our partners on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us or our partner from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. If a third party claims that we or our partners infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management’s attention from our core business;

[Table of Contents](#)

- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling or licensing the product unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties and fees and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We will be obtaining our bupropion, naltrexone, our finished Contrave tablets combining these components, and the packaging for these tablets from third-party manufacturers. Each aspect of product design, formulation, manufacturing, packaging, and use has the potential to implicate third-party patent rights. We have taken various measures to reduce the potential for infringement. However, we could be exposed to potential patent infringement liability from other third parties who hold patents on various formulations of bupropion and naltrexone.

No assurance can be given that patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering these or other aspects of our products, technology or methods, as implemented by us or by third-party manufacturers with whom we contract. Because of the large number of patents issued and patent applications filed in our field, we believe there is a risk that third parties may allege they have patent rights encompassing our products, technology or methods. Such third-party patent rights, if relevant, could prevent us or our partners from adopting or marketing a particular formulation or product, or could expose us to patent infringement liability.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on the Weber/Cowley patents covering Contrave, as well as our other issued patents, are due to be paid to the PTO in several stages over the lifetimes of the patents. We have systems in place to remind us to pay these fees, and we employ an outside firm, Computer Patent Annuities, to pay annuity fees due to foreign patent agencies on our issued and pending foreign patent applications. The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

****We have not yet registered our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.***

We have received U.S. trademark registration number 3396021 for our corporate logo for use in connection with pharmaceutical preparations and substances for the treatment of obesity, inducement of weight loss and prevention of weight gain. We have obtained trademark registrations in Canada, the European Union, and Japan for the same mark. In addition, we have received U.S. trademark registration number 3396807 for our corporate name OREXIGEN for use in connection with pharmaceutical preparations for the treatment of disorders of the central nervous system, or CNS, printed instructional, educational and teaching materials in the field of treatment and management of disorders of the CNS, and providing medical information in the field of disorders of the CNS. We have obtained trademark registrations in Brazil, Canada, the European Union, Japan and Russia for the same mark and have pending applications in Brazil. We have obtained foreign trademark registrations for the corporate name Orexigen Therapeutics, Inc. in the European Union and Japan. We have received U.S. trademark registration number 3393576 for the mark CONTRAVE for use in connection with pharmaceutical preparations for use in the treatment of obesity and inducing weight loss. We have also obtained foreign trademark registrations for the mark CONTRAVE in

[Table of Contents](#)

Australia, Brazil, Canada, Europe, Mexico, Russia, Japan and South Korea and have pending applications in Australia, Brazil, Canada, Mexico, India and Vietnam. In addition, applications for a Contrave logo for use in connection with pharmaceutical preparations for use in the treatment of obesity and inducing weight loss, certain printed materials and medical information services are pending in the U.S. and Canada. The Contrave logo is registered in Europe and Japan. An intent to use application for the mark MYSIMBA has been allowed in the United States in connection with pharmaceutical preparations, printed materials, and medical information services. We have obtained trademark registrations in Australia, the European Union, Norway, South Korea and Switzerland for the same mark. In addition, an application for the mark MYSIMBA is pending in India. However, no assurance can be given that our allowed trademark applications will actually become registered, or that our registered trademarks can be maintained or enforced. During trademark registration proceedings in the various countries, we have received and expect to receive rejections. Although we are given an opportunity to respond to those rejections, there can be no assurance that the rejections can be successfully overcome. In addition, in the PTO and in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to cancel registered trademarks. No assurance can be given that opposition or cancellation proceedings will not be filed against our trademarks, nor can there be any assurance that our trademarks would survive such proceedings.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Finances and Capital Requirements

****We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.***

We have focused primarily on developing our first approved product, Contrave. We have financed our operations almost exclusively through the sale of our preferred and common stock and debt and have incurred losses in each year since our inception in September 2002. As of June 30, 2016, we had an accumulated deficit of approximately \$668.3 million. These losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to continue to incur significant and increasing operating losses for the foreseeable future and such losses have had, and will continue to have, an adverse effect on our stockholders' equity. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the extent of any future losses.

****We have a limited history of generating revenue from our product and may never be profitable.***

Our ability to become profitable depends upon our ability to generate revenue. We have a limited history of generating revenue, and we do not know when, or if, we will generate any significant revenue. Takeda commercially launched Contrave in October 2014 and our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to maintain regulatory approval of, effectively commercialize and successfully complete future clinical trials for Contrave, and our ability to:

- effectively market and sell Contrave in the United States;
- maintain regulatory approval of Mysimba in the European Union;
- manufacture commercial quantities of Contrave at acceptable cost levels; and
- effectively market and sell Contrave/Mysimba in the European Union and elsewhere outside the United States, if approved.

We anticipate incurring significant costs associated with the continued development and commercialization of our approved product, Contrave. We do not expect to be profitable in the near future, if ever. If we or our partners are unable to generate product revenues, we will not become sustainably profitable and may be unable to continue operations without continued funding.

[Table of Contents](#)

We may need additional funds and/or need to enter into additional collaborative or other agreements in order to fund post-marketing studies for Contrave or clinical trials outside the United States for Contrave/Mysimba, and commercialize Contrave/Mysimba outside the United States, and we may be unable to raise capital when needed or enter into such an agreement, which would force us to delay, reduce or eliminate development and commercialization activities required for Contrave/Mysimba, and our commercialization efforts for Contrave/Mysimba outside such countries.

Developing products for the obesity market, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our projected operating requirements through at least the next 12 months. However, we have based these estimates on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Further, we will need additional capital to:

- fund our operations and to conduct post-marketing requirements for Contrave;
- develop and commercialize Contrave/Mysimba; and
- qualify and outsource the commercial-scale of Contrave under cGMP.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the successful commercialization of Contrave/Mysimba;
- the rate of progress and cost of clinical activity, including the new CVOT for Contrave, and the scope and cost of the additional post-marketing requirements for Contrave, including expenses to support the trials and milestone payments that may become payable;
- the terms and timing of any collaborative, licensing, co-promotion, distribution or other arrangements that we may establish with respect to Contrave/Mysimba;
- the costs of establishing sales, marketing and distribution capabilities in order to commercialize Contrave/Mysimba in the United States and geographies outside the United States, should we elect to do so;
- the costs involved in enforcing or defending patent claims or other intellectual property rights;
- the costs and timing of additional regulatory approvals for Contrave/Mysimba; and
- the extent to which we in-license, acquire or invest in other indications, products, technologies and businesses.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no commitments or agreements relating to any of these types of transactions.

Unless and until we can generate a sufficient amount of product revenue and achieve profitability, we expect to finance future cash needs through public or private equity offerings, milestone payments, debt, receivables or royalty financings, or corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

[Table of Contents](#)

****Our quarterly and annual operating results may fluctuate significantly.***

We expect our operating results to be subject to quarterly and annual fluctuations. Our net loss and other operating results may be affected by numerous factors, including:

- the level of underlying demand for Contrave, wholesalers' buying patterns with respect to Contrave, discounts given to certain Contrave customers, and our ability to successfully market Contrave following the transition from Takeda;
- variations in the level of expenses, including, but not limited to, variation based on foreign currency exchange rates, related to our product or future development programs;
- regulatory developments affecting our product or those of our competitors;
- the timing of future payments, if any, we may receive under partnership, distributorship or similar agreements;
- our execution of any additional collaborative, licensing, distribution or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- addition or termination of clinical trials or funding support; and
- any intellectual property infringement lawsuit in which we may become involved.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly and annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

****Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.***

In March 2016, we sold \$165 million aggregate principal amount of 0% Convertible Senior Secured Notes due 2020, or the Secured Notes, initially convertible into an aggregate of up to 21,999,999 shares of common stock and related warrants to purchase up to 21,999,999 shares of common stock. In September 2015, we sold 2,000,000 shares of our common stock and warrants to purchase five million shares of our common stock. In December 2013, we sold \$115 million aggregate principal amount of 2.75% Convertible Senior Notes due 2020, or the 2013 Notes. Any conversions or exercises of some or all of these Secured Notes, 2013 Notes or warrants, as applicable, will result in additional dilution of existing stockholders.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. Debt, receivables and royalty financings typically contain covenants that restrict operating activities and may impair our ability to in-license potential products or product candidates. Debt, receivables and royalty financings may also be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders' ownership.

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our current product candidates, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of our product.

****We sold \$165 million aggregate principal amount of 0% Convertible Senior Secured Notes in March 2016 and \$115 million aggregate principal amount of 2.75% Convertible Senior Notes in December 2013, which may impact our financial results, result in the dilution of existing stockholders, and restrict our ability to take advantage of future opportunities.***

In March 2016, we sold \$165 million aggregate principal amount of Secured Notes and related warrants. The Secured Notes may be converted, under the conditions specified in those Secured Notes, into shares of our common stock and the warrants may be exercised, under the conditions specified in those warrants, into shares of our common stock.

In addition, in December 2013, we sold \$115 million aggregate principal amount of 2013 Notes. We will be required to pay interest on the 2013 Notes until they come due, are called by us, or are converted, and the payment of that interest will reduce our net income. The sale of the 2013 Notes may also affect our earnings per share figures, as

[Table of Contents](#)

accounting requirements require that we include in our calculation of earnings per share the number of shares of our common stock into which the 2013 Notes are convertible. On June 27, 2014, our stockholders approved a flexible conversion option that allows us to pay the conversion right on these 2013 Notes in cash and/or shares. The flexible conversion right may allow us to exclude from the earnings per share calculation the shares of our common stock into which the 2013 Notes are convertible. However, we cannot guarantee that the flexible conversion option would result in the accounting treatment described above. The 2013 Notes may be converted, under the conditions and at the premium specified in those 2013 Notes, into shares of our common stock and/or into the cash equivalent of shares of our common stock.

Upon the occurrence of certain fundamental changes or, in the case of the Secured Notes, adverse events related to the regulatory approval for, commercialization of, and net sales of Contrave®, holders of the 2013 Notes and Secured Notes will, at their option, have the right to require the Company to repurchase for cash all or a portion of their notes, pursuant to the terms and conditions set forth in the applicable indenture.

If converted into shares, the Secured Notes and the 2013 Notes will result in the dilution of our shareholders. Also when exercised, the warrants that we issued in connection with the Secured Notes will result in the dilution of our shareholders. Further, if repurchased, converted or exercised into cash, the 2013 Notes, the Secured Notes and the related warrants may require the payment of significant additional amounts to the holders of these securities. The payment of the interest payments, the repayment of the principal, the potential payment of the conversion premium and/or cash exercise amounts and the potential repurchase of the Secured Notes and the 2013 Notes will require the use of a substantial amount of our cash, and if such cash is not available, we may be required to sell other assets or enter into alternate financing arrangements at terms that may or may not be desirable. The existence of the Secured Notes and the 2013 Notes and the obligations we incurred by issuing them may restrict our ability to take advantage of certain future opportunities, such as engaging in future debt or equity financing activities, which may reduce or impair our ability to acquire new businesses or invest in our existing businesses.

****The Holders of our Secured Notes have the right to require us to repurchase, for cash, their Secured Notes in the case of certain fundamental changes or adverse changes related to the regulatory approval for, commercialization of, and net sales of Contrave.***

The indenture for our Secured Notes provides that the holders of the Secured Notes will, at their option, have the right to require the Company to repurchase, for cash, all or a portion of their Secured Notes in certain circumstances, including: (a) a change in control of the company or other fundamental changes; (b) our common stock ceases to be listed or quoted on NASDAQ; and (c) following specific adverse events related to our business that include: (i) a suspension or withdrawal, by the FDA, of the marketing approval of Contrave; (ii) changes to the drug label for Contrave or the implementation of a REMS for Contrave, in any case, in a manner that would be reasonably expected to have a materially adverse impact on annual net sales of Contrave in the United States; (iii) we cease selling Contrave in the United States, either ourselves or through affiliates, distributors, partners or licensees; (iv) approval, by the FDA, of an ANDA for a AB-rated generic version of Contrave and actual sales of such generic version in the United States; and (v) worldwide net sales of Contrave for fiscal year 2017 that are less than \$100 million, in aggregate. Certain of the events that would trigger the repurchase obligation are outside of our control, including certain of the events that would be classified as a change in control or fundamental change. We cannot assure you that we will avoid these events. If we are required to repurchase the Secured Notes, it will require a significant amount of cash, and if such cash is not available, we may be required to enter into alternate financing arrangements at terms that may or may not be desirable.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Domestic and international equity markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue and the markets continue to remain volatile, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are not federally insured. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

[Table of Contents](#)

Our foreign subsidiaries may not be able to successfully maintain advantageous tax status and resulting tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.

We anticipate being able to achieve favorable tax treatment through the performance of certain business functions and ownership of certain assets in tax-efficient jurisdictions, including Ireland, together with intra-company service and transfer pricing agreements, each on an arm's length basis. Taxing authorities, such as the U.S. Internal Revenue Service, or IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. We expect that these challenges will continue as a result of the recent increase in scrutiny and political attention on corporate tax structures. The IRS may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may lose the ability to use our net operating loss, or NOL, carryforwards, which could prevent or delay us from offsetting future taxable income.

We have incurred substantial losses during our history and do not expect to become profitable in 2016 and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Our federal and state net operating loss carryforwards begin to expire in 2024 and 2025, respectively. Additionally, the future utilization of our net operating loss carryforwards and credits to offset future taxable income is subject to annual limitations, pursuant to Sections 382 and 383 of the Internal Revenue Code, as a result of ownership changes that have occurred in prior years or may occur in the future, which could defer our ability to utilize or prevent us from fully utilizing our net operating loss carryforwards, and credits, which could have an adverse effect on our results of operations. We completed an ownership change analysis in accordance with Section 382 from inception through December 31, 2015. As a result of the study, it was determined that we experienced several ownership changes during this period with the last one occurring in December 2014. We have reduced our NOL and credit carryforwards as disclosed in our financial statement for the effect of Section 382 and 383.

Risks Relating to Securities Markets and Investment in Our Stock

****The market price of our common stock has fluctuated and is likely to continue to fluctuate, which could reduce the market price of our common stock.***

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the last several years, the overall capital markets have been highly volatile. Since the commencement of trading in connection with our initial public offering, or IPO, the publicly traded shares of our common stock have themselves experienced significant price and volume fluctuations. During the quarter ended June 30, 2016, the price per share for our common stock on the Nasdaq Global Market has ranged from a low sale price of \$0.35 to a high sale price of \$0.65 (which prices do not reflect the effect of the reverse stock split effected on July 11, 2016). This market volatility is likely to continue and could reduce the market price of our common stock, regardless of our operating performance. In addition, the trading price of our common stock could change significantly over short periods of time in response to many factors, including:

- announcements regarding the commercial sales and related revenue(s) for Contrave;
- FDA or international regulatory actions, including failure to maintain regulatory approval for Contrave in South Korea or receive approval in other additional foreign jurisdictions;
- announcements regarding our clinical trials, including the Ignite Study, the Light Study and the post-marketing required clinical trials for Contrave;
- announcements regarding Vivus', Novo Nordisk's and Eisai's approved obesity products, including sales, safety and efficacy results, and their respective regulatory submissions and/or the results of their respective clinical trials;
- announcements regarding our other competitors' regulatory submissions and/or the results of their clinical trials;

[Table of Contents](#)

- announcements regarding our relationships with third parties;
- announcements regarding bupropion or naltrexone;
- announcements regarding manufacturing or supply developments for Contrave;
- failure of any of our product to achieve commercial success;
- developments concerning current or future strategic collaborations;
- announcements of the introduction of new products by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our products;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- healthcare reform measures and other third-party coverage and reimbursement policies; and
- changes in or announcements relating to third-party coverage and reimbursement policies for Contrave/Mysimba; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

The realization of any of the risks described in these “Risk Factors” could also have a dramatic and material adverse impact on the market price of our common stock.

Future sales of our common stock may depress our stock price.

Any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of any such shares of common stock or the availability of any such shares of common stock for sale would have on the market price of our common stock.

In addition, persons who were our stockholders prior to the sale of shares in our IPO continue to hold a substantial number of shares of our common stock that they may be able to sell in the public market, subject to the limitations of Rule 144 of the Securities Act of 1933, as amended. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. For example, certain of our executive officers have established selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for the purpose of effecting specified sales of our common stock over a specified period of time.

We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In addition, our directors and executive officers may in the future establish programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock, in addition to the already established plans. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

[Table of Contents](#)

****Our executive officers, directors, principal stockholders and their respective affiliates will exercise significant influence over stockholder voting matters in a manner that may not be in the best interests of all of our stockholders.***

As of June 30, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates together controlled approximately 40.1% of our outstanding common stock, assuming no exercise of outstanding options or warrants. As a result, these stockholders will collectively be able to significantly influence all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of some stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations;
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors, including to delay or impede a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We have never paid dividends on our capital stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our stock.

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may become involved in securities-related litigation, including securities class action litigation, or securities-related investigations, that could divert management's attention and harm our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought

[Table of Contents](#)

against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this and other types of shareholder litigation in the future. Moreover, as a public company, we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources. For example, in April 2015, we received a formal request from the SEC's Division of Enforcement for documentation related to, among other things, a Current Report on Form 8-K that we filed with the SEC on March 3, 2015. We intend to cooperate fully with the SEC regarding this matter. Litigation, and investigations by regulatory authorities, are often expensive and divert management's attention and resources, which could adversely affect our business.

In May 2013, we received a shareholder demand alleging that certain option grants to our President and Chief Executive Officer, Michael A. Narachi, our Chief Business Officer and acting-Chief Financial Officer, Joseph P. Hagan, and our Senior Vice President, General Counsel and Secretary, Heather D. Turner, in 2011 were granted in excess of the 1,500,000 share limit set forth in Section 3.3 of the Orexigen Therapeutics, Inc. 2007 Equity Incentive Award Plan, or Plan, as to the number of shares of our common stock with respect to which one or more stock awards may be granted to any one eligible participant during any of our fiscal years. We refer to this limit as the 162(m) Award Limit. Our board of directors established a demand review committee composed of independent directors to conduct an investigation with respect to the shareholder demand and to make recommendations to our board of directors. The demand review committee engaged independent counsel as part of its investigation and evaluated (1) the terms of the Plan, (2) the initial issuance procedures for the option grants to Mr. Narachi, Mr. Hagan and Ms. Turner during 2011, (3) the authority available to the compensation committee of our board of directors under its charter and the Plan, (4) the expectations of the award recipients and (5) the intent of our board of directors and the compensation committee regarding the availability of an exemption from the deductibility limitations of Section 162(m) of the Internal Revenue Code for such option grants. Following its investigation, the demand review committee determined that the 162(m) Award Limit first became effective as of June 2, 2011, and that, therefore, awards granted under the Plan prior to June 2, 2011, did not count toward the 162(m) Award Limit. The demand review committee determined that the awards granted to Mr. Hagan between June 2, 2011 and December 31, 2011 did not exceed the 162(m) Award Limit. The demand review committee further determined that the options granted to Mr. Narachi and Ms. Turner, including the portion of such awards in excess of the 162(m) Award Limit, were validly approved under the Plan, although the portion of those awards in excess of the 162(m) Award Limit does not qualify as performance-based compensation under Section 162(m). In September 2013, the compensation committee amended the Plan, with the approval of our board of directors, to take the following actions: (1) to clarify that the 162(m) Award Limit only applies to awards or the portion thereof intended to qualify as performance-based compensation under Section 162(m); and (2) to confirm that the compensation committee has the authority to make awards in excess of the 162(m) Award Limit, which board action we refer to as the Plan Amendment. The Plan Amendment is deemed effective as of June 10, 2011, consistent with the authority of the compensation committee as administrator of the Plan as of that date. Any grants under the Plan in excess of the 162(m) Award Limit are not intended to qualify as performance-based compensation under Section 162(m).

On December 9, 2013, the same shareholder who made a demand on the board in May 2013 filed a derivative lawsuit purportedly on behalf of us against certain of our officers and current and former members of our board of directors in the United States District Court, for the Southern District of California, captioned *Turgeman v. Narachi, et al.* The lawsuit asserts claims for breach of fiduciary duty, waste and unjust enrichment based on, among other things, the alleged grant of stock options to certain officers in excess of the 162(m) Award Limit, repricing stock options allegedly in violation of our equity incentive plan, the board of directors' conduct in responding to the May 2013 shareholder demand, and making allegedly false and misleading statements. The lawsuit seeks, among other things, declaratory relief, corporate governance reforms, rescission of certain stock option awards, rescission of the Plan Amendment, injunctive relief, damages, restitution, disgorgement and attorney's fees. On July 23, 2014, we and the individual defendants filed a motion to dismiss the *Turgeman* complaint. On March 9, 2015, the court granted the motion to dismiss with thirty days leave to amend. An amended complaint was filed on April 8, 2015. The amended complaint asserts the same derivative claims as the original complaint and asserts a putative claim on behalf of plaintiff and our shareholders for breach of contract for alleged violations of the 2007 Equity Incentive Plan. On May 8, 2015, we and the individual defendants filed a motion to dismiss the amended complaint. The court has not yet ruled on our motion.

On March 10, 2015, a purported class action lawsuit was filed against us and certain of our officers in the United States District Court, for the Southern District of California, captioned *Colley v. Orexigen, et al.* The following day, two additional putative class action lawsuits were filed in the same court, captioned *Stefanko v. Orexigen, et al.*, and *Yantz v. Orexigen, et al.*, asserting substantially similar claims. On June 22, 2015, the court consolidated the lawsuits and appointed a lead plaintiff. On August 20, 2015, the lead plaintiff filed a consolidated complaint. The consolidated

[Table of Contents](#)

complaint purports to assert claims on behalf of a class of purchasers of the Company's stock between March 3, 2015 and May 12, 2015. It alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by purportedly making false and misleading statements regarding the interim results and termination of the Light Study. The consolidated complaint seeks an unspecified amount of damages, attorneys' fees and equitable or injunctive relief. On October 5, 2015, defendants filed a motion to dismiss the consolidated complaint. On May 19, 2016, the District Court granted the motion to dismiss, dismissing portions of the consolidated complaint with prejudice and portions without prejudice. The Court granted lead plaintiff 30 days to file an amended complaint with respect to those portions not dismissed with prejudice. On June 16, 2016, lead plaintiff filed a notice of intent not to file an amended complaint but to proceed directly to an appeal of the Court's decision dismissing the consolidated complaint. As a result, the court entered judgment dismissing the consolidated complaint with prejudice on June 27, 2016. Lead plaintiff has not yet filed a Notice of Appeal. Although management believes that the claims and any appeal lack merit and intends to defend against them vigorously, there are uncertainties inherent in any litigation and we cannot predict the outcome.

On June 3, 2016, plaintiff Ben Wilkin, a shareholder who had previously made a shareholder demand to inspect certain books and records of the Company, filed a derivative lawsuit purportedly on behalf of us against certain of our current and former officers and members of the board of directors in the Delaware Chancery Court, captioned *Wilkin v. Narachi, et al.* The lawsuit asserts claims for breach of fiduciary duty and waste of corporate assets based on essentially the same set of facts underlying the *Colley, Stefanko* and *Yantz* consolidated class action. The lawsuit seeks, among other things, damages, corporate governance reforms, injunctive relief, restitution, disgorgement and attorney's fees. Management believes that the claims lack merit and intends to defend against them vigorously.

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.

[Table of Contents](#)

ITEM 6. EXHIBITS

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|--|
| 3.1(1) | Amended and Restated Certificate of Incorporation of the Registrant |
| 3.2(2) | Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant |
| 3.3(1) | Amended and Restated Bylaws of the Registrant |
| 3.4(5) | Amendment to Amended and Restated Bylaws of the Registrant |
| 3.5(6) | Certificate of Designations, Preferences and Rights of Series Z Non-Convertible Non-Voting Preferred Stock. |
| 3.6(8) | Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant, as amended |
| 4.1(1) | Form of the Registrant's Common Stock Certificate |
| 4.2(3) | Form of Warrant to Purchase Common Stock |
| 4.3(4) | Indenture dated as of December 6, 2013 by and between the Registrant and Wilmington Trust, National Association, as trustee |
| 4.4(6) | Indenture, dated as of March 21, 2016, by and between the Registrant and U.S. Bank National Association, as trustee and collateral agent, including the Form of 0% Convertible Senior Secured Note due 2020. |
| 4.5(7) | Form of Warrant to Purchase Common Stock |
| 4.5(6) | Investor Rights Agreement, dated as of March 15, 2016, by and among the Registrant, Baupost, and the other investors party thereto. |
| 4.6(6) | Securities Purchase Agreement, dated as of March 15, 2016, by and among the Registrant and each purchaser party thereto |
| 10.1# | Employment Agreement dated February 3, 2015 by and between the Registrant and Jason Keyes |
| 10.2# | Amendment No. 1 to Employment Agreement dated February 2, 2016 by and between the Registrant and Jason Keyes |
| 10.3# | Amendment No. 2 to Employment Agreement dated June 16, 2016 by and between the Registrant and Thomas Cannell |
| 10.4# | Amendment No. 2 to Employment Agreement dated June 16, 2016 by and between the Registrant and Jason Keyes |
| 10.5# | Amended and Restated 2007 Equity Incentive Award Plan |
| 31.1* | Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended |
| 31.2* | Certification of Principal Financial and Accounting Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended |
| 32.1* | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2* | Certification of Principal Financial and Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101 | The following financial statements and footnotes from the Orexigen Therapeutics Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 formatted in eXtensible Business Reporting Language (XBRL): (i) Balance Sheets; (ii) Statements of Operations; (iii) Statements of Comprehensive Income (Loss); (iv) Statements of Cash Flows; and (v) the Notes to Unaudited Financial Statements. |

(1) Filed with the Registrant's Registration Statement on Form S-1 on December 19, 2006, as amended (File No. 333-139496).

(2) Filed with the Registrant's Registration Statement on Form S-8 on June 22, 2011.

(3) Filed with the Registrant's Current Report on Form 8-K on December 15, 2011.

(4) Filed with the Registrant's Current Report on Form 8-K on December 9, 2013.

(5) Filed with the Registrant's Current Report on Form 8-K on July 3, 2014.

(6) Filed with the Registrant's Current Report on Form 8-K on March 25, 2016.

(7) Filed with the Registrant's Current Report on Form 8-K on March 15, 2016.

(8) Filed with the Registrant's Current Report on Form 8-K on July 11, 2016

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Orexigen Therapeutics, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Indicates management contract or compensatory plan or arrangement.

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.

OREXIGEN THERAPEUTICS, INC.

Date: August 5, 2016

By: /s/ Michael A. Narachi
Michael A. Narachi
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 5, 2016

By: /s/ Jason A. Keyes
Jason A. Keyes
SVP, Chief Financial Officer
(Principal Financial and Accounting Officer)

INDEX TO EXHIBITS

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|---|
| 3.1(1) | Amended and Restated Certificate of Incorporation of the Registrant |
| 3.2(2) | Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant |
| 3.3(1) | Amended and Restated Bylaws of the Registrant |
| 3.4(5) | Amendment to Amended and Restated Bylaws of the Registrant |
| 3.5(6) | Certificate of Designations, Preferences and Rights of Series Z Non-Convertible Non-Voting Preferred Stock. |
| 3.6(8) | Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant, as amended |
| 4.1(1) | Form of the Registrant's Common Stock Certificate |
| 4.2(3) | Form of Warrant to Purchase Common Stock |
| 4.3(4) | Indenture dated as of December 6, 2013 by and between the Registrant and Wilmington Trust, National Association, as trustee |
| 4.4(6) | Indenture, dated as of March 21, 2016, by and between the Registrant and U.S. Bank National Association, as trustee and collateral agent, including the Form of 0% Convertible Senior Secured Note due 2020. |
| 4.5(7) | Form of Warrant to Purchase Common Stock |
| 4.5(6) | Investor Rights Agreement, dated as of March 15, 2016, by and among the Registrant, Baupost, and the other investors party thereto. |
| 4.6(6) | Securities Purchase Agreement, dated as of March 15, 2016, by and among the Registrant and each purchaser party thereto |
| 10.1# | Employment Agreement dated February 3, 2015 by and between the Registrant and Jason Keyes |
| 10.2# | Amendment No. 1 to Employment Agreement dated February 2, 2016 by and between the Registrant and Jason Keyes |
| 10.3# | Amendment No. 2 to Employment Agreement dated June 16, 2016 by and between the Registrant and Thomas Cannell |
| 10.4# | Amendment No. 2 to Employment Agreement dated June 16, 2016 by and between the Registrant and Jason Keyes |
| 10.5# | Amended and Restated 2007 Equity Incentive Award Plan |
| 31.1* | Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended |
| 31.2* | Certification of Principal Financial and Accounting Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended |
| 32.1* | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2* | Certification of Principal Financial and Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101 | The following financial statements and footnotes from the Orexigen Therapeutics Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 formatted in eXtensible Business Reporting Language (XBRL): (i) Balance Sheets; (ii) Statements of Operations; (iii) Statements of Comprehensive Income (Loss); (iv) Statements of Cash Flows; and (v) the Notes to Unaudited Financial Statements. |
| (1) | Filed with the Registrant's Registration Statement on Form S-1 on December 19, 2006, as amended (File No. 333-139496). |
| (2) | Filed with the Registrant's Registration Statement on Form S-8 on June 22, 2011. |
| (3) | Filed with the Registrant's Current Report on Form 8-K on December 15, 2011. |
| (4) | Filed with the Registrant's Current Report on Form 8-K on December 9, 2013. |
| (5) | Filed with the Registrant's Current Report on Form 8-K on July 3, 2014. |
| (6) | Filed with the Registrant's Current Report on Form 8-K on March 25, 2016. |
| (7) | Filed with the Registrant's Current Report on Form 8-K on March 15, 2016. |
| (8) | Filed with the Registrant's Current Report on Form 8-K on July 11, 2016. |
| * | These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Orexigen Therapeutics, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing. |
| # | Indicates management contract or compensatory plan or arrangement. |

EMPLOYMENT AGREEMENT

This Employment Agreement (“**Agreement**”) is entered into as of February 3, 2015 (the “**Effective Date**”), by and between Jason Keyes (“**Executive**”) and Orexigen Therapeutics, Inc. (the “**Company**”).

WHEREAS, the Company desires to employ Executive to provide personal services to the Company, and wishes to provide Executive with certain compensation and benefits in return for Executive’s services; and

WHEREAS, Executive wishes to be employed by the Company and provide personal services to the Company in return for certain compensation and benefits.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, it is hereby agreed by and between the parties hereto as follows:

ARTICLE I DEFINITIONS

For purposes of the Agreement, the following terms are defined as follows:

1.1 “Board” means the Board of Directors of the Company.

1.2 “Cause” means the occurrence of any of the following events:

- (a) Executive’s conviction of or plea of guilty or *nolo contendere* to any felony or a crime of moral turpitude;
- (b) Executive’s continued failure or refusal to follow lawful and reasonable instructions of the Chief Executive Officer and/or EVP, Chief Business and Financial Officer of the Company or lawful and reasonable policies and regulations of the Company or its affiliates;
- (c) Executive’s continued failure to faithfully and diligently perform the assigned duties of Executive’s employment with the Company or its affiliates;
- (d) Unprofessional, unethical, immoral or fraudulent conduct by Executive;
- (e) Conduct by Executive that materially discredits the Company or any affiliate or is materially detrimental to the reputation, character and standing of the Company or any affiliate; or
- (f) Executive’s material breach of this Agreement, the Proprietary Information and Inventions Agreement, the Company’s Code of Conduct and/or Insider Trading Policy, or any other contractual, fiduciary, or statutory duty owed to the Company.

An event described in Section 1.2(b) through Section 1.2(f) herein shall not be treated as “Cause” until after Executive has been given written notice of such event, failure, conduct or breach and Executive fails to cure such event, failure, conduct or breach within 30 days from such written notice; provided, however, that such 30-day cure period shall not be required if the event, failure, conduct or breach is incapable of being cured. Failure of the Company to meet financial or performance targets or goals shall not be deemed to be a breach pursuant to Sections 1.2(b) or 1.2(c) herein.

1.3 “Change in Control” means the occurrence of any of the following events:

(a) the direct or indirect acquisition by any person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than 50% of the total combined voting power of the Company’s outstanding securities pursuant to a tender or exchange offer made directly to the Company’s shareholders which the Board does not recommend such shareholders to accept;

(b) a change in the composition of the Board over a period of 36 months or less such that a majority of the Board members ceases, by reason of one or more contested elections for Board membership, to be comprised of individuals who either (i) have been Board members continuously since the beginning of such period, or (ii) have been elected or nominated for election as Board members during such period by at least a majority of the Board members described in clause (i) who were still in office at the time such election or nomination was approved by the Board;

(c) the consummation of any consolidation, share exchange or merger of the Company (i) in which the stockholders of the Company immediately prior to such transaction do not own at least a majority of the voting power of the entity which survives/results from that transaction (or the parent of such surviving/resulting entity), or (ii) in which a stockholder of the Company who does not own a majority of the voting stock of the Company immediately prior to such transaction, owns a majority of the Company’s voting stock immediately after such transaction; or

(d) the liquidation or dissolution of the Company or any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all the assets of the Company, including stock held in subsidiary corporations or interests held in subsidiary ventures.

1.4 “Change in Control Period” means the time period commencing three (3) months before the effective date of a Change in Control and ending on the date that is twelve (12) months after the effective date of a Change in Control.

1.5 “Company” means Orexigen Therapeutics, Inc. or, following a Change in Control, the surviving entity resulting from such transaction.

1.6 “Constructive Termination” means Executive’s resignation from all positions Executive then holds with the Company because of:

(a) a material reduction in the level of responsibility associated with Executive’s employment with the Company or any surviving entity (other than a change in job title or officer title) as compared to Executive’s level of responsibility just prior to the reduction; provided, however, that a merger or acquisition of the Company and subsequent conversion of the Company to a division or unit of the acquiring corporation will not by itself result in a material reduction in Executive’s level of responsibility;

(b) a material reduction in Executive's level of base salary (except for any reduction imposed equally upon all other similarly-situated Company executives); or

(c) a relocation of Executive's principal place of employment by more than 50 miles (other than reasonable business travel required as part of the job duties associated with Executive's position);

provided, however, that (i) such change, reduction or relocation is effected by the Company without Cause and without Executive's consent; (ii) Executive first provides the Company with written notice of the condition described in (a), (b) or (c) above not later than sixty (60) days following its initial occurrence; (iii) the Company is permitted the opportunity to cure such condition within a period of forty-five (45) days following such written notice; and (iv) Executive resigns from employment within thirty (30) days following the end of such cure period, assuming that the condition has not been cured.

1.7 "Exchange Act" means the Securities Exchange Act of 1934, as amended.

1.8 "Involuntary Termination Without Cause" means Executive's dismissal or discharge by the Company other than for Cause. The termination of Executive's employment as a result of Executive's death or disability will not be deemed to be an Involuntary Termination Without Cause.

ARTICLE II EMPLOYMENT BY THE COMPANY

2.1 **Position and Duties.** Subject to terms set forth herein, the Company agrees to employ Executive, on a full time basis in the position of Vice President, Finance hereby accepts such employment. Executive shall perform such duties as are customarily associated with the position of Vice President, Finance, and such other duties as are assigned to Executive by the EVP, Chief Business and Financial Officer of the Company. Subject to the terms of this Agreement, the Company may change Executive's duties, responsibilities, title, and reporting relationship at its discretion. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts (except for vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies or as otherwise set forth in this Agreement) to the business of the Company.

2.2 **Employment at Will.** Both the Company and Executive shall have the right to terminate Executive's employment with the Company at any time, with or without advance notice, and with or without Cause. If applicable, upon the date of Executive's termination of employment with the Company for any reason, Executive shall immediately resign from the Board and the board of directors or comparable body of every subsidiary, parent or other affiliated corporation of the Company, and every committee thereof. Executive shall not receive any compensation of any kind, including, without limitation, severance benefits or change of control severance benefits, following Executive's last day of employment with the Company (the "**Termination Date**"), except as expressly provided for by this Agreement, applicable law, and/or any plan documents governing the compensatory equity awards that have been or may be granted to Executive from time to time in the sole discretion of the Company.

2.3 Employment Policies. The employment relationship between the parties shall also be governed by the general employment policies and practices of the Company, including those relating to protection of confidential information and assignment of inventions, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

ARTICLE III COMPENSATION AND BENEFITS

3.1 Base Salary. Executive shall receive for services to be rendered hereunder an annual base salary of \$220,000 ("**Base Annual Salary**"), less required deductions and withholdings, payable on the regular payroll dates of the Company.

3.2 Annual Bonus. In addition to the Base Annual Salary, during each calendar year Executive will be eligible for an annual performance bonus, equal to up to 50% of the Base Annual Salary, and which is based in part upon the achievement of Executive's performance goals and objectives ("**Annual Bonus**"). The Compensation Committee of the Company's Board shall determine in its sole discretion whether any such Bonus has been earned and, if so, the amount of any such bonus. Executive must be an employee in good standing at the time the Compensation Committee decides to award the Annual Bonus and, if Executive leaves the Company at any time and for any reason prior to such date, he will not be eligible to receive such a bonus or any pro-rata portion of such bonus. If awarded, such Annual Bonus shall be evaluated and paid no later than December 31 of the calendar year following the calendar year to which such Annual Bonus relates.

3.3 Vacation and Paid Time Off. Executive shall be entitled to 20 business days of paid vacation each year, accruing on a monthly basis, and 8 paid holidays each year.

3.4 Expenses. During the term of this Agreement, the Company shall reimburse Executive for all reasonable and necessary out-of-pocket expenses incurred by Executive in connection with services rendered on behalf of the Company subject to Executive providing the Company with appropriate substantiation in accordance with Company policy; provided that commuting expenses shall not be included in such reimburseable expenses. Any amounts payable under this Section 3.4 shall be made in accordance with Treasury Regulation Section 1.409A-3(i)(1)(iv) and shall be paid on or before the last day of Executive's taxable year following the taxable year in which Executive incurred the expenses. The amounts provided under this Section 3.4 during any taxable year of Executive's will not affect such amounts provided in any other taxable year of Executive's, and Executive's right to reimbursement for such amounts shall not be subject to liquidation or exchange for any other benefit.

3.5 Standard Company Benefits. Executive shall be entitled to all rights and benefits for which Executive is eligible under the terms and conditions of the standard Company benefits and compensation practices that may be in effect from time to time and are generally provided by the Company to its executive employees, employed at similar full-time or part-time status, as applicable. Any such benefits and compensation practices shall be subject to the terms of the governing benefit or compensation plans and may be changed by the Company from time to time in its discretion.

ARTICLE IV
SEVERANCE AND CHANGE IN CONTROL BENEFITS

4.1 Term Limitation for Severance and Change in Control Benefits. The term for the Severance Benefits and Change in Control Benefits provided for in this Article IV herein shall commence on the Effective Date and shall continue until March 31, 2016 (the “**Expiration Date**”). If this Article IV is not amended or renewed by the Compensation Committee of the Company’s Board prior to the Expiration Date, this Article IV (including Executive’s right to receive the Severance Benefits and Change in Control Benefits contained herein), shall terminate automatically on such Expiration Date; provided, however, that if this Article IV terminates pursuant to this Section 4.1, the remainder of this Agreement will remain in full force and effect.

4.2 Severance Benefits In Event of Involuntary Termination Without Cause Unrelated to Change in Control. If: (i) Executive’s employment terminates due to an Involuntarily Termination Without Cause (and other than as a result of Executive’s death or disability) at any time except during the Change in Control Period, (ii) such termination constitutes a “separation from service” (within the meaning of Treasury Regulation Section 1.409A-1(h)), (iii) Executive signs and allows to become effective a general release of all known and unknown claims in the form and substance acceptable to the Company within sixty (60) days after the Termination Date, and (iv) Executive fully complies with Executive’s continuing fiduciary, statutory and material contractual obligations to the Company (with a 30-day opportunity to cure after notice of any such non-compliance if Executive has not, unless such non-compliance is not capable of being cured); then the Company shall provide Executive with the following severance benefits (the “**Severance Benefits**”):

(a) **Cash Severance.** The Company shall make a single lump sum severance payment to Executive in an amount equal to **Executive’s Base Annual Salary in effect as of the Termination Date**, less required tax withholdings and deductions (the “**Severance Payment**”). The Severance Payment will be paid within sixty (60) days after the Termination Date, but in no event later than March 15 of the year following the year of termination.

(b) **Health Insurance.** Provided that Executive elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (together with any state or local laws of similar effect, “**COBRA**”) within the time period provided for under COBRA, the Company will pay the premiums necessary to continue Executive’s group health insurance coverage in effect as of the Termination Date of Executive’s employment (including coverage for Executive’s eligible dependents) for a maximum period of **twelve (12) months** following the Termination Date; provided, however, that no premium payments will be made by the Company pursuant to this paragraph following the effective date of Executive’s coverage by a health insurance plan of a subsequent employer or such other date on which Executive (and Executive’s dependents, as applicable) ceases to be eligible for COBRA coverage. Executive agrees that Executive shall notify the Company in writing as soon as practical, but no later than 15 days after Executive receives coverage under a health insurance plan of a subsequent employer.

4.3 Severance Benefits In Event of Involuntary Termination Without Cause or Constructive Termination During Change in Control Period. If: (i) Executive's employment terminates due to an Involuntarily Termination Without Cause (and other than as a result of Executive's death or disability), or as a result of a Constructive Termination, in either event during the Change in Control Period, (ii) such termination constitutes a "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h)), (iii) Executive signs and allows to become effective a general release of all known and unknown claims in the form and substance acceptable to the Company within sixty (60) days after the Termination Date, and (iv) Executive fully complies with Executive's continuing fiduciary, statutory and material contractual obligations to the Company (with a 30-day opportunity to cure after notice of any such non-compliance if Executive has not, unless such non-compliance is not capable of being cured); then the Company shall provide Executive with the following change in control severance benefits (the "**Change in Control Benefits**"):

(a) **Cash Severance.** The Company shall make a single lump sum severance payment to Executive in an amount equal to **Executive's Base Annual Salary in effect as of the Termination Date, multiplied by one point five (1.5)**, less required tax withholdings and deductions (the "**Change in Control Payment**"). The Change in Control Payment will be paid within sixty (60) days after the Termination Date, but in no event later than March 15 of the year following the year of termination.

(b) **Health Insurance.** Provided that Executive elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (together with any state or local laws of similar effect, "**COBRA**") within the time period provided for under COBRA, the Company will pay the premiums necessary to continue Executive's group health insurance coverage in effect as of the Termination Date of Executive's employment (including coverage for Executive's eligible dependents) for a maximum period of **eighteen (18) months** following the Termination Date; provided, however, that no premium payments will be made by the Company pursuant to this paragraph following the effective date of Executive's coverage by a health insurance plan of a subsequent employer or such other date on which Executive (and Executive's dependents, as applicable) ceases to be eligible for COBRA coverage. Executive agrees that Executive shall notify the Company in writing as soon as practical, but no later than 15 days after Executive receives coverage under a health insurance plan of a subsequent employer.

(c) **Equity Acceleration.** After taking into account any additional acceleration of vesting Executive may be entitled to receive under any other plan or agreement, the Company shall cause all outstanding equity awards then held by Executive (including, without limitation, stock options, restricted stock awards or similar awards) to become **fully vested** and, if applicable, exercisable with respect to all the shares subject thereto effective immediately prior to the Termination Date. In all other respects, such equity awards shall continue to be governed by the terms of the applicable award agreements and equity incentive plan documents and any applicable agreements between the Company and Executive.

4.4 Other Compensation and Benefits. If: (i) the Company terminates Executive's employment for Cause or as a result of Executive's death or disability, or (ii) if Executive resigns Executive's employment at any time, except as a result of a Constructive Termination during the Change in Control Period, then this Agreement shall automatically terminate (except for Article V and Article VII, which shall continue in effect), and upon such termination, the Company shall have no further obligation to Executive, Executive's spouse or estate, except that the Company shall pay to Executive the amount of Executive's Base Annual Salary, and unused vacation pay, accrued to the date of such termination.

4.5 Compliance with Section 409A.

(a) It is intended that each installment of the payments and benefits provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). It is also intended that payments of the amounts set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**") (Section 409A of the Code, together, with any state law of similar effect, "**Section 409A**") provided under Treasury Regulation Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9).

(b) Notwithstanding the foregoing, if the Company (or, if applicable, the successor entity thereto) determines that the Severance Payment, the Change in Control Payment and/or other benefits provided under this Agreement (the "**Agreement Payments**") constitute "deferred compensation" under Section 409A and Executive is, on the Termination Date, a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Agreement Payments shall be delayed as follows: on the earlier to occur of (i) the date that is six months and one day after Executive's "separation from service" (as defined above) or (ii) the date of Executive's death (such earlier date, the "**Delayed Initial Payment Date**"), the Company (or the successor entity thereto, as applicable) shall (A) pay to Executive a lump sum amount equal to the sum of the Agreement Payments that Executive would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the Agreement Payments had not been so delayed pursuant to this Section 4.5(b) and (B) commence paying the balance of the Agreement Payments in accordance with the applicable payment schedules set forth in this Agreement.

4.6 Internal Revenue Code Section 280G.

(a) If the payments and benefits (including but not limited to payments and benefits pursuant to this Agreement) that Executive would receive in connection with a Change in Control of the Company, whether from the Company or otherwise (a "**Transaction Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to Executive, which of the following two alternative forms of payment would result in Executive's receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "**Full Payment**"), or (2) payment of only a part of the Transaction Payment so that Executive receives the largest payment possible without the imposition of the Excise Tax (a "**Reduced Payment**").

(b) For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (i) Executive shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (ii) reduction in payments and/or benefits shall occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits (if any) paid to Executive. In the event that acceleration of compensation from Executive's equity awards is to be reduced, such acceleration of vesting shall be canceled in the reverse order of the date of grant.

(c) The independent registered public accounting firm engaged by the Company for general audit purposes as of the day prior to the Termination Date shall make all determinations required to be made under this Section 4.6. If the independent registered public accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such independent registered public accounting firm required to be made hereunder.

(d) The independent registered public accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Transaction Payment is triggered or such other time as reasonably requested by the Company or Executive. If the independent registered public accounting firm determines that no Excise Tax is payable with respect to the Transaction Payment, either before or after the application of the Reduced Amount, it shall furnish the Company and Executive with detailed supporting calculations of its determinations that no Excise Tax will be imposed with respect to such Transaction Payment. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

ARTICLE V PROPRIETARY INFORMATION OBLIGATIONS

5.1 Agreement. As a condition of this Agreement and Executive's employment, Executive agrees to execute and abide by the Company's standard form of Proprietary Information and Inventions Agreement ("**Proprietary Information and Inventions Agreement**").

5.2 Remedies. Executive's duties under the Proprietary Information and Inventions Agreement shall survive termination of Executive's employment with the Company and the termination of this Agreement. Executive acknowledges that a remedy at law for any breach or threatened breach by Executive of the provisions of the Proprietary Information and Inventions Agreement would be inadequate, and Executive therefore agrees that the Company shall be entitled to injunctive relief in case of any such breach or threatened breach.

**ARTICLE VI
OUTSIDE ACTIVITIES**

6.1 Other Activities. Except with the prior written consent of the Chief Executive Officer or EVP, Chief Business and Financial Officer of the Company, Executive shall not during the term of this Agreement undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor; provided that such passive investments will not require services on the part Executive which would in any manner impair the performance of Executive's duties under this Agreement. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder.

6.2 Competition/Investments. During the term of Executive's employment by the Company, except on behalf of the Company, Executive shall not directly or indirectly, whether as an officer, director, stockholder, partner, proprietor, associate, representative, consultant, or in any capacity whatsoever engage in, become financially interested in, be employed by or have any business connection with any other person, corporation, firm, partnership or other entity whatsoever which were known by Executive to compete directly with the Company's products or product candidates, throughout the world. This provision shall not apply to passive stockholdings that the Executive may have at any particular time so long as such stockholdings in any one company do not exceed 5% of the total number of shares outstanding of such company.

**ARTICLE VII
GENERAL PROVISIONS**

7.1 Notices. Any notices provided hereunder must be in writing and shall be deemed effective upon the earlier of personal delivery (including personal delivery by facsimile) or the third day after mailing by first class mail, to the Company at its primary office location and to Executive at Executive's address as listed on the Company payroll.

7.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provisions had never been contained herein.

7.3 Waiver. If either party should waive any breach of any provisions of this Agreement, they shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

7.4 Complete Agreement. This Agreement and the documents and agreements referenced herein constitute the entire agreement between Executive and the Company and is the complete, final, and exclusive embodiment of their agreement with regard to the subject matter contained

herein and therein and supersede all prior agreements, promises, covenants, arrangements, communications, representations or warranties, whether oral or written, by any officer, employee or representative of any party hereto, and any prior agreement of the parties hereto in respect of the subject matter contained herein. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein or therein, and cannot be modified or amended except in a writing signed by an appropriate officer of the Company and Executive.

7.5 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

7.6 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

7.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder, without the written consent of the Company, which shall not be withheld unreasonably.

7.8 Arbitration. Any dispute, claim or controversy of whatever nature arising out of or relating to this Agreement, Executive's employment with the Company, and/or the termination of Executive's employment with the Company, including, without limitation, any action or claim based on tort, contract or statute, or concerning the interpretation, performance, or execution of this Agreement (including any determination of Cause or Constructive Termination hereunder) shall be resolved by confidential, final and binding arbitration administered by Judicial Arbitration and Mediation Services, Inc. ("**JAMS**"), in San Diego, California, before a single arbitrator, in accordance with JAMS' then applicable arbitration rules. **Executive acknowledges that by agreeing to this arbitration procedure, Executive and the Company waive the right to resolve any such dispute, claim or demand through a trial by jury or judge or by administrative proceeding.** Executive will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. Company shall bear all JAMS fees for the arbitration. Nothing in this Agreement shall prevent any of the parties from obtaining injunctive relief in court if necessary to prevent irreparable harm pending the conclusion of any arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in any court of competent jurisdiction.

7.9 Attorneys' Fees. If either party hereto brings any action to enforce rights hereunder, each party in any such action shall be responsible for its own attorneys' fees and costs incurred in connection with such action.

7.10 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the law of the State of California without regard to the conflicts of law provisions thereof.

(Signature page follows)

IN WITNESS WHEREOF, the parties have executed this Agreement on the day and year first above written.

OREXIGEN THERAPEUTICS, INC.

By: /s/ Michael Narachi
Michael Narachi
President and Chief Executive Officer

LEGAL
CH

Accepted and agreed:

/s/ Jason Keyes
JASON KEYES

OREXIGEN THERAPEUTICS, INC.

AMENDMENT NO. 1 TO EMPLOYMENT AGREEMENT

FEBRUARY 2, 2016

This Amendment No. 1 is intended to modify the **EMPLOYMENT AGREEMENT** (the “**Agreement**”) dated February 3, 2015 by and between **OREXIGEN THERAPEUTICS, INC.** (“**Orexigen**” or the “**Company**”) with its principal place of business located at 3344 N. Torrey Pines Ct., Suite 200, La Jolla, CA 92037 and **JASON KEYES** (“**Executive**”). All capitalized terms used herein and not otherwise defined shall have the meanings assigned to such terms in the Agreement.

The parties hereto, intending to be legally bound, agree to amend the Agreement as follows (the “**Amendment**”):

1. Article IV, Section 4.1 of the Agreement shall be amended and restated in its entirety as follows:

Term Limitation for Severance and Change in Control Benefits. The term for the Severance Benefits and Change in Control Benefits provided for in this Article IV herein shall continue through March 31, 2019 (the “**Expiration Date**”). If this Article IV is not amended or renewed by the Compensation Committee of the Company’s Board prior to the Expiration Date, this Article IV (including Executive’s right to receive the Severance Benefits and Change in Control Benefits contained herein), shall terminate automatically on such Expiration Date; provided, however, that if this Article IV terminates pursuant to this Section 4.1, the remainder of this Agreement will remain in full force and effect.

2. Article IV, Section 4.2(b) of the Agreement shall be amended and restated in its entirety as follows:

(b) Health Insurance.

(i) COBRA Premiums. Provided that Executive elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (together with any state or local laws of similar effect, “**COBRA**”) within the time period provided for under COBRA, the Company will pay the premiums necessary to continue Executive’s group health insurance coverage in effect as of the Termination Date (including coverage for Executive’s eligible dependents) (the “**COBRA Premiums**”) for a maximum period of **twelve (12) months** following the Termination Date (the “**COBRA Premium Period**”); provided, however, that no premium payments will be made by the Company pursuant to this paragraph following the effective date of Executive’s coverage by a health insurance plan of a subsequent employer or such other date on which Executive (and Executive’s dependents, as applicable) ceases to be eligible for COBRA coverage (including cessation of non-core coverage, such as dental and vision coverage). Executive agrees that Executive shall notify the Company in writing as soon as practical, but no later than 15 days after Executive receives coverage under a health insurance plan of a subsequent employer.

(ii) Special Cash Payments in Lieu of COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive's eligible dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, as soon as administratively practicable, but in no case more than five (5) business days following, the later of (A) the effective date of the general release of claims executed by Executive and (B) the date on which the Company so determines that it may no longer pay the COBRA Premiums without incurring such financial costs or penalties, a fully taxable lump sum cash payment equal to the applicable remaining unpaid COBRA Premiums for the COBRA Premium Period (including the amount of COBRA Premiums for Executive's eligible dependents), less required tax withholdings and deductions (such amount, the "**Special Cash Payment**"). Executive may, but is not obligated to, use such Special Cash Payment toward the cost of COBRA premiums.

3. Article IV, Section 4.3(a) of the Agreement shall be amended and restated in its entirety as follows:

Cash Severance. The Company shall make a single lump sum severance payment to Executive in an amount equal to **Executive's Base Annual Salary in effect as of the Termination Date *plus* an amount equal to Executive's Annual Bonus target in effect as of the Termination Date**, less required tax withholdings and deductions (the "**Change in Control Payment**"). The Change in Control Payment will be paid within sixty (60) days after the Termination Date, but in no event later than March 15 of the year following the year of termination.

4. Article IV, Section 4.3(b) of the Agreement shall be amended and restated in its entirety as follows:

(b) Health Insurance.

(i) CIC COBRA Premiums. Provided that Executive elects continued coverage under the COBRA within the time period provided for under COBRA, the Company will pay the premiums necessary to continue Executive's group health insurance coverage in effect as of the Termination Date (including coverage for Executive's eligible dependents) (the "**CIC COBRA Premiums**") for a maximum period of **eighteen (18) months** following the Termination Date (the "**CIC COBRA Premium Period**"); provided, however, that no premium payments will be made by the Company pursuant to this paragraph following the effective date of Executive's coverage by a health insurance plan of a subsequent employer or such other date on which Executive (and Executive's dependents, as applicable) ceases to be eligible for COBRA coverage (including cessation of non-core coverage, such as dental and vision coverage). Executive agrees that Executive shall notify the Company in writing as soon as practical, but no later than 15 days after Executive receives coverage under a health insurance plan of a subsequent employer.

(ii) Special Cash Payments in Lieu of CIC COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the CIC COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive's eligible dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, as soon as administratively practicable, but in no case more than five (5) business days following, the later of (A) the effective date of the general release of claims executed by Executive and (B) the date on which the Company so determines that it may no longer pay the CIC COBRA Premiums without incurring such financial costs or penalties, a fully taxable lump sum cash payment equal to the applicable remaining unpaid CIC COBRA Premiums for the CIC COBRA Premium Period (including the amount of CIC COBRA Premiums for Executive's eligible dependents), less required tax withholdings and deductions (such amount, the "**Special CIC Cash Payment**"). Executive may, but is not obligated to, use such Special CIC Cash Payment toward the cost of COBRA premiums.

5. Article IV, Section 4.3(c) of the Agreement shall be amended and restated in its entirety as follows:

Equity Acceleration. After taking into account any additional acceleration of vesting Executive may be entitled to receive under any other plan or agreement, the Company shall cause all outstanding time-based equity awards then held by Executive (including, without limitation, stock options, restricted stock awards or similar awards, but excluding any restricted stock units that vest and/or are earned, in whole or in part, based on the attainment of performance criteria ("**Performance RSUs**")) to become **fully vested** and, if applicable, exercisable with respect to all the shares subject thereto effective immediately prior to the Termination Date. In all other respects, such time-based equity awards shall continue to be governed by the terms of the applicable award agreements and equity incentive plan documents and any applicable agreements between the Company and Executive. With respect to Executive's Performance RSUs, such Performance RSUs shall continue to be governed by the terms of the equity incentive plan documents and Executive's Performance RSU Award Agreements pursuant to which they were granted.

6. The Agreement and this Amendment represent the complete and entire understanding between the parties regarding the subject matter hereof and supersede all prior negotiations, representations or agreements, either written or oral, regarding this subject matter. The Agreement and this Amendment cannot be modified or amended except in a writing signed by an appropriate officer of the Company and Executive.

7. This Amendment and the rights and obligations of the parties hereunder shall be governed by the laws of the State of California, without regard to the conflicts of law provisions thereof.

8. This Amendment may be executed in multiple counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

-
9. Except for the matters set forth in this Amendment, all other terms of the Agreement shall remain unchanged and in full force and effect.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the date set forth above.

OREXIGEN THERAPEUTICS, INC.

By: /s/ Michael A. Narachi
Name: Michael A. Narachi
Title: President and Chief Executive Officer

LEGAL
TR

Accepted and agreed:

/s/ Jason Keyes
Jason Keyes

OREXIGEN THERAPEUTICS, INC.

AMENDMENT NO. 2 TO EMPLOYMENT AGREEMENT

JUNE 16, 2016

Reference is made to the EMPLOYMENT AGREEMENT (the “**Agreement**”) dated March 30, 2015 by and between OREXIGEN THERAPEUTICS, INC. (“**Orexigen**” or the “**Company**”) with its principal place of business located at 3344 N. Torrey Pines Ct., Suite 200, La Jolla, CA 92037 and THOMAS CANNELL (“**Executive**”), and AMENDMENT NO. 1 TO THE EMPLOYMENT AGREEMENT dated February 2, 2016 (the “**First Amendment**”). All capitalized terms used herein and not otherwise defined shall have the meanings assigned to such terms in the Agreement.

WHEREAS, the parties desire to supersede and replace in full the First Amendment, and to amend certain terms of the Agreement in accordance with the terms hereof (this “**Second Amendment**”).

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, the parties hereto, intending to be legally bound, agree to amend the Agreement as follows:

1. Article I, Section 1.6(a) of the Agreement shall be amended and restated in its entirety as follows:

“**Constructive Termination**” means Executive’s resignation from all positions Executive then holds with the Company because of:

(a) a material reduction in the level of responsibility associated with Executive’s employment with the Company or any surviving entity (other than a change in job title or officer title) as compared to Executive’s level of responsibility just prior to the reduction (including a requirement that Executive report to a corporate officer (other than the Chief Executive Officer) instead of reporting directly to the Chief Executive Officer, the Board or the board of directors (or equivalent governing body) of the acquiring entity; provided, however, that a merger or acquisition of the Company and subsequent conversion of the Company to a division or unit of the acquiring corporation will not by itself result in a material reduction in Executive’s level of responsibility;

2. Article II, Section 2.1 of the Agreement shall be amended and restated in its entirety as follows:

Position and Duties. Subject to terms set forth herein, the Company agrees to employ Executive on a full time basis in the position of Chief Operating Officer and President, Global Commercial Products and Executive hereby accepts such employment. Executive shall perform such duties as are customarily associated with the position of Chief Operating Officer and President, Global Commercial Products, and such other duties as are assigned to Executive by the Chief Executive Officer of the Company. Subject to the terms of this Agreement, the Company may change Executive’s duties, responsibilities, title, and reporting relationship at its discretion. During the term of Executive’s employment with the Company, Executive will devote Executive’s best efforts (except for vacation periods and reasonable periods of illness or other incapacities permitted by the Company’s general employment policies or as otherwise set forth in this Agreement) to the business of the Company.

3. Article III, Section 3.1 of the Agreement shall be amended and restated in its entirety as follows:

Base Salary. Executive shall receive for services to be rendered hereunder an annual base salary of \$460,000 (“**Base Annual Salary**”), less required deductions and withholdings, payable on the regular payroll dates of the Company.

4. Article III, Section 3.2 of the Agreement shall be amended and restated in its entirety as follows:

Annual Bonus. In addition to the Base Annual Salary, during each calendar year Executive will be eligible for an annual performance bonus, equal to up to 60% of the Base Annual Salary, and which is based in part upon the achievement of Executive’s performance goals and objectives (“**Annual Bonus**”). The Compensation Committee of the Company’s Board shall determine in its sole discretion whether any such Annual Bonus has been earned and, if so, the amount of any such bonus. Executive must be an employee in good standing at the time the Compensation Committee decides to award the Annual Bonus and, if Executive leaves the Company at any time and for any reason prior to such date, Executive will not be eligible to receive such a bonus or any pro-rata portion of such bonus. If awarded, such Annual Bonus shall be evaluated and paid no later than December 31 of the calendar year following the calendar year to which such Annual Bonus relates.

5. Article IV, Section 4.1 of the Agreement shall be amended and restated in its entirety as follows:

Term Limitation for Severance and Change in Control Benefits. The term for the Severance Benefits and Change in Control Benefits provided for in this Article IV herein shall continue through March 31, 2019 (the “**Expiration Date**”). If this Article IV is not amended or renewed by the Compensation Committee of the Company’s Board prior to the Expiration Date, this Article IV (including Executive’s right to receive the Severance Benefits and Change in Control Benefits contained herein), shall terminate automatically on such Expiration Date; provided, however, that if this Article IV terminates pursuant to this Section 4.1, the remainder of this Agreement will remain in full force and effect.

6. Article IV, Section 4.2(b) of the Agreement shall be amended and restated in its entirety as follows:

(b) Health Insurance.

(i) **COBRA Premiums.** Provided that Executive elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (together with any state or local laws of similar effect, “COBRA”) within the time period provided for under COBRA, the Company will pay the premiums necessary to continue Executive’s group health insurance coverage in effect as of the Termination Date (including coverage for Executive’s eligible dependents) (the “COBRA Premiums”) for a maximum period of **twelve (12) months** following the Termination Date (the “COBRA Premium Period”); provided, however, that no premium payments will be made by the Company pursuant to this paragraph following the effective date of Executive’s coverage by a health insurance plan of a subsequent employer or such other date on which Executive (and Executive’s dependents, as applicable) ceases to be eligible for COBRA coverage (including cessation of non-core coverage, such as dental and vision coverage). Executive agrees that Executive shall notify the Company in writing as soon as practical, but no later than 15 days after Executive receives coverage under a health insurance plan of a subsequent employer.

(ii) **Special Cash Payments in Lieu of COBRA Premiums.** Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive’s eligible dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, as soon as administratively practicable, but in no case more than five (5) business days following, the later of (A) the effective date of the general release of claims executed by Executive and (B) the date on which the Company so determines that it may no longer pay the COBRA Premiums without incurring such financial costs or penalties, a fully taxable lump sum cash payment equal to the applicable remaining unpaid COBRA Premiums for the COBRA Premium Period (including the amount of COBRA Premiums for Executive’s eligible dependents), less required tax withholdings and deductions (such amount, the “Special Cash Payment”). Executive may, but is not obligated to, use such Special Cash Payment toward the cost of COBRA premiums.

7. Article IV, Section 4.3(a) of the Agreement shall be amended and restated in its entirety as follows:

Cash Severance. The Company shall make a single lump sum severance payment to Executive in an amount equal to **Executive’s Base Annual Salary in effect as of the Termination Date plus an amount equal to Executive’s Annual Bonus target in effect as of the Termination Date, multiplied by 1.5**, less required tax withholdings and deductions (the “Change in Control Payment”). The Change in Control Payment will be paid within sixty (60) days after the Termination Date, but in no event later than March 15 of the year following the year of termination.

8. Article IV, Section 4.3(b) of the Agreement shall be amended and restated in its entirety as follows:

(b) Health Insurance.

(i) CIC COBRA Premiums. Provided that Executive elects continued coverage under the COBRA within the time period provided for under COBRA, the Company will pay the premiums necessary to continue Executive's group health insurance coverage in effect as of the Termination Date (including coverage for Executive's eligible dependents) (the "**CIC COBRA Premiums**") for a maximum period of **eighteen (18) months** following the Termination Date (the "**CIC COBRA Premium Period**"); provided, however, that no premium payments will be made by the Company pursuant to this paragraph following the effective date of Executive's coverage by a health insurance plan of a subsequent employer or such other date on which Executive (and Executive's dependents, as applicable) ceases to be eligible for COBRA coverage (including cessation of non-core coverage, such as dental and vision coverage). Executive agrees that Executive shall notify the Company in writing as soon as practical, but no later than 15 days after Executive receives coverage under a health insurance plan of a subsequent employer.

(ii) Special Cash Payments in Lieu of CIC COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the CIC COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive's eligible dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, as soon as administratively practicable, but in no case more than five (5) business days following, the later of (A) the effective date of the general release of claims executed by Executive and (B) the date on which the Company so determines that it may no longer pay the CIC COBRA Premiums without incurring such financial costs or penalties, a fully taxable lump sum cash payment equal to the applicable remaining unpaid CIC COBRA Premiums for the CIC COBRA Premium Period (including the amount of CIC COBRA Premiums for Executive's eligible dependents), less required tax withholdings and deductions (such amount, the "**Special CIC Cash Payment**"). Executive may, but is not obligated to, use such Special CIC Cash Payment toward the cost of COBRA premiums.

9. Article IV, Section 4.3(c) of the Agreement shall be amended and restated in its entirety as follows:

Equity Acceleration. After taking into account any additional acceleration of vesting Executive may be entitled to receive under any other plan or agreement, the Company shall cause all outstanding time-based equity awards then held by Executive (including, without limitation, stock options, restricted stock awards or similar awards, but excluding any restricted stock units that vest and/or are earned, in whole or in part, based on the attainment of performance criteria ("**Performance RSUs**")) to become **fully vested** and, if applicable, exercisable with respect to all the shares subject thereto effective immediately prior to the

Termination Date. In all other respects, such time-based equity awards shall continue to be governed by the terms of the applicable award agreements and equity incentive plan documents and any applicable agreements between the Company and Executive. With respect to Executive's Performance RSUs, such Performance RSUs shall continue to be governed by the terms of the equity incentive plan documents and Executive's Performance RSU Award Agreements pursuant to which they were granted.

10. This Second Amendment supersedes and replaces in full the First Amendment. This Second Amendment, along with the Agreement, represents the complete and entire understanding between the parties regarding the subject matter hereof and supersedes all prior negotiations, representations or agreements, either written or oral, regarding this subject matter. The Agreement and this Second Amendment cannot be modified or amended except in a writing signed by an appropriate officer of the Company and Executive.
11. This Second Amendment and the rights and obligations of the parties hereunder shall be governed by the laws of the State of California, without regard to the conflicts of law provisions thereof.
12. This Second Amendment may be executed in multiple counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.
13. Except for the matters set forth in this Second Amendment, all other terms of the Agreement shall remain unchanged and in full force and effect.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Second Amendment as of the date set forth above.

OREXIGEN THERAPEUTICS, INC.

By: /s/ Michael A. Narachi
Name: Michael A. Narachi
Title: President and Chief Executive Officer

Accepted and agreed:

/s/ Thomas Cannell
Thomas Cannell

OREXIGEN THERAPEUTICS, INC.

AMENDMENT NO. 2 TO EMPLOYMENT AGREEMENT

JUNE 16, 2016

Reference is made to the **EMPLOYMENT AGREEMENT** (the “**Agreement**”) dated February 3, 2015 by and between **OREXIGEN THERAPEUTICS, INC.** (“**Orexigen**” or the “**Company**”) with its principal place of business located at 3344 N. Torrey Pines Ct., Suite 200, La Jolla, CA 92037 and **JASON KEYES** (“**Executive**”), and **AMENDMENT NO. 1 TO THE EMPLOYMENT AGREEMENT** dated February 2, 2016 (the “**First Amendment**”). All capitalized terms used herein and not otherwise defined shall have the meanings assigned to such terms in the Agreement.

WHEREAS, the parties desire to supersede and replace in full the First Amendment, and to amend certain terms of the Agreement in accordance with the terms hereof (this “**Second Amendment**”).

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, the parties hereto, intending to be legally bound, agree to amend the Agreement as follows:

1. Article II, Section 2.1 of the Agreement shall be amended and restated in its entirety as follows:

Position and Duties. Subject to terms set forth herein, the Company agrees to employ Executive on a full time basis in the position of Senior Vice President and Chief Financial Officer and Executive hereby accepts such employment. Executive shall perform such duties as are customarily associated with the position of Senior Vice President and Chief Financial Officer, and such other duties as are assigned to Executive by the Chief Executive Officer of the Company. Subject to the terms of this Agreement, the Company may change Executive’s duties, responsibilities, title, and reporting relationship at its discretion. During the term of Executive’s employment with the Company, Executive will devote Executive’s best efforts (except for vacation periods and reasonable periods of illness or other incapacities permitted by the Company’s general employment policies or as otherwise set forth in this Agreement) to the business of the Company.

2. Article III, Section 3.1 of the Agreement shall be amended and restated in its entirety as follows:

Base Salary. Executive shall receive for services to be rendered hereunder an annual base salary of \$300,000 (“**Base Annual Salary**”), less required deductions and withholdings, payable on the regular payroll dates of the Company.

3. Article IV, Section 4.1 of the Agreement shall be amended and restated in its entirety as follows:

Term Limitation for Severance and Change in Control Benefits. The term for the Severance Benefits and Change in Control Benefits provided for in this Article IV herein shall continue through March 31, 2019 (the “**Expiration Date**”). If this Article IV is not amended or renewed by the Compensation Committee of the Company’s Board prior to the Expiration Date, this Article IV (including Executive’s right to receive the Severance Benefits and Change in Control Benefits contained herein), shall terminate automatically on such Expiration Date; provided, however, that if this Article IV terminates pursuant to this Section 4.1, the remainder of this Agreement will remain in full force and effect.

4. Article IV, Section 4.2(b) of the Agreement shall be amended and restated in its entirety as follows:

(b) Health Insurance.

(i) COBRA Premiums. Provided that Executive elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (together with any state or local laws of similar effect, “**COBRA**”) within the time period provided for under COBRA, the Company will pay the premiums necessary to continue Executive’s group health insurance coverage in effect as of the Termination Date (including coverage for Executive’s eligible dependents) (the “**COBRA Premiums**”) for a maximum period of **twelve (12) months** following the Termination Date (the “**COBRA Premium Period**”); provided, however, that no premium payments will be made by the Company pursuant to this paragraph following the effective date of Executive’s coverage by a health insurance plan of a subsequent employer or such other date on which Executive (and Executive’s dependents, as applicable) ceases to be eligible for COBRA coverage (including cessation of non-core coverage, such as dental and vision coverage). Executive agrees that Executive shall notify the Company in writing as soon as practical, but no later than 15 days after Executive receives coverage under a health insurance plan of a subsequent employer.

(ii) Special Cash Payments in Lieu of COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive’s eligible dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, as soon as administratively practicable, but in no case more than five (5) business days following, the later of (A) the effective date of the general release of claims executed by Executive and (B) the date on which the Company so determines that it may no longer pay the COBRA Premiums without incurring such financial costs or penalties, a fully taxable lump sum cash payment equal to the applicable remaining unpaid COBRA Premiums for the COBRA Premium Period (including the amount of COBRA Premiums for Executive’s eligible dependents), less required tax withholdings and deductions (such amount, the “**Special Cash Payment**”). Executive may, but is not obligated to, use such Special Cash Payment toward the cost of COBRA premiums.

5. Article IV, Section 4.3(a) of the Agreement shall be amended and restated in its entirety as follows:

Cash Severance. The Company shall make a single lump sum severance payment to Executive in an amount equal to **Executive's Base Annual Salary in effect as of the Termination Date *plus* an amount equal to Executive's Annual Bonus target in effect as of the Termination Date**, less required tax withholdings and deductions (the "**Change in Control Payment**"). The Change in Control Payment will be paid within sixty (60) days after the Termination Date, but in no event later than March 15 of the year following the year of termination.

6. Article IV, Section 4.3(b) of the Agreement shall be amended and restated in its entirety as follows:

(b) Health Insurance.

(i) CIC COBRA Premiums. Provided that Executive elects continued coverage under the COBRA within the time period provided for under COBRA, the Company will pay the premiums necessary to continue Executive's group health insurance coverage in effect as of the Termination Date (including coverage for Executive's eligible dependents) (the "**CIC COBRA Premiums**") for a maximum period of **eighteen (18) months** following the Termination Date (the "**CIC COBRA Premium Period**"); provided, however, that no premium payments will be made by the Company pursuant to this paragraph following the effective date of Executive's coverage by a health insurance plan of a subsequent employer or such other date on which Executive (and Executive's dependents, as applicable) ceases to be eligible for COBRA coverage (including cessation of non-core coverage, such as dental and vision coverage). Executive agrees that Executive shall notify the Company in writing as soon as practical, but no later than 15 days after Executive receives coverage under a health insurance plan of a subsequent employer.

(ii) Special Cash Payments in Lieu of CIC COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the CIC COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive's eligible dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, as soon as administratively practicable, but in no case more than five (5) business days following, the later of (A) the effective date of the general release of claims executed by Executive and (B) the date on which the Company so determines that it may no longer pay the CIC COBRA Premiums without incurring such financial costs or penalties, a fully taxable lump sum cash payment equal to the applicable remaining unpaid CIC COBRA Premiums for the CIC COBRA Premium Period (including the amount of CIC COBRA Premiums for Executive's eligible dependents), less required tax withholdings and deductions (such amount, the "**Special CIC Cash Payment**"). Executive may, but is not obligated to, use such Special CIC Cash Payment toward the cost of COBRA premiums.

7. Article IV, Section 4.3(c) of the Agreement shall be amended and restated in its entirety as follows:

Equity Acceleration. After taking into account any additional acceleration of vesting Executive may be entitled to receive under any other plan or agreement, the Company shall cause all outstanding time-based equity awards then held by Executive (including, without limitation, stock options, restricted stock awards or similar awards, but excluding any restricted stock units that vest and/or are earned, in whole or in part, based on the attainment of performance criteria (“**Performance RSUs**”)) to become **fully vested** and, if applicable, exercisable with respect to all the shares subject thereto effective immediately prior to the Termination Date. In all other respects, such time-based equity awards shall continue to be governed by the terms of the applicable award agreements and equity incentive plan documents and any applicable agreements between the Company and Executive. With respect to Executive’s Performance RSUs, such Performance RSUs shall continue to be governed by the terms of the equity incentive plan documents and Executive’s Performance RSU Award Agreements pursuant to which they were granted.

8. This Second Amendment supersedes and replaces in full the First Amendment. This Second Amendment, along with the Agreement, represents the complete and entire understanding between the parties regarding the subject matter hereof and supersedes all prior negotiations, representations or agreements, either written or oral, regarding this subject matter. The Agreement and this Second Amendment cannot be modified or amended except in a writing signed by an appropriate officer of the Company and Executive.
9. This Second Amendment and the rights and obligations of the parties hereunder shall be governed by the laws of the State of California, without regard to the conflicts of law provisions thereof.
10. This Second Amendment may be executed in multiple counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.
11. Except for the matters set forth in this Second Amendment, all other terms of the Agreement shall remain unchanged and in full force and effect.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Second Amendment as of the date set forth above.

OREXIGEN THERAPEUTICS, INC.

By: /s/ Michael A. Narachi

Name: Michael A. Narachi

Title: President and Chief Executive Officer

Accepted and agreed:

/s/ Jason Keyes

Jason Keyes

**OREXIGEN THERAPEUTICS, INC.
AMENDED AND RESTATED 2007 EQUITY INCENTIVE AWARD PLAN**

ARTICLE 1

PURPOSE

The purpose of the Orexigen Therapeutics, Inc. 2007 Equity Incentive Award Plan, as amended and restated herein (the "Plan") is to promote the success and enhance the value of Orexigen Therapeutics, Inc. (the "Company") by linking the personal interests of the members of the Board, Employees, and Consultants to those of Company stockholders and by providing such individuals with an incentive for outstanding performance to generate superior returns to Company stockholders. The Plan is further intended to provide flexibility to the Company in its ability to motivate, attract, and retain the services of members of the Board, Employees, and Consultants upon whose judgment, interest, and special effort the successful conduct of the Company's operation is largely dependent. This Plan amends and restates in its entirety the Orexigen, Inc. 2007 Equity Incentive Award Plan adopted by the Board on April 24, 2007 and shall become effective upon approval of the Company's stockholders.

ARTICLE 2

DEFINITIONS AND CONSTRUCTION

Wherever the following terms are used in the Plan they shall have the meanings specified below, unless the context clearly indicates otherwise. The singular pronoun shall include the plural where the context so indicates.

2.1 "Award" means an Option, a Restricted Stock award, a Stock Appreciation Right award, a Performance Share award, a Performance Stock Unit award, a Dividend Equivalents award, a Stock Payment award, a Deferred Stock award, a Restricted Stock Unit award, an Other Stock-Based Award, a Performance Bonus Award, or a Performance-Based Award granted to a Participant pursuant to the Plan.

2.2 "Award Agreement" means any written agreement, contract, or other instrument or document evidencing an Award, including through an electronic medium.

2.3 "Board" means the Board of Directors of the Company.

2.4 "Cause" means the occurrence of any of the following events:

- (a) a Participant's conviction of or plea of guilty or nolo contendere to any felony or a crime of moral turpitude;
- (b) a Participant's continued failure or refusal to follow lawful and reasonable instructions of such Participant's supervisor or the Board or lawful and reasonable policies and regulations of the Company or its affiliates;
- (c) a Participant's continued failure to faithfully and diligently perform the assigned duties of his or her employment with the Company or its affiliates;
- (d) unprofessional, unethical, immoral or fraudulent conduct by a Participant;
- (e) conduct by a Participant that materially discredits the Company or any affiliate or is materially detrimental to the reputation, character and standing of the Company or any affiliate; or

(f) a Participant's material breach of his or her Employment Agreement, Proprietary Information and Inventions Agreement, the Company's Code of Conduct and/or Insider Trading Policy, each as applicable, or any other contractual, fiduciary, or statutory duty owed to the Company.

An event described in Section 2.4(b) through (f) shall not be treated as "Cause" until after a Participant has been given written notice of such event, failure, conduct or breach and such Participant fails to cure such event, failure, conduct or breach within 30 days from such written notice; *provided, however*, that such 30-day cure period shall not be required if the event, failure, conduct or breach is incapable of being cured. Failure of the Company to meet financial or performance targets or goals shall not be deemed to be a breach pursuant to Section 2.4 (b) or (c).

2.5 "Change in Control" means and includes each of the following:

(a) A transaction or series of transactions (other than an offering of Stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; or

(b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new director(s) (other than a director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in Section 2.4(a) or Section 2.4(c)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof;

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) Which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "Successor Entity")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(ii) After which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; *provided, however*, that no person or group shall be treated for purposes of this Section 2.4(c)(ii) as beneficially owning 50% or more of combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; or

(d) The Company's stockholders approve a liquidation or dissolution of the Company.

The Committee shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control of the Company has occurred pursuant to the above definition, and the date of the occurrence of such Change in Control and any incidental matters relating thereto.

2.6 “Code” means the Internal Revenue Code of 1986, as amended.

2.7 “Committee” means the committee of the Board described in Article 13.

2.8 “Consultant” means any consultant or adviser if:

(a) the consultant or adviser renders bona fide services to the Company or any Parent or Subsidiary;

(b) the services rendered by the consultant or adviser are not in connection with the offer or sale of securities in a capital-raising transaction and do not directly or indirectly promote or maintain a market for the Company’s securities; and

(c) the consultant or adviser is a natural person.

2.9 “Continuous Service” means that the Participant’s service with the Company or a Subsidiary, whether as an Employee, Director or Consultant, is not interrupted or terminated. The Participant’s Continuous Service shall not be deemed to have terminated merely because of a change in the capacity in which the Participant renders service to the Company or a Subsidiary as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant’s Continuous Service. For example, a change in status from an Employee of the Company to a Consultant of a Subsidiary or a Director will not constitute an interruption of Continuous Service. The Board or the chief executive officer of the Company (or Board of Directors or the chief executive officer of any successor thereto), in that party’s sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of any leave of absence approved by that party, including sick leave, military leave or any other personal leave.

2.10 “Covered Employee” means an Employee who is, or could be, a “covered employee” within the meaning of Section 162(m) of the Code.

2.11 “Deferred Stock” means a right to receive a specified number of shares of Stock during specified time periods pursuant to Section 8.5.

2.12 “Director” means a member of the Board, or, as applicable, a member of the board of directors of a Subsidiary.

2.13 “Disability” means “disability,” as such term is defined in Section 22(e)(3) of the Code.

2.14 “Dividend Equivalents” means a right granted to a Participant pursuant to Section 8.3 to receive the equivalent value (in cash or Stock) of dividends paid on Stock.

2.15 “Eligible Individual” means any person who is an Employee, a Consultant or a member of the Board, as determined by the Committee.

2.16 “Employee” means any officer or other employee (as defined in accordance with Section 3401(c) of the Code) of the Company or of any Parent or Subsidiary.

2.17 “Equity Restructuring” shall mean a non-reciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off, rights offering or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind shares of Stock (or other securities of the Company) or the share price of Stock (or other securities) and causes a change in the per share value of the Stock underlying outstanding Awards.

2.18 “Exchange Act” means the Securities Exchange Act of 1934, as amended.

2.19 “Fair Market Value” means, as of any given date,

(a) if Stock is traded on an exchange, the closing price (or the closing bid, if no sales were reported) of a share of Stock as reported in the *Wall Street Journal* (or such other source the Committee deems reliable) for such date, or if no bids or sales were reported for such date, then the closing price (or the closing bid, if no sales were reported) on the trading date immediately prior to such date during which a bid or sale occurred;

(b) if Stock is not traded on an exchange but is quoted on a quotation system, the mean between the closing representative bid and asked prices for the Stock on such date, or if no closing representative bid and asked prices were reported for such date, the date immediately prior to such date during which closing representative bid and asked prices were quoted for the Stock, in each case, as reported in the *Wall Street Journal* or such other source the Committee deems reliable; or

(c) if Stock is not publicly traded, the fair market value established by the Committee acting in good faith.

2.20 “Incentive Stock Option” means an Option that is intended to meet the requirements of Section 422 of the Code or any successor provision thereto.

2.21 “Inducement Award” means an Award granted pursuant to Section 3.4 of the Plan.

2.22 “Independent Director” means a Director of the Company who is not an Employee of the Company or of any Parent or Subsidiary.

2.23 “Non-Employee Director” means a Director of the Company who qualifies as a “Non-Employee Director” as defined in Rule 16b-3(b)(3) of the Exchange Act, or any successor rule.

2.24 “Non-Qualified Stock Option” means an Option that is not intended to be an Incentive Stock Option.

2.25 “Option” means a right granted to a Participant pursuant to Article 5 of the Plan to purchase a specified number of shares of Stock at a specified price during specified time periods. An Option may be either an Incentive Stock Option or a Non-Qualified Stock Option.

2.26 “Other Stock-Based Award” means an Award granted or denominated in Stock or units of Stock pursuant to Section 8.7 of the Plan.

2.27 “Parent” means any “parent corporation,” as defined in Section 424(e) of the Code and any applicable regulations promulgated thereunder, of the Company or any other entity which beneficially owns, directly or indirectly, a majority of the outstanding voting stock or voting power of the Company.

2.28 “Participant” means any Eligible Individual who, as a member of the Board, Consultant or Employee, has been granted an Award pursuant to the Plan.

2.29 “Performance-Based Award” means an Award granted to selected Covered Employees pursuant to Articles 6 and 8, but which is subject to the terms and conditions set forth in Article 9. All Performance-Based Awards are intended to qualify as Qualified Performance-Based Compensation.

2.30 “Performance Bonus Award” has the meaning set forth in Section 8.8.

2.31 “Performance Criteria” means the criteria that the Committee selects for purposes of establishing the Performance Goal or Performance Goals for a Participant for a Performance Period. The Performance Criteria that will be used to establish Performance Goals shall be based on the attainment of specified levels of one or any combination of the following:

- sales (including same store or comparable sales);

-
- net sales;
 - return on sales;
 - revenue, net revenue, product revenue or system-wide revenue (including growth of such revenue measures);
 - operating income (before or after taxes);
 - pre- or after-tax income or loss (before or after allocation of corporate overhead and bonus);
 - earnings or loss per share;
 - net income or loss (before or after taxes);
 - return on equity;
 - total stockholder return;
 - return on assets or net assets;
 - appreciation in and/or maintenance of the price of the Shares or any other publicly-traded securities of the Company;
 - market share;
 - gross profits;
 - gross or net profit margin;
 - gross profit growth;
 - net operating profit (before or after taxes);
 - operating earnings;
 - earnings or losses or net earnings or losses (including earnings or losses before taxes, before interest and taxes, or before interest, taxes, depreciation and amortization);
 - economic value-added models or equivalent metrics;
 - comparisons with various stock market indices;
 - reductions in costs;
 - cash flow (including operating cash flow and free cash flow) or cash flow per share (before or after dividends);
 - return on capital (including return on total capital or return on invested capital);
 - cash flow return on investment;
 - cash flow return on capital;
 - improvement in or attainment of expense levels or working capital levels, including cash, inventory and accounts receivable;
 - general and administrative expense savings;
 - inventory control;
 - operating margin;
 - gross margin;
 - year-end cash;
 - cash margin;

-
- debt reduction;
 - stockholders equity;
 - operating efficiencies;
 - cost reductions or savings;
 - customer satisfaction;
 - customer growth;
 - employee satisfaction;
 - productivity or productivity ratios;
 - regulatory achievements (including submitting or filing applications or other documents with regulatory authorities or receiving approval of any such applications or other documents and passing pre-approval inspections (whether of the Company or the Company's third-party manufacturer) and validation of manufacturing processes (whether the Company's or the Company's third-party manufacturer's));
 - clinical achievements (including initiating clinical studies; initiating enrollment, completing enrollment or enrolling particular numbers of subjects in clinical studies; completing phases of a clinical study (including the treatment phase); or announcing or presenting preliminary or final data from clinical studies; in each case, whether on particular timelines or generally);
 - strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property);
 - establishing relationships with commercial entities with respect to the marketing, distribution and sale of the Company's products (including with group purchasing organizations, distributors and other vendors);
 - supply chain achievements (including establishing relationships with manufacturers or suppliers of component materials and manufacturers of the Company's products);
 - co-development, co-marketing, profit sharing, joint venture or other similar arrangements);
 - financial ratios, including those measuring liquidity, activity, profitability or leverage;
 - cost of capital or assets under management;
 - financing and other capital raising transactions (including sales of the Company's equity or debt securities);
 - debt level year-end cash position; book value;
 - factoring transactions;
 - competitive market metrics;
 - timely completion of new product roll-outs;
 - timely launch of new facilities (such as new store openings, gross or net);
 - sales or licenses of the Company's assets, including its intellectual property, whether in a particular jurisdiction or territory or globally (or through partnering transactions);
 - royalty rates or royalty income;
 - reported prescriptions over a period;
 - implementation, completion or attainment of measurable objectives with respect to research, development, manufacturing, commercialization, products or projects, production volume levels, acquisitions and divestitures, succession and hiring projects, reorganization and other corporate transactions, expansions of specific business operations and meeting divisional or project budgets;
 - and recruiting and maintaining personnel, any of which may be measured either in absolute terms or as compared to any incremental increase or as compared to results of other companies or a peer group. Any

Performance Goals that are financial metrics, may be determined in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”), in accordance with accounting principles established by the International Accounting Standards Board (“IASB Principles”), or may be adjusted when established to include or exclude any items otherwise includable or excludable under GAAP or under IASB Principles. To the extent an Award is intended to be Qualified Performance-Based Compensation, the Committee shall, within the time prescribed by Section 162(m) of the Code, define in an objective fashion the manner of calculating the Performance Criteria it selects to use for such Performance Period for such Participant.

2.32 “Performance Goals” means, for a Performance Period, the goals established in writing by the Committee for the Performance Period based upon the Performance Criteria. Depending on the Performance Criteria used to establish such Performance Goals, the Performance Goals may be expressed in terms of overall Company performance or the performance of a division, business unit, Subsidiary, or an individual. To the extent an Award is intended to be Qualified Performance-Based Compensation, the Committee, in its discretion, may, within the time prescribed by Section 162(m) of the Code, provide for exclusion of the impact of an event or occurrence which the Committee determines should appropriately be excluded, including without limitation (a) in the event of, or in anticipation of, any unusual or extraordinary corporate item, transaction, event, or development, or (b) in recognition of, or in anticipation of, any other unusual or nonrecurring events affecting the Company, or the financial statements of the Company, or in response to, or in anticipation of, changes in applicable laws, regulations, accounting principles, or business conditions.

2.33 “Performance Period” means the one or more periods of time, which may be of varying and overlapping durations, as the Committee may select, over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant’s right to, and the payment of, a Performance-Based Award.

2.34 “Performance Share” means a right granted to a Participant pursuant to Section 8.1, to receive Stock, the payment of which is contingent upon achieving certain Performance Goals or other performance-based targets established by the Committee.

2.35 “Performance Stock Unit” means a right granted to a Participant pursuant to Section 8.2, to receive Stock, cash, or a combination of Stock and cash, the payment of which is contingent upon achieving certain Performance Goals or other performance-based targets established by the Committee.

2.36 “Plan” means this Orexigen Therapeutics, Inc. Amended and Restated 2007 Incentive Award Plan, as it may be amended from time to time.

2.37 “Qualified Performance-Based Compensation” means any compensation that is intended to qualify as “qualified performance-based compensation” as described in Section 162(m)(4)(C) of the Code.

2.38 “Restatement Date” has the meaning set forth in Section 14.1.

2.39 “Restricted Stock” means Stock awarded to a Participant pursuant to Article 6 that is subject to certain restrictions and may be subject to risk of forfeiture.

2.40 “Restricted Stock Unit” means an Award granted pursuant to Section 8.6.

2.41 “Securities Act” shall mean the Securities Act of 1933, as amended.

2.42 “Shares” shall mean shares of Stock of the Company.

2.43 “Stock” means the common stock of the Company, par value \$0.001 per share, and such other securities of the Company that may be substituted for Stock pursuant to Article 12.

2.44 “Stock Appreciation Right” or “SAR” means a right granted pursuant to Article 7 to receive a payment equal to the excess of the Fair Market Value of a specified number of shares of Stock on the date the SAR is exercised over the Fair Market Value on the date the SAR was granted as set forth in the applicable Award Agreement.

2.45 “Stock Payment” means (a) a payment in the form of shares of Stock, or (b) an option or other right to purchase shares of Stock, as part of any bonus, deferred compensation or other arrangement, made in lieu of all or any portion of the compensation, granted pursuant to Section 8.4.

2.46 “Subsidiary” means any “subsidiary corporation” as defined in Section 424(f) of the Code and any applicable regulations promulgated thereunder or any other entity of which a majority of the outstanding voting stock or voting power is beneficially owned directly or indirectly by the Company.

2.47 “Substitute Awards” shall mean Awards granted or Shares issued by the Company in assumption of, or in substitution or exchange for, awards previously granted, or the right or obligation to make future awards, in each case by a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines.

ARTICLE 3

SHARES SUBJECT TO THE PLAN

3.1 Number of Shares.

(a) As of the Restatement Date and subject to adjustment as provided in Article 12, a total of one hundred and three million (103,000,000) Shares shall be authorized for Awards granted under the Plan, plus the number of Shares reserved for Inducement Awards under Section 3.4 of the Plan, less one (1) Share for every one (1) Award granted under the Plan after March 31, 2016 and prior to the Restatement Date. The maximum number of Shares that may be delivered upon exercise of Incentive Stock Options shall not exceed one hundred and three million (103,000,000).

(b) If any Shares subject to an Award are forfeited, an Award expires or otherwise terminates without issuance of Shares, or an Award is settled for cash (in whole or in part) or otherwise does not result in the issuance of all or a portion of the Shares subject to such Award (including on payment in Shares on exercise of a Stock Appreciation Right), such Shares shall, to the extent of such forfeiture, expiration, termination, cash settlement or non-issuance, be added to the Shares available for grant under the Plan on a one-for-one basis.

(c) In the event that (i) any Option or other Award granted hereunder is exercised through the tendering of Shares (either actually or by attestation) or by the withholding of Shares by the Company, or (ii) withholding tax liabilities arising from such Option or other Award are satisfied by the tendering of Shares (either actually or by attestation) or by the withholding of Shares by the Company, then in each such case the Shares so tendered or withheld shall be added to the Shares available for grant under the Plan on a one-for-one basis.

(d) Substitute Awards shall not reduce the Shares authorized for grant under the Plan or the applicable limitations on grants to a Participant under Section 3.3, nor shall Shares subject to a Substitute Award be added to the Shares available for Awards under the Plan as provided above. Additionally, in the event that a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines has shares available under a pre-existing plan approved by stockholders and not adopted in contemplation of such

acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Shares authorized for grant under the Plan (and Shares subject to such Awards shall not be added to the Shares available for Awards under the Plan as provided above); provided that Awards using such available shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not employees or directors prior to such acquisition or combination.

3.2 Stock Distributed. Any shares of Stock distributed pursuant to an Award may consist, in whole or in part, of authorized and unissued Stock, treasury Stock or Stock purchased on the open market.

3.3 Limitation on Number of Shares Subject to Awards. Subject to adjustment as provided in Article 12, no Participant may be granted (i) Options or Stock Appreciation Rights during any 12-month period with respect to more than 15,000,000 Shares and (ii) any Awards (other than Options or Stock Appreciation Rights) during any calendar year that are intended to constitute Qualified Performance-Based Compensation and are denominated in Shares under which more than 15,000,000 Shares may be earned within any applicable vesting period or Performance Period. During any calendar year no Participant may be granted Awards of Qualified Performance-Based Compensation that are denominated in cash under which more than \$15,000,000 may be earned within any applicable vesting period or Performance Period. Each of the limitations in this section shall be multiplied by two (2) with respect to Awards granted to a Participant during the first calendar year in which the Participant commences employment with the Company and its Subsidiaries. If an Award is cancelled, the cancelled Award shall continue to be counted toward the applicable limitation in this Section.

Notwithstanding any other provision of the Plan to the contrary, the aggregate grant date fair value (computed as of the date of grant in accordance with applicable financial accounting rules) of all Awards granted to any Independent Director during any single calendar year, taken together with any cash fees paid to such Independent Director during such calendar year, shall not exceed \$750,000.

3.4 Inducement Shares. This Section 3.4 shall apply with respect to the two million five hundred thousand (2,500,000) Shares reserved under this Plan by action of the Board (or a committee thereof) to be used exclusively for the grant of Inducement Awards. The persons who are eligible for Inducement Awards shall consist of Eligible Individuals who are Employees and whose potential contribution, in the judgment of the Committee, will benefit the future success of the Company and/or an affiliated corporation. Notwithstanding anything to the contrary in Article 4, an Inducement Award may be granted only to an Eligible Individual not previously an Employee or an Independent Director of the Company, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules. In addition, notwithstanding any other provision of the Plan to the contrary, all such Inducement Awards must be granted either by a majority of the Company's Independent Directors or a committee comprised of a majority of Independent Directors.

ARTICLE 4

ELIGIBILITY AND PARTICIPATION

4.1 Eligibility. Each Eligible Individual shall be eligible to be granted one or more Awards pursuant to the Plan, each such Award not to exceed a term of ten (10) years; *provided* that Inducement Awards may be granted only to Eligible Individuals as provided in Section 3.4.

4.2 Participation. Subject to the provisions of the Plan, the Committee may, from time to time, select from among all Eligible Individuals those to whom Awards shall be granted and shall determine the nature and amount of each Award. No Eligible Individual shall have any right to be granted an Award pursuant to the Plan.

4.3 Foreign Participants. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in other countries in which the Company and its Subsidiaries operate or have Eligible Individuals, the Committee, in its sole discretion, shall have the power and authority to: (i) determine which Subsidiaries shall be covered by the Plan; (ii) determine which Eligible Individuals outside the United States are eligible to participate in the Plan; (iii) modify the terms and conditions of any Award granted to Eligible Individuals outside the United States to comply with applicable foreign laws; (iv) establish subplans and modify exercise procedures and other terms and procedures, to the extent such actions may be necessary or advisable (any such subplans and/or modifications shall be attached to this Plan as appendices); *provided, however*, that no such subplans and/or modifications shall increase the share limitations contained in Sections 3.1 and 3.3 of the Plan; and (v) take any action, before or after an Award is made, that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals. Notwithstanding the foregoing, the Committee may not take any actions hereunder, and no Awards shall be granted, that would violate the Exchange Act, the Code, any securities law or governing statute or any other applicable law.

ARTICLE 5

STOCK OPTIONS

5.1 General. The Committee is authorized to grant Options to Eligible Individuals on the following terms and conditions:

(a) Exercise Price. The exercise price per share of Stock subject to an Option shall be determined by the Committee and set forth in the Award Agreement; *provided* that the exercise price for any Option shall not be less than 100% of the Fair Market Value of a share of Stock on the date of grant.

(b) Time and Conditions of Exercise. The Committee shall determine the time or times at which an Option may be exercised in whole or in part. The Committee shall also determine the performance or other conditions, if any, that must be satisfied before all or part of an Option may be exercised.

(c) Payment. The Committee shall determine the methods by which the exercise price of an Option may be paid, the form of payment, including, without limitation: (i) cash, (ii) shares of Stock held for such period of time as may be required by the Committee in order to avoid adverse accounting consequences and having a Fair Market Value on the date of delivery equal to the aggregate exercise price of the Option or exercised portion thereof, or (iii) other property acceptable to the Committee (including through the delivery of a notice that the Participant has placed a market sell order with a broker with respect to shares of Stock then issuable upon exercise of the Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the Option exercise price; *provided* that payment of such proceeds is then made to the Company upon settlement of such sale). The Committee shall also determine the methods by which shares of Stock shall be delivered or deemed to be delivered to Participants. Notwithstanding any other provision of the Plan to the contrary, no Participant who is a member of the Board or an "executive officer" of the Company within the meaning of Section 13(k) of the Exchange Act shall be permitted to pay the exercise price of an Option in any method which would violate Section 13(k) of the Exchange Act.

(d) Evidence of Grant. All Options shall be evidenced by an Award Agreement between the Company and the Participant. The Award Agreement shall include such additional provisions as may be specified by the Committee.

5.2 Incentive Stock Options. The terms of any Incentive Stock Options granted pursuant to the Plan must comply with the conditions and limitations contained in Section 14.2 and this Section 5.2.

(a) Eligibility. Incentive Stock Options may be granted only to Employees.

(b) Exercise Price. The exercise price per share of Stock shall be set by the Committee; *provided* that subject to Section 5.2(e), the exercise price for any Incentive Stock Option shall not be less than 100% of the Fair Market Value on the date of grant.

(c) Expiration. Subject to Section 5.2(e), an Incentive Stock Option may not be exercised to any extent by anyone after the first to occur of the following events: the tenth anniversary of the date it is granted, unless an earlier time is set in the Award Agreement; the later of (x) three months after the Participant's termination of employment as an Employee or, if applicable, (y) one year after the date of the Participant's termination of employment or service on account of Disability or death. Upon the Participant's Disability or death, any Incentive Stock Options exercisable at the Participant's Disability or death may be exercised by the Participant's legal representative or representatives, by the person or persons entitled to do so pursuant to the Participant's last will and testament, or, if the Participant fails to make testamentary disposition of such Incentive Stock Option or dies intestate, by the person or persons entitled to receive the Incentive Stock Option pursuant to the applicable laws of descent and distribution.

(d) Individual Dollar Limitation. The aggregate Fair Market Value (determined as of the time the Option is granted) of all shares of Stock with respect to which Incentive Stock Options are first exercisable by a Participant in any calendar year may not exceed \$100,000 or such other limitation as imposed by Section 422(d) of the Code, or any successor provision. To the extent that Incentive Stock Options are first exercisable by a Participant in excess of such limitation, the excess shall be considered Non-Qualified Stock Options.

(e) Ten Percent Owners. An Incentive Stock Option shall be granted to any individual who, at the date of grant, owns stock possessing more than ten percent of the total combined voting power of all classes of Stock of the Company only if such Option is granted at a price that is not less than 110% of Fair Market Value on the date of grant and the Option is exercisable for no more than five years from the date of grant.

(f) Notice of Disposition. The Participant shall give the Company prompt notice of any disposition of shares of Stock acquired by exercise of an Incentive Stock Option within (i) two years from the date of grant of such Incentive Stock Option or (ii) one year after the transfer of such shares of Stock to the Participant.

(g) Right to Exercise. During a Participant's lifetime, an Incentive Stock Option may be exercised only by the Participant.

(h) Failure to Meet Requirements. Any Option (or portion thereof) purported to be an Incentive Stock Option, which, for any reason, fails to meet the requirements of Section 422 of the Code shall be considered a Non-Qualified Stock Option.

5.3 Substitution of Stock Appreciation Rights. The Committee may provide in the Award Agreement evidencing the grant of an Option that the Committee, in its sole discretion, shall have to right to substitute a Stock Appreciation Right for such Option at any time prior to or upon exercise of such Option, subject to the provisions of Sections 7.2 and 13.6; provided that such Stock Appreciation Right shall be exercisable with respect to the same number of shares of Stock for which such substituted Option would have been exercisable.

ARTICLE 6

RESTRICTED STOCK AWARDS

6.1 Grant of Restricted Stock. The Committee is authorized to make Awards of Restricted Stock to any Eligible Individual selected by the Committee in such amounts and subject to such terms and conditions as determined by the Committee. All Awards of Restricted Stock shall be evidenced by an Award Agreement.

6.2 Issuance and Restrictions. Restricted Stock shall be subject to such restrictions on transferability and other restrictions as the Committee may impose (including, without limitation, limitations on the right to vote Restricted Stock or the right to receive dividends on the Restricted Stock). These restrictions may lapse separately or in combination at such times, pursuant to such circumstances, in such installments, or otherwise, as the Committee determines at the time of the grant of the Award or thereafter.

6.3 Forfeiture. Except as otherwise determined by the Committee at the time of the grant of the Award or thereafter, upon termination of employment or service during the applicable restriction period, Restricted Stock that is at that time subject to restrictions shall be forfeited; *provided, however*, that the Committee may (a) provide in any Restricted Stock Award Agreement that restrictions or forfeiture conditions relating to Restricted Stock will be waived in whole or in part in the event of terminations resulting from specified causes, and (b) in other cases waive in whole or in part restrictions or forfeiture conditions relating to Restricted Stock.

6.4 Certificates for Restricted Stock. Restricted Stock granted pursuant to the Plan may be evidenced in such manner as the Committee shall determine. If certificates representing shares of Restricted Stock are registered in the name of the Participant, certificates must bear an appropriate legend referring to the terms, conditions, and restrictions applicable to such Restricted Stock, and the Company may, at its discretion, retain physical possession of the certificate until such time as all applicable restrictions lapse.

ARTICLE 7

STOCK APPRECIATION RIGHTS

7.1 Grant of Stock Appreciation Rights. A Stock Appreciation Right may be granted to any Eligible Individual selected by the Committee. A Stock Appreciation Right shall be subject to such terms and conditions not inconsistent with the Plan as the Committee shall impose and shall be evidenced by an Award Agreement.

7.2 Stock Appreciation Rights.

(a) A Stock Appreciation Right (“SAR”) shall have a term set by the Committee. An SAR shall be exercisable in such installments as the Committee may determine. An SAR shall cover such number of shares of Stock as the Committee may determine. The exercise price per share of Stock subject to each SAR shall be set by the Committee; *provided, however*, that the Committee in its sole and absolute discretion may provide that the SAR may be exercised subsequent to a termination of employment or service, as applicable, or following a Change in Control of the Company, or because of the Participant’s retirement, death or Disability, or otherwise.

(b) An SAR shall entitle the Participant (or other person entitled to exercise the SAR pursuant to the Plan) to exercise all or a specified portion of the SAR (to the extent then exercisable pursuant to its terms) and to receive from the Company an amount equal to the product of (i) the excess of (A) the Fair Market Value of a share of Stock on the date the SAR is exercised over (B) the Fair Market Value of a share of Stock on the date the SAR was granted and (ii) the number of shares of Stock with respect to which the SAR shall have been exercised, subject to any limitations the Committee may impose.

7.3 Payment and Limitations on Exercise.

(a) Subject to Section 7.3(b), payment of the amounts determined under Section 7.2(b) above shall be in cash, in Stock (based on its Fair Market Value as of the date the SAR is exercised) or a combination of both, as determined by the Committee.

(b) To the extent any payment under Section 7.2(b) is effected in Stock it shall be made subject to satisfaction of all provisions of Article 5 above pertaining to Options.

ARTICLE 8

OTHER TYPES OF AWARDS

8.1 Performance Share Awards. Any Eligible Individual selected by the Committee may be granted one or more Performance Share awards which shall be denominated in a number of shares of Stock and which may be

linked to any one or more of the Performance Criteria or other specific performance criteria determined appropriate by the Committee, in each case on a specified date or dates or over any period or periods determined by the Committee. In making such determinations, the Committee shall consider (among such other factors as it deems relevant in light of the specific type of award) the contributions, responsibilities and other compensation of the particular Participant.

8.2 Performance Stock Units. Any Eligible Individual selected by the Committee may be granted one or more Performance Stock Unit awards which shall be denominated in units of value including dollar value of shares of Stock and which may be linked to any one or more of the Performance Criteria or other specific performance criteria determined appropriate by the Committee, in each case on a specified date or dates or over any period or periods determined by the Committee. In making such determinations, the Committee shall consider (among such other factors as it deems relevant in light of the specific type of award) the contributions, responsibilities and other compensation of the particular Participant.

8.3 Dividend Equivalents.

(a) Any Eligible Individual selected by the Committee may be granted Dividend Equivalents based on the dividends declared on the shares of Stock that are subject to any Award, to be credited as of dividend payment dates, during the period between the date the Award is granted and the date the Award is exercised, vests or expires, as determined by the Committee. Such Dividend Equivalents shall be converted to cash or additional shares of Stock by such formula and at such time and subject to such limitations as may be determined by the Committee. Notwithstanding the provisions of this Section, Dividend Equivalents, cash dividends, stock and any other property (other than cash) distributed as a dividend or otherwise with respect to any Award that vests based on achievement of performance goals shall either (i) not be paid or credited or (ii) be accumulated, shall be subject to restrictions and risk of forfeiture to the same extent as the underlying Award and shall be paid at the time such restrictions and risk of forfeiture lapse.

(b) Dividend Equivalents shall not be granted with respect to Options or SARs.

8.4 Stock Payments. Any Eligible Individual selected by the Committee may receive Stock Payments in the manner determined from time to time by the Committee. The number of shares of Stock or the number of options or other rights to purchase shares of Stock subject to a Stock Payment shall be determined by the Committee and may be based upon the Performance Criteria or other specific performance criteria determined appropriate by the Committee, determined on the date such Stock Payment is made or on any date thereafter.

8.5 Deferred Stock. Any Eligible Individual selected by the Committee may be granted an award of Deferred Stock in the manner determined from time to time by the Committee in accordance with Section 409A of the Code. The number of shares of Deferred Stock shall be determined by the Committee and may be linked to the Performance Criteria or other specific performance criteria determined to be appropriate by the Committee, in each case on a specified date or dates or over any period or periods determined by the Committee. Stock underlying a Deferred Stock award will not be issued until the Deferred Stock award has vested, pursuant to a vesting schedule or performance criteria set by the Committee. Unless otherwise provided by the Committee, a Participant awarded Deferred Stock shall have no rights as a Company stockholder with respect to such Deferred Stock until such time as the Deferred Stock Award has vested and the Stock underlying the Deferred Stock Award has been issued. In addition, the Committee shall be authorized to establish procedures pursuant to which the payment of any Award may be deferred.

8.6 Restricted Stock Units. The Committee is authorized to make Awards of Restricted Stock Units to any Eligible Individual selected by the Committee in such amounts and subject to such terms and conditions as determined by the Committee. At the time of grant, the Committee shall specify the date or dates on which the Restricted Stock Units shall become fully vested and nonforfeitable, and may specify such conditions to vesting as it deems appropriate. At the time of grant, the Committee shall specify the maturity date applicable to each

grant of Restricted Stock Units which shall be no earlier than the vesting date or dates of the Award and may be determined at the election of the grantee; *provided*, that such dates and such election shall be subject to compliance with Section 409A of the Code. On the maturity date, the Company shall, subject to Section 11.5(b), transfer to the Participant one unrestricted, fully transferable share of Stock for each Restricted Stock Unit (or an equivalent value in cash, or a combination thereof) scheduled to be paid out on such date and not previously forfeited. The Committee shall specify the purchase price, if any, to be paid by the grantee to the Company for such shares of Stock.

8.7 Other Stock-Based Awards. Any Eligible Individual selected by the Committee may be granted one or more Awards that provide Participants with shares of Stock or the right to purchase shares of Stock or that have a value derived from the value of, or an exercise or conversion privilege at a price related to, or that are otherwise payable in shares of Stock and which may be linked to any one or more of the Performance Criteria or other specific performance criteria determined appropriate by the Committee, in each case on a specified date or dates or over any period or periods determined by the Committee. In making such determinations, the Committee shall consider (among such other factors as it deems relevant in light of the specific type of Award) the contributions, responsibilities and other compensation of the particular Participant.

8.8 Performance Bonus Awards. Any Participant selected by the Committee may be granted one or more Performance-Based Awards in the form of a cash bonus (a "Performance Bonus Award") payable upon the attainment of Performance Goals that are established by the Committee and relate to one or more of the Performance Criteria, in each case on a specified date or dates or over any period or periods determined by the Committee. Any such Performance Bonus Award paid to a Covered Employee shall be based upon objectively determinable bonus formulas established in accordance with Article 9.

8.9 Term. Except as otherwise provided herein, the vesting schedule of any Award of Performance Shares, Performance Stock Units, Dividend Equivalents, Stock Payments, Deferred Stock, Restricted Stock Units or Other Stock-Based Award shall be set by the Committee in its discretion.

8.10 Exercise or Purchase Price. The Committee may establish the exercise or purchase price, if any, of any Award of Performance Shares, Performance Stock Units, Deferred Stock, Stock Payments, Restricted Stock Units or Other Stock-Based Award; *provided, however*, that such price shall not be less than the par value of a share of Stock on the date of grant, unless otherwise permitted by applicable state law.

8.11 Exercise Upon Termination of Employment or Service. An Award of Performance Shares, Performance Stock Units, Dividend Equivalents, Deferred Stock, Stock Payments, Restricted Stock Units and Other Stock-Based Award shall only be exercisable or payable while the Participant is an Employee, Consultant or a Director, as applicable; *provided, however*, that the Committee in its sole and absolute discretion may provide that an Award of Performance Shares, Performance Stock Units, Dividend Equivalents, Stock Payments, Deferred Stock, Restricted Stock Units or Other Stock-Based Award may be exercised or paid subsequent to a termination of employment or service, as applicable, or following a Change in Control of the Company, or because of the Participant's retirement, death or Disability, or otherwise; *provided, however*, that any such provision with respect to Awards of Qualified Performance-Based Compensation shall be subject to the requirements of Section 162(m) of the Code that apply to Qualified Performance-Based Compensation.

8.12 Form of Payment. Payments with respect to any Awards granted under this Article 8 shall be made in cash, in Stock or a combination of both, as determined by the Committee.

8.13 Award Agreement. All Awards under this Article 8 shall be subject to such additional terms and conditions as determined by the Committee and shall be evidenced by an Award Agreement.

ARTICLE 9

PERFORMANCE-BASED AWARDS

9.1 Purpose. The purpose of this Article 9 is to provide the Committee the ability to qualify Awards other than Options and SARs and that are granted pursuant to Articles 6 and 8 as Qualified Performance-Based Compensation. If the Committee, in its discretion, decides to grant a Performance-Based Award to a Covered Employee, the provisions of this Article 9 shall control over any contrary provision contained in Articles 6 or 8; *provided, however*, that the Committee may in its discretion grant Awards to Covered Employees that are based on Performance Criteria or Performance Goals but that do not satisfy the requirements of this Article 9, *provided, however*, that all Performance-Based Awards are intended to qualify as Qualified Performance-Based Compensation.

9.2 Applicability. This Article 9 shall apply only to those Covered Employees selected by the Committee to receive Performance-Based Awards. The designation of a Covered Employee as a Participant for a Performance Period shall not in any manner entitle the Participant to receive an Award for the period. Moreover, designation of a Covered Employee as a Participant for a particular Performance Period shall not require designation of such Covered Employee as a Participant in any subsequent Performance Period and designation of one Covered Employee as a Participant shall not require designation of any other Covered Employees as a Participant in such period or in any other period.

9.3 Procedures with Respect to Performance-Based Awards. To the extent necessary to comply with the Qualified Performance-Based Compensation requirements of Section 162(m)(4)(C) of the Code, with respect to any Award granted under Articles 6 or 8 which may be granted to one or more Covered Employees, prior to the earlier of ninety (90) days following the commencement of the applicable Performance Period and the expiration of 25% of the Performance Period (or such other time as may be required or permitted by Section 162(m) of the Code), the Committee shall, in writing, (a) designate one or more Covered Employees, (b) select the Performance Criteria applicable to the Performance Period, (c) establish the Performance Goals, and amounts of such Awards, as applicable, which may be earned for such Performance Period, and (d) specify the relationship between Performance Criteria and the Performance Goals and the amounts of such Awards, as applicable, to be earned by each Covered Employee for such Performance Period. Following the completion of each Performance Period, the Committee shall certify in writing whether the applicable Performance Goals have been achieved for such Performance Period. In determining the amount earned by a Covered Employee, the Committee shall have the right to reduce or eliminate (but not to increase) the amount payable at a given level of performance to take into account additional factors that the Committee may deem relevant to the assessment of individual or corporate performance for the Performance Period.

9.4 Payment of Performance-Based Awards. Unless otherwise provided in the applicable Award Agreement, a Participant must be employed by the Company or a Parent or Subsidiary on the day a Performance-Based Award for such Performance Period is paid to the Participant. Furthermore, a Participant shall be eligible to receive payment pursuant to a Performance-Based Award for a Performance Period only if the Performance Goals for such period are achieved. In determining the amount earned under a Performance-Based Award, the Committee may reduce or eliminate the amount of the Performance-Based Award earned for the Performance Period, if in its sole and absolute discretion, such reduction or elimination is appropriate.

9.5 Additional Limitations. Notwithstanding any other provision of the Plan, any Award which is granted to a Covered Employee and is intended to constitute Qualified Performance-Based Compensation, including all Performance-Based Awards, shall be subject to any additional limitations set forth in Section 162(m) of the Code (including any amendment to Section 162(m) of the Code) or any regulations or rulings issued thereunder that are requirements for qualification as qualified performance-based compensation as described in Section 162(m)(4)(C) of the Code, and the Plan shall be deemed amended to the extent necessary to conform to such requirements.

ARTICLE 10

INDEPENDENT DIRECTOR AWARDS

10.1 The Board may grant Awards to Independent Directors, subject to the limitations of the Plan, pursuant to a written plan established by the Committee, or any successor committee thereto carrying out its responsibilities on the date of grant of any such Award (the “Independent Director Compensation Policy”). The Independent Director Compensation Policy shall set forth the type of Award(s) to be granted to Independent Directors, the number of shares of Common Stock to be subject to Independent Director Awards, the conditions on which such Awards shall be granted, become exercisable and/or payable, and such other terms and conditions as the Committee (or such other successor committee as described above) shall determine in its discretion. For the avoidance of doubt, Awards granted to Independent Directors shall be subject to all of the limitations set forth in the Plan.

ARTICLE 11

PROVISIONS APPLICABLE TO AWARDS

11.1 Stand-Alone and Tandem Awards. Awards granted pursuant to the Plan may, in the discretion of the Committee, be granted either alone, in addition to, or in tandem with, any other Award granted pursuant to the Plan. Awards granted in addition to or in tandem with other Awards may be granted either at the same time as or at a different time from the grant of such other Awards.

11.2 Award Agreement. Awards under the Plan shall be evidenced by Award Agreements that set forth the terms, conditions and limitations for each Award which may include the term of an Award, the provisions applicable in the event the Participant’s employment or service terminates, and the Company’s authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind an Award.

11.3 Limits on Transfer. Except as set forth in this Section 11.3 and Section 11.4, no right or interest of a Participant in any Award may be pledged, encumbered, or hypothecated to or in favor of any party other than the Company, a Parent, or a Subsidiary, or shall be subject to any lien, obligation, or liability of such Participant to any other party other than the Company, a Parent, or a Subsidiary. Except as otherwise provided by the Committee, no Award shall be assigned, transferred, or otherwise disposed of by a Participant other than by will or the laws of descent and distribution. The Committee by express provision in the Award or an amendment thereto may permit an Award (other than an Incentive Stock Option) to be transferred to, exercised by and paid to certain persons or entities related to the Participant, including but not limited to members of the Participant’s family, charitable institutions, or trusts or other entities whose beneficiaries or beneficial owners are members of the Participant’s family and/or charitable institutions, or to such other persons or entities as may be expressly approved by the Committee, pursuant to such conditions and procedures as the Committee may establish. Any permitted transfer shall be subject to the condition that the Committee receive evidence satisfactory to it that the transfer is being made for estate and/or tax planning purposes (or to a “blind trust” in connection with the Participant’s termination of employment or service with the Company, a Parent, or a Subsidiary to assume a position with a governmental, charitable, educational or similar non-profit institution) and on a basis consistent with the Company’s lawful issue of securities.

11.4 Beneficiaries. Notwithstanding Section 11.3, a Participant may, in the manner determined by the Committee, designate a beneficiary to exercise the rights of the Participant and to receive any distribution with respect to any Award upon the Participant’s death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and any Award Agreement applicable to the Participant, except to the extent the Plan and Award Agreement otherwise provide, and to any additional restrictions deemed necessary or appropriate by the Committee. If the Participant is married

and resides in a community property state, a designation of a person other than the Participant's spouse as his or her beneficiary with respect to more than 50% of the Participant's interest in the Award shall not be effective without the prior written consent of the Participant's spouse. If no beneficiary has been designated or survives the Participant, payment shall be made to the person entitled thereto pursuant to the Participant's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by a Participant at any time provided the change or revocation is filed with the Committee.

11.5 Stock Certificates: Book Entry Procedures.

(a) Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates evidencing shares of Stock pursuant to the exercise of any Award, unless and until the Board has determined, with advice of counsel, that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any exchange on which the shares of Stock are listed or traded. All Stock certificates delivered pursuant to the Plan are subject to any stop-transfer orders and other restrictions as the Committee deems necessary or advisable to comply with federal, state, or foreign jurisdiction, securities or other laws, rules and regulations and the rules of any national securities exchange or automated quotation system on which the Stock is listed, quoted, or traded. The Committee may place legends on any Stock certificate to reference restrictions applicable to the Stock. In addition to the terms and conditions provided herein, the Board may require that a Participant make such reasonable covenants, agreements, and representations as the Board, in its discretion, deems advisable in order to comply with any such laws, regulations, or requirements. The Committee shall have the right to require any Participant to comply with any timing or other restrictions with respect to the settlement or exercise of any Award, including a window-period limitation, as may be imposed in the discretion of the Committee.

(b) Notwithstanding any other provision of the Plan, unless otherwise determined by the Committee or required by any applicable law, rule or regulation, the Company shall not deliver to any Participant certificates evidencing shares of Stock issued in connection with any Award and instead such shares of Stock shall be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator).

11.6 Paperless Administration. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, then the paperless documentation, granting or exercise of Awards by a Participant may be permitted through the use of such an automated system.

ARTICLE 12

CHANGES IN CAPITAL STRUCTURE

12.1 Adjustments.

(a) In the event of any stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (whether in cash, shares or other property and other than normal cash dividends), or any other change affecting the shares of Stock or the share price of the Stock other than an Equity Restructuring, the Committee shall make such equitable adjustments, if any, as the Committee in its discretion may deem appropriate to reflect such change with respect to (i) the aggregate number and kind of shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Sections 3.1 and 3.3); (ii) the terms and conditions of any outstanding Awards (including, without limitation, any applicable performance targets or criteria with respect thereto); and (iii) the grant or exercise price per share for any outstanding Awards under the Plan. Any adjustment affecting an Award intended as Qualified Performance-Based Compensation shall be made consistent with the requirements of Section 162(m) of the Code.

(b) In the event of any transaction or event described in Section 12.1 or any unusual or nonrecurring transactions or events affecting the Company, any affiliate of the Company, or the financial statements of the

Company or any affiliate, or of changes in applicable laws, regulations or accounting principles, the Committee, in its sole and absolute discretion, and on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Committee determines that such action is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any Award under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:

(i) To provide for either (A) termination of any such Award in exchange for an amount of cash, if any, equal to the amount that would have been attained upon the exercise of such Award or realization of the Participant's rights (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction or event described in this Section 12.1(b) the Committee determines in good faith that no amount would have been attained upon the exercise of such Award or realization of the Participant's rights, then such Award may be terminated by the Company without payment) or (B) the replacement of such Award with other rights or property selected by the Committee in its sole discretion;

(ii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar options, rights or awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices;

(iii) To make adjustments in the number and type of shares of Stock (or other securities or property) subject to outstanding Awards, and in the number and kind of outstanding Restricted Stock or Deferred Stock and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding options, rights and awards and options, rights and awards which may be granted in the future;

(iv) To provide that such Award shall be exercisable or payable or fully vested with respect to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the applicable Award Agreement; and

(v) To provide that the Award cannot vest, be exercised or become payable after such event.

(c) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in Sections 12.1(a) and 12.1(b):

(i) The number and type of securities subject to each outstanding Award and the exercise price or grant price thereof, if applicable, will be equitably adjusted. The adjustments provided under this Section 12.1(c)(i) shall be nondiscretionary and shall be final and binding on the affected Participant and the Company.

(ii) The Committee shall make such equitable adjustments, if any, as the Committee in its discretion may deem appropriate to reflect such Equity Restructuring with respect to the aggregate number and kind of shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Sections 3.1 and 3.3).

12.2 Change in Control.

(a) In the event of a dissolution or liquidation of the Company, then all outstanding Awards shall terminate immediately prior to such event.

(b) In the event of a Change in Control, then any surviving corporation or acquiring corporation shall assume any Awards outstanding under the Plan or shall substitute similar awards (including an award to acquire the same consideration paid to the stockholders in the transaction described in such Change in Control) for those outstanding under the Plan. In the event any surviving corporation or acquiring corporation refuses to assume such Awards or to substitute similar awards for those outstanding under the Plan, then the vesting of such

Awards (and, if applicable, the time during which such Awards may be exercised) shall be accelerated in full (provided, however, that performance-based awards shall be treated as provided for in the applicable Award Agreements), and the Awards shall terminate if not exercised (if applicable) at or prior to such event. With respect to any other Awards outstanding under the Plan, such Awards shall terminate if not exercised (if applicable) prior to such event. The Committee shall have the right to provide that in the event of a Change in Control, performance-based awards shall be (x) considered to be earned and payable based on achievement of performance goals or based on target performance (either in full or pro rata based on the portion of Performance Period completed as of the date of the Change in Control), and any limitations or other restrictions shall lapse and such performance-based awards shall be immediately settled or distributed or (y) converted into Restricted Stock or Restricted Stock Unit Awards based on achievement of performance goals or based on target performance (either in full or pro rata based on the portion of Performance Period completed as of the date of the Change in Control).

(c) Notwithstanding any other provisions of this Plan to the contrary other than Sections 12.3 or 12.5 below, and unless otherwise provided in an Award Agreement, if within twelve (12) months after the date of a Change in Control the Continuous Service of a Participant terminates due to an involuntary termination (not including death or Disability) without Cause, then the vesting and exercisability of all time-based Awards held by such Participant shall be fully accelerated and all performance-based Awards shall be treated as provided for in the applicable Award Agreements, or any reacquisition or repurchase rights held by the Company with respect to an Award shall fully lapse.

12.3 Qualified Performance-Based Compensation. With respect to Awards granted to Covered Employees and are intended to qualify as Qualified Performance-Based Compensation, no adjustment or action described in Section 12.1 or 12.2 or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause such Award to fail to so qualify as Qualified Performance-Based Compensation, unless the Committee determines that the Award should not so qualify. No adjustment or action described in Section 12.1 or 12.2 or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause the Plan to violate Section 422(b)(1) of the Code. Furthermore, no such adjustment or action shall be authorized to the extent such adjustment or action would result in short-swing profits liability under Section 16 of the Exchange Act or violate the exemptive conditions of Rule 16b-3 under the Exchange Act unless the Committee determines that the Award is not to comply with such exemptive conditions.

12.4 No Other Rights. Except as expressly provided in the Plan, no Participant shall have any rights by reason of any subdivision or consolidation of shares of stock of any class, the payment of any dividend, any increase or decrease in the number of shares of stock of any class or any dissolution, liquidation, merger, or consolidation of the Company or any other corporation. Except as expressly provided in the Plan or pursuant to action of the Committee under the Plan, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number of shares of Stock subject to an Award or the grant or exercise price of any Award.

12.5 Section 409A. No action shall be taken under Section 12.1 or 12.2 which shall cause an Award to fail to comply with Section 409A of the Code or the Treasury Regulations thereunder, to the extent applicable to such Award.

12.6 Restrictions on Exercise. In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of Stock or the share price of the Stock including any Equity Restructuring, for reasons of administrative convenience, the Company in its sole discretion may refuse to permit the exercise of any Award during a period of thirty (30) days prior to the consummation of any such transaction.

ARTICLE 13

ADMINISTRATION

13.1 Committee. Unless and until the Board delegates administration of the Plan to a Committee as set forth below, the Plan shall be administered by the full Board, and for such purposes the term “Committee” as used in the Plan shall be deemed to refer to the Board. The Board, at its discretion or as otherwise necessary to comply with the requirements of Section 162(m) of the Code, Rule 16b-3 promulgated under the Exchange Act or to the extent required by any other applicable rule or regulation, shall delegate administration of the Plan to a Committee. The Committee shall consist solely of two or more members of the Board each of whom is a Non-Employee Director, and with respect to awards that are intended to be Performance-Based Awards, an “outside director” within the meaning of Section 162(m) of the Code. Notwithstanding the foregoing: (a) the full Board, acting by a majority of its members in office, shall conduct the general administration of the Plan with respect to all Awards granted to Independent Directors and for purposes of such Awards the term “Committee” as used in the Plan shall be deemed to refer to the Board and (b) the Committee may delegate its authority hereunder to the extent permitted by Section 13.5. Appointment of Committee members shall be effective upon acceptance of appointment. The Board may abolish the Committee at any time and revert in the Board the administration of the Plan. Committee members may resign at any time by delivering written notice to the Board. Vacancies in the Committee may only be filled by the Board.

13.2 Action by the Committee. Unless otherwise established by the Board or in any charter of the Committee, a majority of the Committee shall constitute a quorum, and the acts of a majority of the members present at any meeting at which a quorum is present, and acts approved in writing by a majority of the Committee in lieu of a meeting, shall be deemed the acts of the Committee. Each member of the Committee is entitled to, in good faith, rely or act upon any report or other information furnished to that member by any officer or other employee of the Company or of any Parent or Subsidiary, the Company’s independent certified public accountants, or any executive compensation consultant or other professional retained by the Company or any Parent or Subsidiary to assist in the administration of the Plan.

13.3 Authority of Committee. Subject to any specific designation in the Plan, the Committee has the exclusive power, authority and discretion to:

- (a) Designate Participants to receive Awards;
- (b) Determine the type or types of Awards to be granted to each Participant;
- (c) Determine the number of Awards to be granted and the number of shares of Stock to which an Award will relate;
- (d) Determine the terms and conditions of any Award granted pursuant to the Plan, including, but not limited to, the exercise price, grant price, or purchase price, any restrictions or limitations on the Award, any schedule for lapse of forfeiture restrictions or restrictions on the exercisability of an Award, and accelerations or waivers thereof, any provisions related to non-competition and recapture of gain on an Award, based in each case on such considerations as the Committee in its sole discretion determines; *provided, however*, that the Committee shall not have the authority to accelerate the vesting or waive the forfeiture of any Performance-Based Awards;
- (e) Determine whether, to what extent, and pursuant to what circumstances an Award may be settled in, or the exercise price of an Award may be paid in, cash, Stock, other Awards, or other property, or an Award may be canceled, forfeited, or surrendered;
- (f) Prescribe the form of each Award Agreement, which need not be identical for each Participant;
- (g) Decide all other matters that must be determined in connection with an Award;
- (h) Establish, adopt, or revise any rules and regulations as it may deem necessary or advisable to administer the Plan;

(i) Interpret the terms of, and any matter arising pursuant to, the Plan or any Award Agreement; and

(j) Make all other decisions and determinations that may be required pursuant to the Plan or as the Committee deems necessary or advisable to administer the Plan.

13.4 **Decisions Binding.** The Committee's interpretation of the Plan, any Awards granted pursuant to the Plan, any Award Agreement and all decisions and determinations by the Committee with respect to the Plan are final, binding, and conclusive on all parties.

13.5 **Delegation of Authority.** To the extent permitted by applicable law, the Committee may from time to time delegate its authority under the Plan to a sub-committee or to one or more senior executive officers of the Company to the extent such delegation is appropriate under Section 162(m) of the Code and Rule 16b-3 under the Exchange Act. Any delegation hereunder shall be subject to the restrictions and limits that the Committee specifies at the time of such delegation, and the Committee may at any time rescind the authority so delegated or appoint a new delegatee. At all times, the delegatee appointed under this Section 13.5 shall serve in such capacity at the pleasure of the Committee.

13.6 **Prohibition on Repricing of Awards.** Other than pursuant to Article 12, the Committee shall not without the approval of the Company's stockholders (a) lower the exercise price per Share of an Option or Stock Appreciation Right after it is granted, (b) cancel an Option or Stock Appreciation Right when the exercise price per Share exceeds the Fair Market Value of one Share in exchange for cash or another Award (other than in connection with a Change in Control), or (c) take any other action with respect to an Option or Stock Appreciation Right that would be treated as a repricing under the rules and regulations of the principal U.S. national securities exchange on which the Shares are listed.

ARTICLE 14

EFFECTIVE, RESTATEMENT AND EXPIRATION DATE

14.1 **Effective Date.** The Plan was effective as of April 24, 2007. The Plan was amended and restated effective July 8, 2016 (the "Restatement Date"). The Plan is deemed to be approved by the stockholders if it is approved either:

(a) By a majority of the votes cast at a duly held stockholder's meeting at which a quorum representing a representing a majority of outstanding voting stock is, either in person or by proxy, present and voting on the plan; or

(b) By a method and in a degree that would be treated as adequate under Delaware law in the case of an action requiring stockholder approval.

14.2 **Expiration Date.** The Plan will expire on, and no Award may be granted pursuant to the Plan after April 21, 2026 (the tenth anniversary of the date the Plan, as amended and restated, was approved by the Board). Any Awards that are outstanding upon the expiration of the Plan shall remain in force according to the terms of the Plan and the applicable Award Agreement.

ARTICLE 15

AMENDMENT, MODIFICATION, AND TERMINATION

15.1 **Amendment, Modification, and Termination.** Subject to Section 16.13, with the approval of the Board, at any time and from time to time, the Committee may terminate, amend or modify the Plan; *provided, however*, that (a) to the extent necessary and desirable to comply with any applicable law, regulation, or stock exchange

rule, the Company shall obtain stockholder approval of any Plan amendment in such a manner and to such a degree as required, and (b) stockholder approval is required for any amendment to the Plan that (i) increases the number of shares of Stock available under the Plan (other than any adjustment as provided by Article 12), (ii) permits the Committee to grant Options with an exercise price that is below Fair Market Value on the date of grant, (iii) permits the Committee to extend the exercise period for an Option beyond ten years from the date of grant; or (iv) amends Section 13.6.

15.2 Awards Previously Granted. Except with respect to amendments made pursuant to Section 16.13, no termination, amendment, or modification of the Plan shall adversely affect in any material way any Award previously granted pursuant to the Plan without the prior written consent of the Participant.

ARTICLE 16

GENERAL PROVISIONS

16.1 No Rights to Awards. No Eligible Individual or other person shall have any claim to be granted any Award pursuant to the Plan, and neither the Company nor the Committee is obligated to treat Eligible Individuals, Participants or any other persons uniformly.

16.2 No Stockholders Rights. Except as otherwise provided herein, a Participant shall have none of the rights of a stockholder with respect to shares of Stock covered by any Award until the Participant becomes the record owner of such shares of Stock.

16.3 Withholding. The Company or any Parent or Subsidiary shall have the authority and the right to deduct or withhold, or require a Participant to remit to the Company, an amount sufficient to satisfy federal, state, local and foreign taxes (including the Participant's employment tax obligation) required by law to be withheld with respect to any taxable event concerning a Participant arising as a result of the Plan. The Committee may in its discretion and in satisfaction of the foregoing requirement allow a Participant to elect to have the Company withhold shares of Stock otherwise issuable under an Award (or allow the return of shares of Stock) having a Fair Market Value equal to the sums required to be withheld. Notwithstanding any other provision of the Plan, the number of shares of Stock which may be withheld with respect to the issuance, vesting, exercise or payment of any Award (or which may be repurchased from the Participant of such Award within six months (or such other period as may be determined by the Committee) after such shares of Stock were acquired by the Participant from the Company) in order to satisfy the Participant's federal, state, local and foreign income and payroll tax liabilities with respect to the issuance, vesting, exercise or payment of the Award shall be limited to the number of shares of Stock which have a Fair Market Value on the date of withholding or repurchase equal to the aggregate amount of such liabilities based on the minimum statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such supplemental taxable income (or such other rate that will not cause an adverse accounting consequence or cost).

16.4 No Right to Employment or Services. Nothing in the Plan or any Award Agreement shall interfere with or limit in any way the right of the Company or any Parent or Subsidiary to terminate any Participant's employment or services at any time, nor confer upon any Participant any right to continue in the employ or service of the Company or any Parent or Subsidiary.

16.5 Unfunded Status of Awards. The Plan is intended to be an "unfunded" plan for incentive compensation. With respect to any payments not yet made to a Participant pursuant to an Award, nothing contained in the Plan or any Award Agreement shall give the Participant any rights that are greater than those of a general creditor of the Company or any Parent or Subsidiary.

16.6 Indemnification. To the extent allowable pursuant to applicable law, each member of the Committee or of the Board shall be indemnified and held harmless by the Company from any loss, cost, liability, or expense

that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action or failure to act pursuant to the Plan and against and from any and all amounts paid by him or her in satisfaction of judgment in such action, suit, or proceeding against him or her; *provided* he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled pursuant to the Company's Certificate of Incorporation or Bylaws, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

16.7 Relationship to other Benefits. No payment pursuant to the Plan shall be taken into account in determining any benefits pursuant to any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Parent or Subsidiary except to the extent otherwise expressly provided in writing in such other plan or an agreement thereunder.

16.8 Expenses. The expenses of administering the Plan shall be borne by the Company and its Subsidiaries.

16.9 Titles and Headings. The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control.

16.10 Fractional Shares. No fractional shares of Stock shall be issued and the Committee shall determine, in its discretion, whether cash shall be given in lieu of fractional shares of Stock or whether such fractional shares of Stock shall be eliminated by rounding up or down (on an aggregated basis) as appropriate.

16.11 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan but subject to Section 12.3, the Plan, and any Award granted or awarded to any Participant who is then subject to Section 16 of the Exchange Act, shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by applicable law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

16.12 Government and Other Regulations. The obligation of the Company to make payment of awards in Stock or otherwise shall be subject to all applicable laws, rules, and regulations, and to such approvals by government agencies as may be required. The Company shall be under no obligation to register pursuant to the Securities Act of 1933, as amended, any of the shares of Stock paid pursuant to the Plan. If the shares of Stock paid pursuant to the Plan may in certain circumstances be exempt from registration pursuant to the Securities Act of 1933, as amended, the Company may restrict the transfer of such shares of Stock in such manner as it deems advisable to ensure the availability of any such exemption.

16.13 Section 409A. To the extent that the Committee determines that any Award granted under the Plan is subject to Section 409A of the Code, the Award Agreement evidencing such Award shall incorporate the terms and conditions required by Section 409A of the Code. To the extent applicable, the Plan and Award Agreements shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Restatement Date. Notwithstanding any provision of the Plan to the contrary, in the event that following the Restatement Date the Committee determines that any Award may be subject to Section 409A of the Code and related Department of Treasury guidance (including such Department of Treasury guidance as may be issued after the Restatement Date), the Committee may adopt such amendments to the Plan and the applicable Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Committee determines are necessary or

appropriate to (a) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Award, or (b) comply with the requirements of Section 409A of the Code and related Department of Treasury guidance and thereby avoid the application of any penalty taxes under such Section. If any amount shall be payable with respect to any Award hereunder as a result of a Participant's termination of employment or service and such amount is subject to the provisions of Code Section 409A, then notwithstanding any other provision of this Plan, a termination of employment or service will be deemed to have occurred only at such time as the Participant has experienced a "separation from service" as such term is defined for purposes of Code Section 409A.

16.14 Compensation Recoupment Policy. All Awards shall be subject to the Company's Recoupment Policy, as may be in effect from time to time.

16.15 Governing Law. The Plan and all Award Agreements shall be construed in accordance with and governed by the laws of the State of Delaware.

I hereby certify that the foregoing Plan was duly adopted by the Board of Directors of Orexigen Therapeutics, Inc. on April 21, 2016.

I hereby certify that the foregoing Plan was approved by the stockholders of Orexigen Therapeutics, Inc. on July 8, 2016.

Executed on this day of , 2016.

[Title]

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael A. Narachi, certify that:

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

Date: August 5, 2016

/s/ Michael A. Narachi

Michael A. Narachi
President and Chief Executive Officer

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jason A. Keyes, certify that:

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

Date: August 5, 2016

/s/ Jason A. Keyes

Jason A. Keyes
SVP, Chief Financial Officer
(principal financial and accounting officer of the registrant)

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 Orexigen Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael A. Narachi, President and 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, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 5, 2016

/s/ Michael A. Narachi

Michael A. Narachi
President and Chief Executive Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

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 Orexigen Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jason A. Keyes, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 5, 2016

/s/ Jason A. Keyes

Jason A. Keyes

SVP, Chief Financial Officer

(principal financial and accounting officer of the registrant)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.