Table of Contents

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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED June 30, 2013

or

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

FOR THE TRANSITION PERIOD FROM_____ TO _____.

Commission file number 033-80623

OncoGenex Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**95-4343413**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

1522 217th Place SE, Suite 100, Bothell, Washington 98021
(Address of Principal Executive Offices)

(425) 686-1500
(Registrant's telephone number, including area code)

Indicate by check 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at August 8, 2013
Common Stock, $0.001 par value	**14,680,395**

Table of Contents

OncoGenex Pharmaceuticals, Inc.
Index to Form 10-Q

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

OncoGenex Pharmaceuticals, Inc.
Consolidated Balance Sheets
(In thousands, except per share and share amounts)

	June 30, 2013 (Unaudited) $	December 31, 2012 $
ASSETS		
Current		
Cash and cash equivalents *[note 4]*	18,749	18,075
Short-term investments *[note 4]*	38,243	57,308
Interest receivable	300	327
Amounts receivable	6,439	714
Prepaid expenses and other current assets	3,542	3,755
Total current assets	**67,273**	**80,179**
Restricted cash *[note 4]*	314	314
Property and equipment, net	496	371
Other assets	1,225	1,152
Total assets	**69,308**	**82,016**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current		
Accounts payable	130	1,329
Accrued liabilities	9,273	4,180
Accrued compensation	1,137	1,541
Current portion of long-term obligations *[note 6]*	1,089	1,084
Warrant liability *[note 4 and note 5]*	1,087	3,422
Total current liabilities	**12,716**	**11,556**
Long-term obligations, less current portion *[note 6]*	3,907	4,253
Total liabilities	**16,623**	**15,809**
Commitments and contingencies *[note 7]*		
Stockholders' equity:		
Common shares *[note 5]*:		
$0.001 par value, 50,000,000 and 25,000,000 shares authorized and 14,680,395 and 14,656,916 issued and outstanding at June 30, 2013 and December 31, 2012, respectively	15	15
Additional paid-in capital	167,011	165,395
Accumulated deficit	(116,957)	(101,840)
Accumulated other comprehensive income	2,616	2,637
Total stockholders' equity	**52,685**	**66,207**
Total liabilities and stockholders' equity	**69,308**	**82,016**

Subsequent events [note 8]

See accompanying notes.

OncoGenex Pharmaceuticals, Inc.
Consolidated Statements of Loss and Comprehensive Loss
(Unaudited)
(In thousands, except per share and share amounts)

	Three months Ended June 30,		Six months Ended June 30,	
	2013	2012	2013	2012
	$	$	$	$
COLLABORATION REVENUE *[note 3]*	6,340	2,429	11,416	3,745
EXPENSES				
Research and development	13,263	6,326	24,118	11,408
General and administrative	2,473	2,047	4,973	3,784
Total operating expenses	15,736	8,373	29,091	15,192
OTHER INCOME (EXPENSE)				
Interest income	39	91	91	141
Other	36	(6)	132	17
Gain on warrants	901	1,644	2,335	214
Total other income	976	1,729	2,558	372
Net loss	**(8,420)**	**(4,215)**	**(15,117)**	**(11,075)**
OTHER COMPREHENSIVE LOSS				
Net unrealized loss on securities	(15)	(19)	(21)	(19)
Comprehensive loss	**(8,435)**	**(4,234)**	**(15,138)**	**(11,094)**
Basic and diluted net loss per common share *[note 5]*	(0.57)	(0.29)	(1.03)	(0.89)
Weighted average number of common shares *[note 5]*	14,673,771	14,554,502	14,667,244	12,394,869

See accompanying notes.

OncoGenex Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Six months ended June 30,	
	2013	2012
	$	$
OPERATING ACTIVITIES		
Net loss	(15,117)	(11,075)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on warrants	(2,335)	(214)
Depreciation	100	43
Stock-based compensation *[note 5[c]]*	1,603	1,029
Changes in operating assets and liabilities:		
Interest receivable	27	(109)
Amounts receivable	(5,725)	(35)
Prepaid expenses	140	(7,154)
Accounts payable	(1,199)	(896)
Accrued liabilities	5,093	718
Accrued compensation	(404)	(156)
Restricted Cash	—	63
Excess lease liability *[note 6]*	(331)	(388)
Lease Obligations	(10)	12
Deferred collaboration revenue	—	(2,899)
Cash used in operating activities	**(18,158)**	**(21,061)**
FINANCING ACTIVITIES		
Proceeds from exercise of stock options	10	114
Issuance of common shares, net of share issue costs	—	53,777
Cash provided by financing activities	**10**	**53,891**
INVESTING ACTIVITIES		
Purchase of investments	(30,065)	(74,302)
Proceeds from maturities of investments	49,130	26,905
Purchase of property and equipment	(225)	(89)
Cash provided by (used in) investing activities	**18,840**	**(47,486)**
Effect of exchange rate changes on cash	(18)	(19)
Increase (decrease) in cash and cash equivalents during the period	674	(14,675)
Cash and cash equivalents, beginning of the period	18,075	28,517
Cash and cash equivalents, end of the period	**18,749**	**13,842**
Supplemental cash flow information		
Property and equipment acquired under lease obligation	24	—

See accompanying notes.

OncoGenex Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
(Unaudited)

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

OncoGenex Pharmaceuticals, Inc. (referred to as "OncoGenex," "we," "us," or "our") is a biopharmaceutical company committed to the development and commercialization of new therapies that address treatment resistance in cancer patients. We were incorporated in the state of Delaware and are headquartered in Bothell, Washington and have a subsidiary in Vancouver, British Columbia.

The unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying unaudited consolidated financial statements reflect all adjustments (consisting only of normal recurring items) which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented. The accompanying consolidated Balance Sheet at December 31, 2012 has been derived from the audited consolidated financial statements included in our Annual Report on Form 10-K for the year then ended. The unaudited consolidated financial statements and related disclosures have been prepared with the assumption that users of the interim financial information have read or have access to the audited consolidated financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2012 and filed with the United States Securities and Exchange Commission, or the SEC, on March 7, 2013.

The consolidated financial statements include the accounts of OncoGenex and our wholly owned subsidiary, OncoGenex Technologies Inc., or OncoGenex Technologies. All intercompany balances and transactions have been eliminated. Certain comparative figures have been reclassified to conform with the financial presentation adopted for the current year. Accrued liabilities and accrued compensation were reclassified and shown separately on the face of the consolidated balance sheet rather than combined with accounts payable.

2. ACCOUNTING POLICIES

Recently Adopted Accounting Policies

In February 2013, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Updates, or ASU, No. 2013-02, "Other Comprehensive Income." This ASU requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under generally accepted accounting principles in the United States, or U.S. GAAP, to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under U.S. GAAP that provide additional detail about those amounts. The adoption of this standard did not have a significant impact on our financial position or results of operations.

In December 2011, the FASB issued ASU No. 2011-12, "Comprehensive Income." This ASU defers the effective date for amendments to the presentation of reclassification of items out of accumulated other comprehensive income in ASU No. 2011-05. The amendments are being made to allow the FASB time to redeliberate whether to present on the face of the financial statements the

effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income for all periods presented. While the FASB is considering the operational concerns about the presentation requirements for reclassification adjustments and the needs of financial statement users for additional information about reclassification adjustments, entities should continue to report reclassifications out of accumulated other comprehensive income consistent with the presentation requirements in effect before Update 2011-05.

All other requirements in ASU 2011-05 are not affected by this ASU, including the requirement to report comprehensive income either in a single continuous financial statement or in two separate but consecutive financial statements. Public entities are required to apply these requirements for fiscal years, and interim periods within those years, beginning after December 15, 2011. We adopted this standard on a prospective basis beginning in the quarter ended March 31, 2012.

In May 2011, the FASB issued ASU No. 2011-04, “Fair Value Measurement.” This ASU clarifies the concepts related to highest and best use and valuation premise, blockage factors and other premiums and discounts, the fair value measurement of financial instruments held in a portfolio and of those instruments classified as a component of shareowners’ equity. The guidance includes enhanced disclosure requirements about recurring Level 3 fair value measurements, the use of nonfinancial assets, and the level in the fair value hierarchy of assets and liabilities not recorded at fair value. The provisions of this ASU are effective prospectively for interim and annual periods beginning on or after December 15, 2011. We adopted this standard on a prospective basis beginning in the quarter ended March 31, 2012.

3. COLLABORATION AGREEMENT

On December 20, 2009, we, through our wholly-owned subsidiary, OncoGenex Technologies, entered into a Collaboration Agreement with Teva Pharmaceutical Industries Ltd., or Teva, for the development and global commercialization of custirsen (and related compounds), a pharmaceutical compound designed to inhibit the production of clusterin, a protein we believe is associated with cancer treatment resistance, or the Licensed Product. Under the Collaboration Agreement, Teva paid us upfront payments in the aggregate amount of $50 million, acquired $10 million of our common stock at a premium under a separate Stock Purchase Agreement and agreed to pay up to $370 million upon the achievement of developmental and commercial milestones and royalties at percentage rates ranging from the mid-teens to mid-twenties on net sales, depending on aggregate annual net sales of the Licensed Product. We do not expect to receive any payments from Teva resulting from the achievement of developmental or commercial milestones or royalties in 2013.

Under the Stock Purchase Agreement, Teva’s $10 million equity investment in us was made at a 20% premium to a thirty-day average closing price, resulting in the issuance of 267,531 of our common shares purchased at a price of $37.38 per share. The 20% share premium was included as consideration for the custirsen license and was included in Collaboration Revenue in 2009.

In connection with the Collaboration Agreement and pursuant to the terms of agreements between us and Isis Pharmaceuticals, Inc., or Isis, relating to custirsen, we paid Isis $10 million which was recorded as research and development expense in 2009. We also paid approximately $0.3 million to the University of British Columbia, or UBC, pursuant to the terms of their license agreement relating to custirsen, which has been recorded as research and development expense in 2009. Pursuant to the terms of the agreements, we anticipate that we would be required to pay third parties 31% of any milestone payments that are not based on a percentage of net sales of the Licensed Product. Pursuant to the terms of these agreements, we anticipate we will pay royalties to third-parties of 4.88% to 8.00% of net sales, unless our royalties are adjusted for competition from generic compounds, in which case royalties to third parties will also be subject to adjustment on a country-by-country basis. Certain third-party royalties are tiered based on the royalty rate received by us. Minimum royalty rates payable by us assume certain third-party royalties are not paid at the time that the

Licensed Product is marketed due to the expiration of patents held by such third parties. Maximum royalty rates assume all third-party royalty rates currently in effect continue in effect at the time the Licensed Product is marketed. We do not expect to make any royalty payments to Isis in 2013. Teva has the exclusive worldwide right and license to develop and commercialize products containing custirsen and related compounds. We have an option to co-promote any Licensed Product in the United States and Canada.

Teva is responsible for all costs relating to product commercialization including costs incurred in relation to our co-promotion option, except for start-up costs in advance of commercialization.

On March 6, 2012, OncoGenex Technologies and Teva entered into an amendment to the Collaboration Agreement, or the Collaboration Agreement Amendment. Under the Collaboration Agreement Amendment, OncoGenex Technologies and Teva revised the clinical development plan, or Amended Clinical Development Plan, under which the following three Phase 3 clinical trials have been initiated:

- The SYNERGY Trial: The Phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with first-line docetaxel treatment in patients with castrate resistant prostate cancer, or CRPC.
- The AFFINITY Trial: The Phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with cabazitaxel treatment as second-line chemotherapy in patients with CRPC.
- The ENSPIRIT Trial: The Phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with docetaxel treatment as second-line chemotherapy in patients with non-small cell lung cancer, or NSCLC.

Teva will be responsible for conducting any other trials and development work necessary to obtain required regulatory approvals. We may assume some of these activities if assigned by the joint steering committee. Teva will be responsible for all such costs. The joint steering committee will oversee the development and regulatory approval of any Licensed Product. We may terminate our participation in the joint steering committee at any time.

We were required to spend $30 million in direct and indirect development costs such as full-time equivalent, or FTE, reimbursement for time incurred by OncoGenex personnel for the benefit of the custirsen development plan, such contribution to be funded by the upfront payment provided by Teva as an advanced reimbursement for our Development Expenses. As of December 31, 2012, we had spent the entire $30 million related to the development of custirsen. Teva will fund all other expenses under the Clinical Development Plan.

The Collaboration Agreement will remain in effect, on a country-by-country basis, until the expiration of the obligation of Teva to pay royalties on sales of the Licensed Product in such country (or earlier termination under its terms). After the completion of all three Phase 3 clinical trials set forth in the Clinical Development Plan, or upon early termination due to a material adverse change in our patent rights related to custirsen or safety issues or “futility” as defined in the Collaboration Agreement, Teva may terminate the Collaboration Agreement at its sole discretion upon three months’ notice if notice is given prior to regulatory approval of a Licensed Product and upon six months’ notice if notice is given after such regulatory approval. If Teva terminates the Collaboration Agreement for any reasons other than an adverse change in custirsen patent rights, safety issues or “futility” determination as previously described, it will remain responsible for paying for any remaining costs of all three Phase 3 clinical trials, except for specified development expenses that are our responsibility. Either party may terminate the Collaboration Agreement for an uncured material breach by the other party, unless such breach is not curable, in which case the agreement may not be terminated unless the other party fails to use commercially reasonable efforts to prevent a similar subsequent breach. Either party also may terminate the Collaboration

Agreement upon the bankruptcy of either party. If the Collaboration Agreement is terminated by us for other than an uncured material breach by Teva, we will pay Teva a royalty on sales of Licensed Products. The percentage rates of such royalties (which are in the single digits) vary depending on whether termination occurs prior to the first regulatory approval in the United States or a primary European Market or after one of these approvals. These royalties would expire on a country-by-country basis on the earlier of ten years after the first commercial sale of a Licensed Product or certain thresholds related to generic competition.

In the event of a change of control of OncoGenex, within 90 days of the change of control, Teva may terminate the joint steering committee at its sole discretion, terminate the co-promotion option at its sole discretion if the option has not been exercised by us or, if exercised, but not yet executed by us, or terminate the co-promotion option if in its commercially reasonable opinion co-promotion with our successor would be materially detrimental to Teva's interests.

Of the total $6.4 million amount receivable at June 30, 2013, $6.3 million represents unbilled expense reimbursements from Teva. Consequently, we are exposed to a significant concentration of credit risk. Revenue under the Teva agreement for the three and six months ended June 30, 2013 was $6.3 million and $11.4 million, respectively.

4. FAIR VALUE MEASUREMENTS

With the adoption of ASC 820 "Fair Value Measurements and Disclosures," beginning January 1, 2008, assets and liabilities recorded at fair value in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair value. For certain of our financial instruments including amounts receivable, interest receivable and accounts payable, the carrying values approximate fair value due to their short-term nature.

ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. In accordance with ASC 820, these inputs are summarized in the three broad levels listed below:

- Level 1 – Quoted prices in active markets for identical securities.
- Level 2 – Other significant inputs that are observable through corroboration with market data (including quoted prices in active markets for similar securities).
- Level 3 – Significant unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability.

As quoted prices in active markets are not readily available for certain financial instruments, we obtain estimates for the fair value of financial instruments through third-party pricing service providers.

In determining the appropriate levels, we performed a detailed analysis of the assets and liabilities that are subject to ASC 820.

We invest our excess cash in accordance with investment guidelines that limit the credit exposure to any one financial institution other than securities issued by the U.S. Government. These securities are not collateralized and mature within one year or less.

A description of the valuation techniques applied to our financial instruments measured at fair value on a recurring basis follows.

Financial Instruments

Cash

Substantially all of our cash and cash equivalents are held on deposit with large well established U.S. and Canadian financial institutions.

U.S. Government and Agency Securities

U.S. Government Securities U.S. government securities are valued using quoted market prices. Valuation adjustments are not applied. Accordingly, U.S. government securities are categorized in Level 1 of the fair value hierarchy.

U.S. Agency Securities U.S. agency securities are comprised of two main categories consisting of callable and non-callable agency issued debt securities. Non-callable agency issued debt securities are generally valued using quoted market prices. Callable agency issued debt securities are valued by benchmarking model-derived prices to quoted market prices and trade data for identical or comparable securities. Actively traded non-callable agency issued debt securities are categorized in Level 1 of the fair value hierarchy. Callable agency issued debt securities are categorized in Level 2 of the fair value hierarchy.

Corporate and Other Debt

Corporate Bonds and Commercial Paper The fair value of corporate bonds and commercial paper is estimated using recently executed transactions, market price quotations (where observable), bond spreads or credit default swap spreads adjusted for any basis difference between cash and derivative instruments. The spread data used are for the same maturity as the bond. If the spread data does not reference the issuer, then data that reference a comparable issuer are used. When observable price quotations are not available, fair value is determined based on cash flow models with yield curves, bond or single name credit default swap spreads and recovery rates based on collateral values as significant inputs. Corporate bonds and commercial paper are generally categorized in Level 2 of the fair value hierarchy; in instances where prices, spreads or any of the other aforementioned key inputs are unobservable, they are categorized in Level 3 of the hierarchy.

Warrants

As of June 30, 2013, we recorded a $1.1 million warrant liability. We reassess the fair value of the common stock warrants at each reporting date utilizing a Black-Scholes pricing model. Inputs used in the pricing model include estimates of stock price volatility, expected warrant life and risk-free interest rate. The computation of expected volatility was based on the historical volatility of shares of our common stock for a period that coincides with the expected life of the warrants. Warrants are categorized in Level 3 of the fair value hierarchy.

The following table presents information about our assets and liabilities that are measured at fair value on a recurring basis, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value (in thousands):

June 30, 2013	Level 1	Level 2	Level 3	Total
Assets				
Cash	$ 3,986	$ —	$ —	$ 3,986
Money market securities	15,077	—	—	15,077
Government securities	—	—	—	—
Corporate bonds and commercial paper	—	38,243	—	38,243
Total assets	**$19,063**	**$38,243**	**$ —**	**$57,306**
Liabilities				
Warrants	**$ —**	**$ —**	**$**1,087	**$** 1,087

The following table presents the changes in fair value of our total Level 3 financial liabilities for the six months ended June 30, 2013. There have been no transfers of assets or liabilities to or from level 3 (in thousands):

	Liability at December 31, 2012	Gain on warrants	Liability at June 30, 2013
Warrant liability	$ 3,422	$ 2,335	$ 1,087

Marketable securities consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
June 30, 2013				
Cash	$ 3,986	$ —	$ —	$ 3,986
Money market securities	14,763	—	—	14,763
Total cash and cash equivalents	**$ 18,749**	**$ —**	**$ —**	**$ 18,749**
Money market securities	314	—	—	314
Total restricted cash	**$ 314**	**$ —**	**$ —**	**$ 314**
Corporate bonds and commercial paper	38,268	2	(27)	38,243
Total short-term investments	**$ 38,268**	**$ 2**	**$ (27)**	**$ 38,243**

Our gross realized gains and losses on sales of available-for-sale securities were not material for the three and six months ended June 30, 2013 and 2012.

All securities included in cash and cash equivalents had maturities of 90 days or less at the time of purchase. All securities included in short-term investments have maturities of within one year of the balance sheet date. The cost of securities sold is based on the specific identification method.

We only invest in A (or equivalent) rated securities. We do not believe that there are any other than temporary impairments related to our investment in marketable securities at June 30, 2013, given the quality of the investment portfolio and subsequent proceeds collected on sale of securities that reached maturity.

5. COMMON STOCK

[a] Authorized

50,000,000 authorized common shares, par value of $0.001, and 5,000,000 preferred shares, par value of $0.001.

[b] Issued and outstanding shares

At-The-Market Issuance Sales Agreement

On June 18, 2012, we entered into an At-the-Market Issuance Sales Agreement, or Sales Agreement, with MLV & Co. LLC, or MLV, under which we may offer and sell shares of our common stock having aggregate sales proceeds of up to $25 million from time to time through MLV as our sales agent. Sales of our common stock through MLV, if any, will be made by any method permitted that is deemed an "at the market" offering as defined in Rule 415 under the Securities Act of 1933, as amended, including by means of ordinary brokers' transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and MLV. MLV will use commercially reasonable efforts to sell our common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay MLV a commission of up to 3.0% of the gross sales proceeds of any shares of common stock sold through MLV under the Sales Agreement. We are not obligated to make any sales of common stock under the Sales Agreement. The offering of our shares of common stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms. To date, no shares have been sold under the Sales Agreement.

Equity Award Issuances and Settlements

During the six month period ended June 30, 2013, we issued 3,475 and 20,004 common shares to satisfy stock option exercises and restricted stock unit settlements, respectively, compared with the issuance of 33,938 common shares to satisfy stock option exercises during the six month period ended June 30, 2012. There were no restricted stock unit settlements in 2012.

[c] Stock options

2010 Performance Incentive Plan

As of June 30, 2013 we had reserved, pursuant to various plans, 2,407,507 common shares for issuance upon exercise of stock options and settlement of restricted stock units by employees, directors, officers and consultants of ours, of which 1,000,227 are reserved for options currently outstanding, 384,182 are reserved for restricted stock units currently outstanding and 1,023,098 are available for future equity grants.

Stock Option Summary

Options vest in accordance with terms as determined by our Board of Directors, or the Board, which terms are typically four years for employee grants and one to three years for Board option grants. The expiry date for each option is set by the Board, which is typically seven to ten years. The exercise price of the options is determined by the Board, but generally will be at least equal to the fair value of the share at the grant date.

Stock option transactions and the number of stock options outstanding are summarized below:

	Number of Optioned Common Shares #	Weighted Average Exercise Price $
Balance, December 31, 2012	**804,781**	**11.34**
Option grants	209,282	11.81
Option expirations	(3,061)	4.11
Option exercises	(3,475)	3.00
Option forfeitures	(7,300)	12.23
Balance, June 30, 2013	**1,000,227**	**11.48**

The fair value of each stock award is estimated on the grant date using the Black-Scholes option-pricing model based on the weighted-average assumptions noted in the following table:

	Six months ended June 30,	
	2013	2012
Risk-free interest rates	1.16%	0.97%
Expected dividend yield	0%	0%
Expected life	5.8 years	6.0 years
Expected volatility	87.17%	95.82%

The expected life was calculated based on the simplified method as permitted by the SEC's Staff Accounting Bulletin 110, Share-Based Payment. The expected volatility of options granted in 2012 and 2013 was calculated based on the historical volatility of the shares of our common stock. The computation of expected volatility of options granted prior to 2012 was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. The risk-free interest rate is based on a U.S. Treasury instrument whose term is consistent with the expected life of the stock options. In addition to the assumptions above, as required under ASC 718, management made an estimate of expected forfeitures and is recognizing compensation costs only for those equity awards expected to vest.

The results for the periods set forth below included share-based compensation expense for stock options and restricted stock units in the following expense categories of the consolidated statements of loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2013	2012	2013	2012
	$	$	$	$
Research and development	415	293	727	428
General and administrative	440	416	876	601
Total share-based compensation	**855**	**709**	**1,603**	**1,029**

As of June 30, 2013 and December 31, 2012, the total unrecognized compensation expense related to stock options granted was $3.5 million and $2.7 million respectively, which is expected to be recognized as expense over a period of approximately 2.6 years.

As of June 30, 2013 and December 31, 2012, a total of 3.0 million and 2.6 million, respectively, of options, restricted stock units and warrants have not been included in the calculation of potential common shares in the loss per share computation as their effect on diluted per share amounts would have been anti-dilutive.

[d] Restricted Stock Unit Awards

We grant restricted stock unit awards that generally vest and are expensed over a four year period. In 2013, we also granted restricted stock unit awards that vest in conjunction with certain performance conditions to certain executive officers, key employees and consultants. At each reporting date, we are required to evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon our assessment of accomplishing each performance provision. For the three and six months ended June 30, 2013, $0.4 million and $0.7 million, respectively, of compensation expense was recognized related to these awards, compared to $0.2 million and $0.2 million for the three and six months ended June 30, 2012, respectively.

The following table summarizes our restricted stock unit award activity during the six months ended June 30, 2013:

	2013	
	Stock Awards #	Weighted-Average Grant Date Fair Value $
Outstanding January 1	172,035	13.01
Granted	238,895	11.89
Vested	(23,899)	12.82
Forfeited or expired	(2,849)	12.54
Outstanding June 30	**384,182**	**12.33**

As of June 30, 2013, we had approximately $3.0 million in total unrecognized compensation expense related to our restricted stock unit awards that is to be recognized over a weighted-average period of approximately three years.

[e] Non-employee options and restricted stock units

We recognize non-employee stock-based compensation expense over the period of expected service by the non-employee. As the service is performed, we are required to update our valuation assumptions, re-measure unvested options and restricted stock units and record the stock-based compensation using the valuation as of the vesting date. This differs from the accounting for employee awards where the fair value is determined at the grant date and is not subsequently adjusted. This re-measurement may result in higher or lower stock-based compensation expense in the Consolidated Statements of Loss and Comprehensive Loss. As such, changes in the market price of our stock could materially change the value of an option or restricted stock unit and the resulting stock-based compensation expense.

[f] Stock Warrants

As of June 30, 2013, there were exercisable warrants outstanding to purchase 1,587,301 shares of common stock at an exercise price of $20 per share, expiring in October 2015. No warrants were exercised during the six month periods ended June 30, 2013 or 2012. The estimated fair value of warrants issued is reassessed at each balance sheet date using the Black-Scholes option pricing model. The following assumptions were used to value the warrants on the following balance sheet dates:

	Six Months Ended June 30,	
	2013	2012
Risk-free interest rates	0.45%	0.46%
Expected dividend yield	0%	0%
Expected life	2.3 years	3.3 years
Expected volatility	44%	67%

6. EXCESS LEASE LIABILITY

On August 21, 2008, Sonus Pharmaceuticals, Inc., or Sonus, completed a transaction, or the Arrangement, with OncoGenex Technologies whereby Sonus acquired all of the outstanding preferred shares, common shares and convertible debentures of OncoGenex Technologies. Sonus then changed its name to OncoGenex Pharmaceuticals, Inc. Prior to the Arrangement, Sonus entered into a non-cancellable lease arrangement for office space located in Bothell, Washington, which is considered to be in excess of our current requirements. The estimated value of the liability remaining with respect to excess facilities was $4.6 million as of December 31, 2012. In the six months ended June 30, 2013, with respect to excess facilities, $0.3 million was amortized into income resulting in a remaining liability of $4.3 million at June 30, 2013. The liability is computed as the present value of the difference between the remaining lease payments due less the estimate of net sublease income and expenses and has been accounted for in accordance with the then effective Emerging Issues Task Force No. 95-3, “Recognition of Liabilities in Connection with a Purchase Business Combination.” This represents our best estimate of the liability. Subsequent changes in the liability due to changes in estimates of sublease and occupancy assumptions are recognized as adjustments to the related liability with an offset to restructuring (gain)/loss in future periods.

(In thousands)	Liability at December 31, 2012	Amortization of excess lease facility	Additional liability recorded	Liability at June 30, 2013
Current portion of excess lease facility	1,050	15	—	1,065
Long-term portion of excess lease facility	3,536	(346)	—	3,190
Total	**4,586**	**(331)**	**—**	**4,255**

7. COMMITMENTS AND CONTINGENCIES

Teva Pharmaceutical Industries Ltd.

In December 2009, we, through our wholly-owned subsidiary, OncoGenex Technologies, entered into a Collaboration Agreement with Teva for the development and global commercialization of custirsen (and related compounds). Under the Collaboration Agreement, Teva made upfront payments in the aggregate amount of $50 million, and may make additional payments up to $370

million upon the achievement of developmental and commercial milestones and royalties at percentage rates ranging from the mid-teens to mid-twenties on net sales. Teva also acquired $10 million of our common stock at a premium under a separate Stock Purchase Agreement. We were required to contribute $30 million in direct and indirect costs towards the Clinical Development Plan. As of December 31, 2012, the full amount of the $30 million in direct and indirect costs was incurred by us. Accordingly, Teva will fund all other expenses under the Clinical Development Plan, which represents all of our revenues in the three and six months ended June 30, 2013.

Pursuant to the Collaboration Agreement, we agreed to collaborate with Teva in the development and global commercialization of custirsen. Teva received the exclusive worldwide right and license to develop and commercialize products containing custirsen and related compounds, or the Licensed Products. We have an option to co-promote custirsen in the United States and Canada.

In addition to the development costs noted above, Teva is also responsible for all costs relating to product commercialization including costs incurred in relation to our co-promotion option, except for start-up costs in advance of commercialization.

Isis Pharmaceuticals Inc. and University of British Columbia

We are obligated to pay milestone payments of up to CAD $1.6 million and $7.75 million pursuant to license agreements with the UBC and Isis, respectively, upon the achievement of specified product development milestones related to apatorsen, the United States Adopted Names, or USAN, Council approved name, or generic name, for OGX-427, and OGX-225 and low to mid-single digit royalties on future product sales.

In addition, we are required to pay to Isis 30% of all non-royalty revenue (defined to mean revenue not based on net sales of products) it receives. Isis has disclosed in its SEC filings that it is entitled to receive 30% of the up to $370 million in milestone payments we may receive from Teva as part of the Collaboration Agreement; however, we believe that certain of the milestone payments related to sales targets may qualify as royalty revenue (defined to mean revenue based on net sales of products), and therefore be subject to the lesser payment obligations. No assurance can be provided that we will be entitled to receive these milestone payments or, if it is, that the applicable amount payable to Isis will be less than 30%. We are also obligated to pay to UBC certain patent costs and annual license maintenance fees for the extent of the patent life of CAD $8,000 per year. We paid Isis and UBC USD $0.8 million and CAD $0.1 million, respectively, in 2010 upon the initiation of a Phase 2 clinical trial of apatorsen (OGX-427) in patients with CRPC. We do not anticipate making any royalty payments to Isis under the terms of the agreement in 2013. The UBC agreements have effective dates ranging from November 1, 2001 to April 5, 2005 and each agreement expires upon the later of 20 years from its effective date or the expiry of the last patent licensed thereunder, unless otherwise terminated.

Unless otherwise terminated, the Isis agreements for custirsen and apatorsen (OGX-427) will continue for each product until the later of 10 years after the date of the first commercial product sale, or the expiration of the last to expire of any patents required to be licensed in order to use or sell the product, unless OncoGenex Technologies abandons either custirsen or apatorsen (OGX-427) and Isis does not elect to unilaterally continue development. The Isis agreement for OGX-225 will continue into perpetuity unless OncoGenex Technologies abandons the product and Isis does not elect to unilaterally continue development.

To facilitate the execution and performance of the Collaboration Agreement with Teva, we and Isis agreed to amend the Isis License Agreement and we and UBC agreed to make a corresponding amendment to the UBC License Agreement, in each case, effective December 19, 2009 and December 20, 2009, respectively.

The amendment to the Isis License Agreement provides, among other things, that if we are subject to change of control with a third party, where the surviving company immediately following such change of control has the right to develop and sell the product, then (i) a milestone payment of $20 million will be due and payable to Isis 21 days following the first commercial sale of the product in the United States; and (ii) unless such surviving entity had previously sublicensed the product and a royalty rate payable to Isis by us has been established, the applicable royalty rate payable to Isis will thereafter be the maximum amount payable under the Isis License Agreement. Any non-royalty milestone amounts previously paid will be credited toward the $20 million milestone if not already paid. As a result of the $10 million milestone payment payable to Isis in relation to the Collaboration Agreement, the remaining amount owing in the event of change of control discussed above is a maximum of $10 million. Because we have now licensed the product to Teva and established a royalty rate payable to Isis, no royalty rate adjustments would apply if Teva were to acquire us and become the surviving company.

Lease Arrangements

We have an operating lease agreement for office space being used in Vancouver, Canada, which expires in September 2014.

Future minimum lease payments under the Vancouver lease are as follows (in thousands):

	CAD
2013	$ 51
2014	76
Total	**$127**

In November 2006, prior to the Arrangement, Sonus entered into a non-cancellable operating lease agreement for office space in Bothell, Washington, expiring in 2017 (note 6). In connection with the lease, Sonus was required to provide a cash security deposit of approximately $0.5 million, which is included in Other Assets. In addition, a standby letter of credit for $0.3 million is deposited in a restricted money market account as collateral. We have recorded a liability in the excess facilities lease charge of $4.3 million as at June 30, 2013 (note 6).

If we are unable to exit or sublet portions of this leased space, the future minimum lease payments are as follows (in thousands):

2013	$ 1,090
2014	2,246
2015	2,313
Remainder	4,836
Total	**$10,485**

Consolidated rent expense related to the Bothell, Washington and Vancouver, Canada offices in the three and six months ended June 30, 2013 was $0.7 million $1.4 million, respectively. Consolidated rent expense for the three and six months ended June 30, 2012 was $0.7 million and $1.3 million, respectively.

Guarantees and Indemnifications

We indemnify our officers, directors and certain consultants for certain events or occurrences, subject to certain limits, while the officer, director or consultant is or was serving at our request in such capacity. The term of the indemnification period is equal to the officers', directors' and certain consultants' lifetime.

The maximum amount of potential future indemnification is unlimited; however, we have obtained director and officer insurance that limits our exposure and may enable us to recover a portion of any future amounts paid. We believe that the fair value of these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations as of June 30, 2013.

We have agreements with certain organizations with which we do business that contain indemnification provisions pursuant to which we typically agree to indemnify the party against certain types of third-party claims. We accrue for known indemnification issues when a loss is probable and can be reasonably estimated. There were no accruals for or expenses related to indemnification issues for any period presented.

8. SUBSEQUENT EVENTS

We performed an evaluation of events occurring subsequent to June 30, 2013. Based on this evaluation, no material events have occurred requiring financial statement disclosure.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

INFORMATION REGARDING FORWARD LOOKING STATEMENTS

This document contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve a number of risks and uncertainties. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, interest rates, outcome of contingencies, financial condition, results of operations, liquidity, business strategies, cost savings, objectives of management and other statements that are not historical facts. You can find many of these statements by looking for words like "believes," "expects," "anticipates," "estimates," "may," "should," "will," "could," "plan," "intend" or similar expressions in this document or in documents incorporated by reference into this document. We intend that such forward-looking statements be subject to the safe harbors created thereby. Examples of these forward-looking statements include, but are not limited to:

- progress and preliminary and future results of clinical trials conducted by us or our collaborators;
- anticipated regulatory filings and requirements and future clinical trials conducted by us or our collaborators;
- timing and amount of future contractual payments, product revenue and operating expenses;
- market acceptance of our products and the estimated potential size of these markets; and
- our anticipated future capital requirements and the terms of any capital financing agreements.

These forward-looking statements are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. Factors that might cause such a difference include those discussed in Item 1A "Risk Factors," as well as those discussed elsewhere in the Quarterly Report on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document or, in the case of documents referred to or incorporated by reference, the date of those documents.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

Overview

We are a biopharmaceutical company committed to the development and commercialization of new therapies that address treatment resistance in cancer patients. We have three product candidates in our pipeline: custirsen, apatorsen (OGX-427) and OGX-225, each of which has a distinct mechanism of action and represents a unique opportunity for cancer drug development. Of the product candidates in our pipeline, custirsen and apatorsen (OGX-427) are clinical-stage assets.

Our product candidates focus on mechanisms of treatment resistance in cancer patients and are designed to block the production of specific proteins that we believe promote treatment resistance and survival of tumor cells and are over-produced in response to a variety of cancer treatments. Our aim in targeting these particular proteins is to disable the tumor cell's adaptive defenses, thereby rendering the tumor cells more susceptible to attack with a variety of cancer therapies. We believe this approach will increase survival time and improve the quality of life for cancer patients.

Product Candidate Custirsen

In December 2009, we announced our entry into the Collaboration Agreement with Teva for the development and global commercialization of custirsen (and related compounds targeting clusterin, excluding apatorsen (OGX-427) and OGX-225).

We and Teva have developed an Amended Clinical Development Plan under which the following three Phase 3 clinical trials have been initiated:

- The SYNERGY Trial: The Phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with first-line docetaxel treatment in patients with castrate resistant prostate cancer, or CRPC. During discussions with the U.S. Food and Drug Administration, or FDA, the FDA informed us that an application supported primarily by the results of SYNERGY alone would be acceptable for submission for market approval. SYNERGY patient enrollment was completed in the fourth quarter of 2012. Over 1,000 men have now been enrolled in order to show a survival benefit with 90% power based on a hazard ratio of 0.75. The SYNERGY trial is continuing as planned per the recommendation of an independent Data Monitoring Committee, or DMC, who have completed the second futility analyses per the Special Protocol Assessment, or SPA, approved protocol. The planned efficacy interim analysis has not yet occurred. As a result of death events occurring more slowly than previously expected, the anticipated timing of the pre-specified number of events is currently projected to occur late in the first quarter or early in the second quarter of 2014. Survival results are expected to be announced in mid-2014. No conclusion regarding the possible outcome of the trial can or should be drawn from the fact that death events have occurred more slowly than expected.
- The AFFINITY Trial: The Phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with cabazitaxel treatment as second-line chemotherapy in patients with CRPC. We expect to enroll approximately 630 patients to show a survival benefit with 85% power based on a hazard ratio of 0.75. We initiated this Phase 3 clinical trial in August 2012 and enrollment continues.
- The ENSPIRIT Trial: The Phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with docetaxel treatment as second-line chemotherapy in patients with non-small cell lung cancer, or NSCLC. We expect to enroll approximately 1,100 patients in order to show a survival benefit with 90% power based on a hazard ratio of 0.80. This trial was initiated by Teva in September 2012. Two formal interim analyses are planned, which may result in early termination of the trial if there is inadequate evidence of clinical benefit or futility**.** We expect to evaluate both progression-free survival, or PFS, and overall survival, or OS, during the first interim analysis. If both endpoints meet the predefined criteria for inadequate PFS clinical benefit and OS futility, the trial would be stopped. The second interim analysis is based on OS futility determination only. The trial will not be stopped early in order to claim efficacy.

Custirsen received Fast Track designation from the FDA for the treatment of progressive metastatic prostate cancer in combination with docetaxel. The FDA has also agreed on the design of the SYNERGY trial via the SPA process including the increase in the accrual target to 1,000 patients. Custirsen has also received Fast Track designation from the FDA for the second-line treatment of advanced NSCLC when combined with docetaxel in patients with disease progression following treatment with a first-line, platinum-based chemotherapy doublet regimen.

We have also received written, scientific advice from the European Medicines Agency, or EMA, on our development plan for custirsen for treating patients with CRPC in combination with docetaxel, which aligned with our development plan regarding our proposed preclinical studies, the SYNERGY trial design and analyses for the Phase 3 SYNERGY trial. In addition, the Committee for Medicinal Products for Human Use agreed that the intended safety database would enable a sufficient qualified risk-benefit assessment for market approval.

We and collaborating investigators have conducted five Phase 2 clinical trials to evaluate the ability of custirsen to enhance the effects of therapy in patients with prostate, non-small cell lung and breast cancers. Results have been presented for each of these Phase 2 trials. Our Phase 3 registration trials have been designed based on our Phase 2 clinical trials. Data from these Phase 2 trials demonstrate the potential benefit of adding custirsen, a second generation antisense molecule, to existing cancer therapies.

Product Candidate Apatorsen (OGX-427)

Apatorsen (OGX-427) is our product candidate that is designed to inhibit production of heat shock protein 27, or Hsp27, a cell-survival protein expressed in many types of cancers including bladder, prostate, breast and non-small cell lung cancer. Hsp27 expression is stress-induced, including by many anti-cancer therapies. Overexpression of Hsp27 is thought to be an important factor leading to the development of treatment resistance and is associated with metastasis and negative clinical outcomes in patients with various tumor types. The United States Adopted Names, or USAN, Council has approved the use of the nonproprietary generic name "apatorsen" for OGX-427.

In 2013, we initiated the "ORCA™" (**O**n-going Studies Evaluating Treatment **R**esistance in **CA**ncer) program, which encompasses clinical trials designed to evaluate whether inhibition of Hsp27 can lead to improved prognosis and treatment outcomes for cancer patients. Our goal is to advance cancer treatment by conducting clinical trials for apatorsen (OGX-427) across multiple cancer indications including bladder, lung, pancreatic and prostate cancers. We are conducting parallel clinical trials to evaluate apatorsen (OGX-427) in several cancer indications and treatment combinations to accelerate the development of apatorsen (OGX-427). In addition, we are supporting and intend to support specific investigator-sponsored trials to allow assessment of a broader range of clinical indications for future OncoGenex-sponsored trials for possible market approval.

Our current apatorsen (OGX-427) development activities for bladder cancer include the following clinical trials:

- The BL-01 Trial: An investigator-sponsored Phase 1 trial to evaluate apatorsen (OGX-427) when administered directly into the bladder in patients with bladder cancer. The trial is currently enrolling 36 patients. It is designed to determine the safety and will measure the direct effect of apatorsen (OGX-427) on expression of Hsp27 in bladder tumor cells, as well as determine the pharmacokinetics and pharmacodynamics of apatorsen (OGX-427) when delivered by intravesical instillation. This clinical trial is being funded by the National Cancer Institute of Canada. Preliminary data were presented at the ASCO GU Symposium in February 2012.
- The Borealis-1™ Trial: An OncoGenex-sponsored Phase 2 trial of apatorsen (OGX-427) in patients with metastatic bladder cancer. Borealis-1 is a three-arm, randomized, placebo-controlled trial evaluating apatorsen (OGX-427) in combination with first-line gemcitabine and cisplatin treatment in the metastatic setting. Each arm has enrolled approximately 60 patients and the trial is being conducted in sites throughout the United States, Canada and Europe. The trial is being conducted as an event-driven trial such that we anticipate the final analysis will have at least 80% power to show a critical hazard ratio of approximately 0.66 to 0.72. This type of Phase 2 trial design will allow us to better predict the potential size of and success for a Phase 3 trial where a survival benefit will be the primary endpoint. Borealis-1™ patient enrollment was completed in July 2013 and data are expected to be available in the second-half of 2014.
- The Borealis-2™ Trial: The investigator-sponsored, randomized Phase 2 trial evaluating apatorsen (OGX-427) in combination with docetaxel treatment compared to docetaxel treatment alone in patients with advanced or metastatic bladder cancer who have disease progression following first-line platinum-based chemotherapy. This trial is designed to have adequate power to detect a survival benefit corresponding to a hazard ratio of approximately 0.667. The primary analysis is to be performed at one-sided 0.10 significance level with 90% power to detect a difference in overall survival. We expect to enroll approximately 200 patients. Patients may also continue weekly apatorsen (OGX-427) infusions as maintenance treatment until disease progression or unacceptable toxicity if they complete all 10 cycles of docetaxel, or are discontinued from docetaxel due to docetaxel toxicity. This trial was initiated in April 2013.

Our current apatorsen (OGX-427) development activities for NSCLC include the following clinical trials:

- The Spruce™ Trial: An investigator-sponsored, randomized, placebo-controlled Phase 2 trial evaluating apatorsen (OGX-427) in patients with previously untreated advanced non-squamous NSCLC. The trial is expected to randomize approximately 155 patients with non-squamous NSCLC to receive either apatorsen (OGX-427) plus carboplatin and pemetrexed therapy or placebo plus carboplatin and pemetrexed therapy. The aim of the trial is to determine if adding apatorsen (OGX-427) to carboplatin and pemetrexed therapy can extend PFS outcome. Additional analyses are expected to include tumor response rates, overall survival, safety, tolerability, and the effect of therapy on Hsp27 levels. This trial was initiated in August 2013 and is enrolling patients.
- The Cedar™ Trial: An investigator-sponsored, randomized Phase 2 trial evaluating apatorsen (OGX-427) in patients with previously untreated advanced squamous NSCLC. The trial is expected to randomize approximately 140 patients with squamous NSCLC to receive apatorsen (OGX-427) plus gemcitabine and carboplatin therapy or gemcitabine and carboplatin therapy alone. The aim of the trial is to determine if adding apatorsen (OGX-427) to gemcitabine and carboplatin therapy can extend PFS outcome. Additional analyses will include tumor response rates, overall survival, safety, and health-related quality of life. Additional analyses are expected to determine the effect of therapy on Hsp27 levels and to explore potential biomarkers that may help predict response to treatment. Plans to initiate Cedar later this year were announced in May 2013.

Our current apatorsen (OGX-427) development activities for pancreatic cancer include the following clinical trial:

- The Rainier™ Trial: An investigator-sponsored, randomized, placebo-controlled Phase 2 trial evaluating apatorsen (OGX-427) in combination with Abraxane® (paclitaxel protein-bound particles for injectable suspension)(albumin-bound) and gemcitabine in approximately 130 patients with previously untreated metastatic pancreatic cancer. The trial will randomize patients to receive either apatorsen (OGX-427) or placebo in combination with Abraxane and gemcitabine therapy. The primary objective of the trial will be overall survival, with additional analyses to evaluate PFS, tumor response rates, safety, tolerability, and the effect of therapy on Hsp27 levels. Patient enrollment for this trial is expected to begin in the second-half of 2013.

Our current apatorsen (OGX-427) development activities for prostate cancer include the following clinical trials:

- The PR-01 Trial: An investigator-sponsored Phase 2 trial evaluating apatorsen (OGX-427) when administered with prednisone to patients with CRPC. PR-01 has completed enrollment with data collection ongoing. This randomized, controlled trial enrolled 74 patients who had minimally symptomatic or asymptomatic advanced prostate cancer and who had not yet received chemotherapy. This trial is measuring the direct effect of apatorsen (OGX-427) on prostate-specific

antigen, or PSA, levels, time to progression by PSA or measurable disease, numbers of circulating tumor cells, or CTCs, and other relevant secondary endpoints. Preliminary data were presented at several conferences throughout 2012, most recently at the European Society for Medical Oncology, or ESMO, meeting in September 2012.

- The Pacific™ Trial: An investigator-sponsored, randomized Phase 2 trial evaluating apatorsen (OGX-427) in men with CRPC who are experiencing a rising PSA while receiving Zytiga® (abiraterone acetate). The aim of the trial is to determine if adding apatorsen (OGX-427) to Zytiga treatment can reverse or delay treatment resistance by evaluating the PFS rate at a milestone Day 60 assessment. Other secondary endpoints such as PSA and objective responses, time to disease progression, CTCs and Hsp27 levels are expected to be evaluated. We expect approximately 80 patients will be enrolled. The trial was initiated in December 2012.

Results of these trials may direct future company-sponsored trials in indications that show promising clinical benefits.

Product Candidate OGX-225

OGX-225, an inhibitor of insulin growth factor binding proteins 2 and 5, is in preclinical development. We are currently evaluating various alternatives, including partnering, which would allow us to further the development of this preclinical asset. We have begun development activities for OGX-225 and we expect to initiate toxicology studies in the second half of 2013.

Collaboration Revenue

Revenue recognized to date is attributable solely to the upfront payment we received in the fourth quarter of 2009 pursuant to our Collaboration Agreement with Teva, as well as cash reimbursements from Teva for certain costs incurred by us under the Clinical Development Plan. Our policy is to account for these reimbursements as collaboration revenue.

We are eligible to receive payments of up to $370 million upon the achievement of developmental and commercial milestones set forth in the Collaboration Agreement. At present, we are unable to predict the timing or likelihood of such milestone payments. We do not expect to receive any payments from Teva resulting from the achievement of developmental or commercial milestones in 2013. Moreover, Isis has disclosed in its Securities and Exchange Commission, or SEC, filings that it is entitled to receive 30% of the up to $370 million in milestone payments we may receive from Teva as part of the Collaboration Agreement. We disagree with its assessment but believe there may be some lesser payment obligation. See Note 3 of Notes to Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q for further details on our collaboration with Teva.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of costs for clinical trials, contract manufacturing, personnel costs, milestone payments to third parties, facilities, regulatory activities, preclinical studies and allocations of other R&D-related costs. External expenses for clinical trials include fees paid to clinical research organizations, clinical trial site costs and patient treatment costs.

Currently, we manage our company-sponsored clinical trials through contract research organizations and independent medical investigators at their sites and at hospitals and expect this practice to continue. Through our clinical development programs, we are developing each of our product candidates in parallel for multiple disease indications. Due to the number of ongoing projects and our ability to utilize resources across several projects, we do not record or maintain information regarding the indirect operating costs

incurred for our research and development programs on a program-specific basis. In addition, we believe that allocating costs on the basis of time incurred by our employees does not accurately reflect the actual costs of a project.

Several of our clinical trials have been supported by grant funding that was received directly by the hospitals and/or clinical investigators conducting the clinical trials as investigator-sponsored trials, thereby allowing us to complete these clinical trials at a lower cost to us.

Per the terms of the agreement with Teva, we have spent the required $30 million in development costs related to custirsen. Teva is required to fund all additional expenses under the Amended Clinical Development Plan. We expect aggregate full-time equivalent reimbursement of between $1.2 and $2.0 million annually from 2013 to 2014, which will be reimbursed to us from Teva.

Since our drug candidates are in the early stages of development, we cannot estimate completion dates for development activities or when we might receive material net cash inflows from our R&D projects, if ever.

Our projects or intended R&D activities may be subject to change from time to time as we evaluate our R&D priorities and available resources.

We expect our R&D expenses to increase in 2013 and into the future, likely significantly, as we further expand development of custirsen, apatorsen (OGX-427), and our other programs. Our programs or anticipated programs may be subject to change from time to time as we evaluate our R&D priorities and available resources.

General and Administrative Expenses

General and administrative, or G&A, expenses consist primarily of salaries and related costs for our personnel in executive, business development, human resources, external communications, finance and other administrative functions, as well as consulting costs, including market research, business consulting and intellectual property. Other costs include professional fees for legal and auditing services, insurance and facility costs. While we believe that G&A resources are sufficient to carry on existing development activities, we anticipate that G&A expenses will increase in the future as we continue to expand our operating activities.

Warrant liability

At June 30, 2013, there were exercisable warrants outstanding to purchase 1,587,301 shares of common stock at an exercise price of $20 per share, expiring in October 2015. No warrants were exercised during the six months ended June 30, 2013 or 2012.

We reassess the fair value of the common stock warrants at each reporting date utilizing a Black-Scholes pricing model. Inputs used in the pricing model include estimates of stock price volatility, expected warrant life and risk-free interest rate. The computation of expected volatility was based on the historical volatility of shares of our common stock for a period that coincides with the expected life of the warrants.

Results of Operations

Three and Six Months Ended June 30, 2013 and 2012

Revenue

Revenue for the three and six months ended June 30, 2013 increased to $6.3 million and $11.4 million, respectively, from $2.4 million and $3.7 million for the three and six months ended June 30, 2012, respectively. The increase in 2013 as compared to 2012 was due to an increase in revenue earned through our strategic collaboration with Teva, as a result of the clinical development activities associated with the AFFINITY trial which we initiated in August 2012.

Research and Development Expenses

Our research and development expenses for our clinical development programs as of the three and six months ended June 30, 2013 and 2012 are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Clinical development programs:				
Custirsen	$ 5,939	$2,034	$10,568	$ 2,923
Apatorsen (OGX-427)	4,416	2,214	7,972	4,338
Other research and development	2,908	2,078	5,578	4,147
Total research and development expenses	**$13,263**	**$6,326**	**$24,118**	**$11,408**

R&D expenses for the three and six months ended June 30, 2013 increased to $13.3 million and $24.1 million, respectively, from $6.3 million and $11.4 million in the three and six months ended June 30, 2012, respectively. The increase in 2013 as compared to 2012 was due primarily to higher clinical trial expenses associated with patient enrollment in the AFFINITY and Borealis-1 trials, higher costs directly associated with efforts to increase patient enrollment, increased employee expenses due to an increase in the number of employees to support our clinical development activities, and toxicology and preclinical expenses related to apatorsen (OGX-427). These increases were partially offset by lower manufacturing expenses due to timing of apatorsen (OGX-427) manufacturing activities. Costs for the AFFINITY trial, custirsen manufacturing costs, compensation for work performed by our employees and certain other costs under the Clinical Development Plan are reimbursed by Teva. We expect R&D expenses to increase as we expand development of custirsen and our proprietary product candidates, apatorsen (OGX-427) and OGX-225.

General and Administrative Expenses

G&A expenses for the three and six months ended June 30, 2013 increased to $2.5 million and $5.0 million, respectively, from $2.0 million and $3.8 million in the three and six months ended June 30, 2012, respectively, primarily due to higher employee expenses compared with the same period in 2012.

Gain on Warrants

We recorded gains of $0.9 million and $2.3 million on the revaluation of our outstanding warrants during the three and six months ended June 30, 2013, respectively. We recorded gains of $1.6 million and $0.2 million on revaluation of the warrants during the three and six months ended June 30, 2012, respectively. We revalue the warrants at each balance sheet date to fair value. If unexercised, the warrants will expire in October 2015.

Liquidity and Capital Resources

We have incurred an accumulated deficit of $117.0 million through June 30, 2013, and we expect to incur substantial and increasing additional losses in the future as we expand our R&D activities and other operations, as more fully described below under the heading "Operating Capital and Capital Expenditure Requirements". We have not generated any revenue from product sales to date, and we do not expect to generate product sales revenue for the foreseeable future, if ever.

On June 18, 2012, we entered into an At-the-Market Issuance Sales Agreement, or Sales Agreement, with MLV & Co. LLC, or MLV, under which we may offer and sell shares of our common stock having aggregate sales proceeds of up to $25,000,000 from time to time through MLV as our sales agent. Sales of our common stock through MLV, if any, will be made by any method permitted that is deemed an "at the market" offering as defined in Rule 415 under the Securities Act of 1933, as amended, including by means of ordinary brokers' transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and MLV. MLV will use commercially reasonable efforts to sell our common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay MLV a commission of up to 3.0% of the gross sales proceeds of any shares of common stock sold through MLV under the Sales Agreement. To date, no shares have been sold under the Sales Agreement.

All of our operations to date have been funded through the sale of our equity securities and payments received from Teva. As of June 30, 2013, our cash, cash equivalents and short-term investments decreased to $57.0 million in the aggregate from $75.4 million as of December 31, 2012.

Based on our current expectations, we believe our cash, cash equivalents, short-term investments and receivables from Teva will be sufficient to fund our currently planned operations into 2015. Our currently planned operations are set forth below under the heading "Operating Capital and Capital Expenditure Requirements."

Cash Flows

Cash Used in Operations

For the six months ended June 30, 2013, net cash used in operating activities decreased to $18.2 million from $21.1 million in the six months ended June 30, 2012. The decrease in cash used in operations is primarily attributable to upfront payments made in the first six months of 2012 for clinical trial costs. This was partially offset by higher clinical trial expenses associated with patient enrollment in the AFFINITY and Borealis-1 trials, higher costs directly associated with efforts to increase patient enrollment, increased employee expenses due to an increase in the number of employees to support our clinical development activities, and toxicology and preclinical expenses related to apatorsen (OGX-427).

Cash Provided by Financing Activities

For the six months ended June 30, 2013, net cash provided by financing activities decreased to $10,000 from $53.9 million in the six months ended June 30, 2012. Net cash provided by financing activities in the six months ended June 30, 2013 was the result of proceeds from the exercise of stock options. Net cash provided by financing activities in the six months ended June 30, 2012 was primarily attributable to the net proceeds we received from the public offering of our common stock in March 2012.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2013 was $18.8 million compared with $47.5 million used in investing activities in for the six months ended June 30, 2012. Net cash provided by (used in) investing activities in the six months ended June 30, 2013 and 2012 was due to transactions involving marketable securities in the normal course of business.

Operating Capital and Capital Expenditure Requirements

Based on our current expectations we also believe that our cash, cash equivalents, short-term investments and receivables from Teva will be sufficient to fund our currently planned operations into 2015 which may include:

- completing the SYNERGY trial, a Phase 3 trial that is evaluating a survival benefit for custirsen in combination with docetaxel as first-line chemotherapy. SYNERGY patient enrollment was completed in the fourth quarter of 2012. As a result of death events occurring more slowly than previously expected, the anticipated timing of the pre-specified number of events is currently projected to occur late in the first quarter or early in the second quarter of 2014. Survival results are expected to be announced in mid-2014.
- completing patient enrollment in the AFFINITY trial, a Phase 3 trial that is evaluating a survival benefit for custirsen in combination with cabazitaxel as second-line chemotherapy in approximately 630 patients with CRPC, which was initiated in August 2012;
- continued enrollment of patients in the ENSPIRIT trial, a Phase 3 trial that is evaluating a survival benefit for custirsen in combination with docetaxel as second-line chemotherapy in approximately 1,100 patients with NSCLC, which was initiated in September 2012 and is being conducted by our partner Teva;
- completing the Borealis-1 OncoGenex-sponsored randomized, placebo-controlled Phase 2 trial evaluating apatorsen (OGX-427) in combination with standard first-line chemotherapy in approximately 180 patients with metastatic bladder cancer for which enrollment was completed in July 2013 and data are expected in the second-half of 2014;
- enrolling patients in the Borealis-2 trial, an investigator-sponsored, randomized, controlled Phase 2 trial evaluating apatorsen (OGX-427) in patients with advanced or metastatic bladder cancer who have disease progression following initial platinum-based chemotherapy first-line treatment and are eligible to receive docetaxel second-line chemotherapy;
- completing the BL-01 trial, an investigator-sponsored Phase 1 trial evaluating apatorsen (OGX-427) when administered directly into the bladder in patients with superficial or muscle-invasive bladder cancer;
- continuing enrollment in the Spruce trial, an investigator-sponsored, randomized, placebo-controlled Phase 2 trial evaluating apatorsen (OGX-427) treatment with carboplatin and pemetrexed chemotherapy in patients with previously untreated advanced non-squamous NSCLC;
- initiating the Cedar trial, an investigator-sponsored, randomized Phase 2 trial evaluating apatorsen (OGX-427) treatment with gemcitabine and carboplatin chemotherapy in patients with previously untreated advanced squamous NSCLC;

- initiating the Rainier trial, an investigator-sponsored, randomized, placebo-controlled Phase 2 trial evaluating apatorsen (OGX-427) in combination with Abraxane® and gemcitabine in patients with previously untreated metastatic pancreatic cancer;
- completing the PR-01 trial, an investigator-sponsored Phase 2 trial evaluating apatorsen (OGX-427) treatment in combination with prednisone in patients with prostate cancer who have not received chemotherapy;
- continued enrollment of patients in the Pacific trial, an investigator-sponsored randomized Phase 2 trial evaluating apatorsen (OGX-427) treatment in combination with Zytiga in patients with prostate cancer; and
- initiating OGX-225 toxicology studies.

We currently have sufficient operating capital to fund our currently planned operations into 2015 and through the expected release of survival results from the SYNERGY trial in mid-2014. Survival results from the additional custirsen and apatorsen (OGX-427) trials may be released at a date that is beyond the period for which we currently project we have available cash resources. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. If we were to conduct development activities with respect to our other product candidates beyond those development activities described above, including activities with respect to OGX-225, or if the clinical trials cost more than we anticipate, we would require additional funding to support such operations. If we need to extend our cash availability or to conduct any such currently unplanned development activities, we would seek such necessary funding through the licensing or sale of certain of our product candidates, by executing a partnership or collaboration agreement, or through private or public offerings of our equity or debt, including the sale of common stock pursuant to the Sales Agreement for our at-the market offering. However, we can provide no assurance that such funding would be available to us on favorable terms, or at all.

Our future capital requirements will depend on many factors, including:

- timing, costs and results of clinical trials, preclinical development and regulatory approvals;
- success of custirsen, including receipt of milestone and royalty payments;
- maintaining our relationship with Teva and Teva's ongoing level of focus and efforts to develop custirsen;
- timing, costs and results of drug discovery and R&D;
- entering into new collaborative or product license agreements for products in our pipeline;
- our ability to obtain additional funding through a partnership or collaboration agreement with a third party or licenses of certain of our product candidates, or through private or public offerings of our equity or debt; and
- costs related to obtaining, defending and enforcing patents.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet financing arrangements at June 30, 2013.

Contingencies and Commitments

We previously disclosed certain contractual obligations and contingencies and commitments relevant to us within the financial statements and Management Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2012, as filed with the SEC on March 7, 2013. There have been no material changes to our "Contractual Obligations" table in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our 2012 Form 10-K. For more information regarding our current contingencies and commitments, see note 7 to the financial statements included above.

Material Changes in Financial Condition

(In thousands)	June 30, 2013 $	December 31, 2012 $
Total assets	69,308	82,016
Total liabilities	16,623	15,809
Total equity	52,685	66,207

The decrease in assets at June 30, 2013 compared with December 31, 2012 primarily relates to decreased cash, cash equivalents and marketable securities as these assets have been used to fund operations. The increase in liabilities at June 30, 2013 from December 31, 2012 is primarily due to higher clinical trial accruals associated with patient enrollment in the AFFINITY and Borealis-1 trials.

Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts and related disclosures. We have discussed those estimates that we believe are critical and require the use of complex judgment in their application in our Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on March 7, 2013. Since December 31, 2012, there have been no material changes to our critical accounting policies or the methodologies or assumptions we apply under them.

New Accounting Standards

See Note 2, "Accounting Policies," of the consolidated financial statements for information related to the adoption of new accounting standards in 2013, none of which had a material impact on our financial statements, and the future adoption of recently issued accounting standards, which we do not expect to have a material impact on our financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Interest rate risk is the risk that the fair values and future cash flows of financial instruments will fluctuate because of the changes in market interest rates. We invest our cash in a variety of financial instruments, primarily in short-term bank deposits, money market funds, and domestic and foreign commercial paper and government securities. These investments are denominated in U.S. dollars, and we monitor our exposure to interest rate changes. We have very limited interest rate risk due to having only a few assets or liabilities subject to fluctuations in interest rates. Our investment portfolio includes only marketable securities with active secondary or resale markets to help ensure portfolio liquidity. Due to the nature of our highly liquid marketable securities, a change in interest rates would not materially change the fair market value. We have estimated the effect on our portfolio of a hypothetical increase in interest rates by one percent to be a reduction of approximately $0.4 million in the fair value of our investments as of June 30, 2013.

Foreign Currency Exchange Risk

We are exposed to risks associated with foreign currency transactions on certain contracts and payroll expenses related to our Canadian subsidiary, OncoGenex Technologies, denominated in Canadian dollars, and we have not hedged these amounts. As our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. Accordingly, changes in the value of the U.S. dollar relative to the Canadian dollar might have an adverse effect on our reported results of operations and financial condition, and fluctuations in exchange rates might harm our reported results and accounts from period to period. We have estimated the effect on our reported results of operations of a hypothetical increase of 10 percent in the exchange rate of the Canadian dollar against the U.S. dollar to be approximately $0.1 million for the six months ended June 30, 2013.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that material information required to be disclosed in our periodic reports filed or submitted 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 SEC's rules and forms. Our disclosure controls and procedures are also designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act are accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure.

During the quarter ended June 30, 2013, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in

Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective, as of the end of the period covered by this report.

Changes in Internal Control Over Financial Reporting

We have not made any changes to our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls

Our management does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

Risks Related to Our Business

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, before deciding to invest in our common stock. If any of the following risks materialize, our business, financial condition, results of operation and future prospects will likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.

Risks Related to Our Business

We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have never had any products available for commercial sale and we may never achieve or sustain profitability.

We are a clinical-stage biopharmaceutical company, are not profitable, have incurred losses in each year since our inception and do not expect to become profitable in the foreseeable future. We have never had any products available for commercial sale, and we have not generated any revenue from product sales nor do we anticipate that we will generate revenue from product sales in the foreseeable future. Our revenue to date has been collaboration revenue under our Collaboration Agreement with Teva. We have not yet submitted any products for approval by regulatory authorities, and we continue to incur research and development and general and administrative expenses related to our operations. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research activities and conduct development of, and seek regulatory approvals for, our product candidates, and prepare for and begin to commercialize any approved products. If our product candidates fail in clinical trials or do not gain regulatory approval, or if our product candidates do not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Our clinical trials may be suspended or terminated at any time, including by the FDA, other regulatory authorities, a Data Safety Monitoring Board overseeing the clinical trial at issue, by a clinical trial site or investigator, by Teva in the case of custirsen or by us. Any failure or significant delay in completing clinical trials for our product candidates could materially harm our financial results and the commercial prospects for our product candidates.

We do not know whether any of our currently planned or on-going clinical trials for custirsen or apatorsen (OGX-427) will proceed or be completed on schedule, if at all, or, with respect to our other product candidates, whether we will be able to initiate any future preclinical studies or clinical trials, as applicable, beyond those currently planned. The completion or commencement of future preclinical studies or clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable patients with the particular types of cancer required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct clinical trials;
- introduction of new product candidates to the market in therapeutic areas similar to those that we are developing for our product candidates;
- concurrent evaluation of new investigational product candidates in therapeutic areas similar to those that we are developing for our product candidates;

- delay or failure to obtain the FDA's or non-U.S. regulatory agencies' approval or agreement to commence a clinical trial, including our Phase 3 or registration clinical trials or amendment of those trials under a special protocol assessment;
- delay or failure to obtain sufficient manufacturing supply of custirsen or apatorsen (OGX-427);
- delay or failure to obtain sufficient supplies for our clinical trials;
- delay or failure to obtain required future additional funding, when needed, through private or public offerings of our equity securities, debt financings, or the execution of a licensing, partnership or collaboration agreement with a third party for any of our product candidates;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators;
- delay or failure to obtain the approval of the Institutional Review Board to conduct a clinical trial at a prospective site;
- decrease in Teva's level of focus and efforts to develop custirsen; and
- our decision to alter the development strategy for one or more clinical or preclinical products.

The completion of our clinical trials currently in progress could also be substantially delayed or prevented by several factors, including:

- lack of efficacy evidenced during clinical trials;
- inadequate evidence of clinical benefit or futility;
- slower than expected rates of patient recruitment, enrollment and final analysis;
- failure of patients to complete the clinical trial;
- unforeseen safety issues;
- termination of our clinical trials by one or more clinical trial sites, investigators, data safety monitoring boards, or FDA;
- inability or unwillingness of patients or medical investigators to follow clinical trial protocols;
- inability to monitor patients adequately during or after treatment;
- introduction of competitive products that may impede our ability to retain patients in clinical trials;
- delay or failure to obtain sufficient manufacturing supply of custirsen or apatorsen (OGX-427); and
- delay or failure to obtain future additional funding through private or public offerings of our equity securities, debt financings, or the execution of a licensing, partnership or collaboration agreement with a third party for any of our product candidates in the event of material unforeseen costs relating to our clinical trials currently in progress.

We are highly dependent on the success of our lead product candidates, custirsen and apatorsen (OGX-427), and we cannot give any assurance that they, or any of our other product candidates, will receive regulatory approval or will be successfully commercialized.

In order to market custirsen, we and Teva must, among other things, conduct additional clinical trials, including Phase 3 or registration clinical trials, to demonstrate safety and efficacy. We have an ongoing registration trial with custirsen in patients with CRPC, referred to as the SYNERGY trial. In the second half of 2012, we initiated the AFFINITY trial, in combination with cabazitaxel as second-line chemotherapy in patients with CRPC and our partner, Teva, initiated an additional registration trial in patients with NSCLC, referred to as the ENSPIRIT trial.

Apatorsen (OGX-427) has been evaluated in humans, although we have limited safety data and have not yet established efficacy in humans. Completing the additional chronic toxicity studies and clinical trials will be required for apatorsen (OGX-427) to establish the safety and efficacy of this product candidate. We intend to conduct parallel clinical trials to evaluate apatorsen (OGX-427) in several cancer indications and treatment combinations to accelerate the development of apatorsen (OGX-427).

OGX-225 has not been tested in humans. Our preclinical testing of this product candidate may not be favorable and we may not be able to clinically evaluate OGX-225.

Our clinical development programs for our product candidates may not receive regulatory approval either if such product candidates fail to demonstrate that they are safe and effective in clinical trials and consequently fail to obtain necessary approvals from the FDA, or similar non-U.S. regulatory agencies, or if we have inadequate financial or other resources to advance these product candidates through the clinical trial process. If competitive products developed by third parties show significant benefit in the cancer indications in which we are developing our product candidates, any planned supportive or primary registration trials may be delayed, altered or not initiated and custirsen, apatorsen (OGX-427) and our other product candidates may never receive regulatory approval. Any failure to obtain regulatory approval of custirsen, apatorsen (OGX-427) or our other product candidates could have a material and adverse effect on our business.

Clinical trials may not demonstrate a clinical benefit of our product candidates.

Positive results from preclinical studies and early clinical trials, including those results from the custirsen or apatorsen (OGX-427) clinical trials conducted to date, should not be relied on as evidence that later-stage or large-scale clinical trials will succeed. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other non-U.S. regulatory authorities, despite having progressed through initial clinical trials. Further, preliminary results from our clinical trials may not be confirmed in final data, or may change materially.

Even after the completion of our planned Phase 3 clinical trials, the FDA or other non-U.S. regulatory authorities may disagree with our clinical trial design and our interpretation of data, and may require us to conduct additional clinical trials to demonstrate the efficacy of our product candidates.

We depend on our collaborative relationship with Teva to further develop and commercialize custirsen, and if our relationship is not successful or is terminated, we may not be able to effectively develop and/or commercialize custirsen, which would have a material adverse effect on our business.

We depend on Teva to collaborate with us to develop and globally commercialize custirsen. Furthermore, under the Collaboration Agreement, we and Teva must agree on any changes to the Clinical Development Plan for custirsen. As a result of our dependence on Teva, the eventual success or commercial viability of custirsen is largely beyond our control. The financial returns to us, if any, under the Collaboration Agreement depend in large part on the achievement of development and commercialization milestones, plus a share of any revenue from sales. Therefore, our success, and any associated financial returns to us and our investors, will depend in large part on Teva's performance under the Collaboration Agreement. We are subject to a number of additional specific risks associated with our dependence on our collaborative relationship with Teva, including:

- adverse decisions by Teva or the Joint Steering Committee regarding the development and commercialization of custirsen;
- possible disagreements as to the timing, nature and extent of our development plans, including clinical trials or regulatory approval strategy;
- loss of significant rights if we fail to meet our obligations under the Collaboration Agreement;
- our limited control over clinical trials of custirsen;
- changes in key management personnel at Teva, including in members of the Joint Steering Committee; and
- possible disagreements with Teva regarding the Collaboration Agreement, sharing of costs for clinical trials or ownership of proprietary rights.

If we and Teva are unable to reach an agreement under the Clinical Development Plan, or if either we or Teva fail to perform our respective obligations or effectively manage our relationship, any clinical trial, regulatory approval or development progress could be significantly delayed or halted, could result in costly or time-consuming litigation or arbitration and could have a material adverse effect on our business.

Decisions by Teva to either reduce or eliminate its participation in the oncology field, to emphasize other competitive agents currently in its portfolio, or to add additional competitive agents to its portfolio could result in a decision to terminate the Collaboration Agreement, in which event, among other things, we may be responsible for paying any remaining costs of all three Phase 3 clinical trials. Any such termination could adversely affect the timing and extent of our development and commercialization activities, which could cause significant delays and funding shortfalls for those activities and seriously harm our business.

We rely on third parties to manufacture and supply our product candidates and other agents used in our clinical trials. A decrease in the availability or quality of any of these products or agents could increase clinical trial costs, delay or halt clinical development or regulatory approval of our product candidates or commercialization of our future product candidates, resulting in additional losses and depriving us of potential product revenue.

We do not own or operate manufacturing facilities, and we depend on third-party contract manufacturers for production of all of our product candidates and rely on other companies and their manufacturers for other agents used in all of our clinical trials. We lack the resources and the capability to manufacture any of our product candidates ourselves. To date, our product candidates have been manufactured in limited quantities for preclinical studies and clinical trials. All active pharmaceutical ingredient, or API, and drug product for custirsen and apatorsen (OGX-427) have been manufactured for us by third parties pursuant to a purchase order or short-term contract that has been fulfilled.

If, in the future, one of our product candidates is approved for commercial sale, we, or a pharmaceutical partner that has licensed such product candidate, will need to manufacture that product candidate in commercial quantities. We cannot provide assurance that the third-party manufacturers with which we have contracted in the past will have sufficient capacity to satisfy our future manufacturing needs, that we will be able to negotiate additional purchases of API or drug product from these or alternative manufacturers on terms favorable to us, if at all, or that a pharmaceutical partner that has licensed such product candidate will have sufficient capacity or expertise to satisfy future needs.

Third-party manufacturers may fail to perform under their contractual obligations, or may fail to deliver the required commercial quantities of bulk API or finished drug product on a timely basis and at commercially reasonable prices. We have experienced manufacturing quality issues resulting in an unusable lot of product candidate in the past. Any performance failure on the part of our contract manufacturers could delay clinical development or regulatory approval of our product candidates or commercialization of our future product candidates, depriving us of potential product revenue and resulting in additional losses. If we are required to identify and qualify an alternate manufacturer, we may be forced to delay or suspend our clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, which may cause us to incur higher costs and could prevent us from commercializing our product candidates successfully. If we are unable to find one or more replacement manufacturers capable of production at a reasonably favorable cost, in adequate volumes, of adequate quality and on a timely basis, we would likely be unable to meet demand for our product candidates and our clinical trials could be delayed or we could lose potential revenue. Our ability to replace an existing API manufacturer may be difficult because the number of potential manufacturers is limited to approximately five manufacturers, and the FDA must inspect any replacement manufacturer and review information related to product produced at the manufacturer before they can begin manufacturing our product candidates. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, if at all. We expect to continue to depend on third-party contract manufacturers for the foreseeable future.

Our product candidates require precise, high-quality manufacturing. Any of our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and non-U.S. regulatory authorities to ensure strict compliance with current Good Manufacturing Practices, or cGMP, and other applicable government regulations and corresponding standards. If our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our product candidates, cost overruns or other problems that could seriously affect our business.

Significant manufacturing scale-up may require additional validation studies, which the FDA must review and approve. Additionally, any third-party manufacturers we retain to manufacture our product candidates on a commercial scale must pass an FDA pre-approval inspection for conformance to cGMP regulations before we can obtain approval of our product candidates. If we are unable to successfully increase the manufacturing capacity for a product candidate in conformance with cGMP regulations, the regulatory approval or commercial launch of any related products may be delayed or there may be a shortage in supply.

We also rely on third-parties for the provision of other agents used in our clinical trials, and in some circumstances these agents are provided to us at no cost. We have no assurance that these third-parties will continue to provide their products to us at no cost.

Our product candidates may cause undesirable and potentially serious side effects during clinical trials that could delay or prevent their regulatory approval or commercialization.

Since patients in our clinical trials have advanced stages of cancer, we expect that additional adverse events, including serious adverse events, will occur.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or non-U.S. regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing our product candidates and generating revenue from their sale. In addition, if our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- Teva may elect to terminate the ongoing clinical trials and cease development of custirsen;
- regulatory authorities may withdraw their approval of the product;
- we may be required to recall the product, change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- a product may become less competitive and product sales may decrease; and
- our reputation may suffer.

Any one or a combination of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenue from the sale of the product. Recent events have raised questions about the safety of marketed drugs and may result in increased cautiousness by the FDA in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals, additional clinical trials being required, or more stringent product labeling requirements. Any delay in obtaining, or the inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

We rely, in part, on third parties to conduct clinical trials for our product candidates and plan to rely on third parties to conduct future clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our current and future product candidates.

To implement our product development strategies, we rely on third parties, such as collaborators, contract research organizations, medical institutions, clinical investigators and contract laboratories, to conduct clinical trials of our product candidates. In particular, we will have limited control over the two custirsen Phase 3 trials over which Teva will have primary oversight. Although we rely on third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with our investigational plan and protocol. Moreover, the FDA and non-U.S. regulatory authorities require us to comply with regulations and standards, commonly referred to as Good Clinical Practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the clinical trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines or need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to GCPs or for any other reason, we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. In addition, a failure by such third parties to perform their obligations in compliance with GCPs may cause our clinical trials to fail to meet regulatory requirements, which may require us to repeat our clinical trials.

If our competitors develop and market products that are more effective, safer or less expensive than our future product candidates, our clinical trials and commercial opportunities will be negatively affected.

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address cancer indications for which we are currently developing products or for which we may develop products in the future. For example, cabazitaxel, abiraterone acetate and enzalutamide have been approved by the FDA for the treatment of patients with CRPC. Additionally, alpharadin has demonstrated meaningful improvement in Phase 3 trials. We are aware of several other companies that are developing therapeutics that seek to promote tumor cell death. Any products we may develop in the future are also likely to face competition from other drugs and therapies. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. These companies also have significantly greater research and marketing capabilities than we do. In addition, many universities and private and public research institutes are, or may become, active in cancer research, and develop products that may directly compete with ours. If our competitors market products that are more effective, safer or less expensive than our future product candidates, if any, or that reach the market sooner than our future product candidates, if any, we may not achieve commercial success.

If new therapies become broadly used, we may need to conduct clinical trials of our product candidates in combination with these new therapies to demonstrate safety and efficacy of the combination. Additional trials will delay the development of our product candidates and increase our costs. The failure of certain of our product candidates to work in combination with these new therapies would have an adverse effect on our business.

Our intention is to combine certain of our product candidates with therapies that are broadly used by clinicians and considered highly effective. As new therapies are developed, we will need to assess these therapies to determine whether to conduct clinical trials of our product candidates in combination with them to demonstrate safety and efficacy of the combination. If we determine that it is appropriate to conduct additional clinical trials of our product candidates in combination with these new therapies, the development of our product candidates will be delayed and our costs will be increased. If these clinical trials generate safety concerns or lack of efficacy, our business would be adversely affected.

If our product candidates are approved in combination with a specific therapy that is broadly used and that therapy is displaced by another product, the market for our product candidate may decrease.

Because we depend on financing from third parties for our operations, our business may fail if such financing becomes unavailable or is not available on commercially reasonable terms.

To date, we have financed our operations primarily through the sale of our equity securities and from payments we receive pursuant to the Collaboration Agreement with Teva. We believe that our existing capital resources and interest on such resources will be sufficient to meet our current operating requirements into 2015. If, however, the Collaboration Agreement with Teva is terminated, Teva fails to fulfill its obligations under the Collaboration Agreement, patients live longer as a result of new or investigational therapies, the trials proceed slower than expected or are initiated later than expected, we change our development plans, acquire rights to new product candidates or cannot find third-party collaborators for our other product candidates, we may need additional capital sooner than we expect. Our future capital requirements will depend on many factors, including, without limitation:

- maintaining our partnership with Teva and Teva's ongoing commitment to develop custirsen in a timely manner;
- the scope and results of our clinical trials and preclinical studies;
- whether we experience delays in our clinical and preclinical development programs, or slower-than-anticipated product development or rate of events;
- whether opportunities to acquire additional product candidates arise and the costs of acquiring and developing those product candidates;
- whether we are able to enter into additional third-party collaborative partnerships to develop and/or commercialize any of our other product candidates on terms that are acceptable to us;
- the timing and requirements of, and the costs involved in, conducting studies required to obtain regulatory approvals for our product candidates from the FDA and comparable foreign regulatory agencies;
- the availability of third parties to perform the key development tasks for our product candidates, including conducting preclinical studies and clinical trials and manufacturing our product candidates to be tested in those studies and trials and the associated costs of those services;
- the costs involved in preparing, filing, prosecuting, maintaining, defending the validity of and enforcing patent claims and other costs related to patent rights and other intellectual property rights, including litigation costs and the results of such litigation; and
- whether we modify our development program, including terminating and starting new trials.

If we are unable to raise funds on acceptable terms when it becomes necessary to do so, we may not be able to continue developing our product candidates, acquire or develop additional product candidates or respond to competitive pressures or unanticipated requirements. For these reasons, any inability to raise additional funds when we require it could have a material adverse effect on our business.

Although we have entered into a Collaboration Agreement with Teva for custirsen, we have not yet partnered with third-party collaborators with respect to any of our other product candidates, and we cannot control whether we will be able to do so on favorable terms, if at all.

Our business strategy relies in part on potentially partnering successful product candidates with larger companies to complement our internal development and commercialization efforts. While we have successfully entered into a Collaboration Agreement with Teva with respect to custirsen, it may be difficult for us to find third parties that are willing to enter into a collaboration on acceptable economic terms, if at all, with respect to our other product candidates. We also will be competing with many other companies as we seek partners for our other product candidates and may not be able to compete successfully against

those companies. If we are not able to enter into collaboration arrangements for our other product candidates and custirsen does not achieve regulatory approval or is delayed, we would be required to undertake and fund further development, clinical trials, manufacturing and commercialization activities solely at our own expense and risk. If we are unable to finance and/or successfully execute those expensive activities, our business could be materially and adversely affected, and we may be forced to discontinue clinical development of these product candidates.

Even if we or Teva receive regulatory approval to market our product candidates, the market may not be receptive to our products.

Even if our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and/or the medical community. We believe that the degree of market acceptance will depend on a number of factors, including:

- timing of market introduction of competitive products;
- safety and efficacy of our products;
- prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support;
- price of our products, both in absolute terms and relative to alternative treatments; and
- availability of coverage and reimbursement from government and other third-party payors.

If our future product candidates fail to achieve market acceptance, we may not be able to generate significant revenue or achieve or sustain profitability.

If we were to be successfully sued related to our products or operations, we could face substantial liabilities that may exceed our resources.

We may be held liable if any of our products or operations cause injury or death or are found otherwise unsuitable during product testing, manufacturing, marketing or sale. These risks are inherent in the development of pharmaceutical products. We currently maintain commercial general and umbrella liability policies with combined limits of $10 million per occurrence and in the aggregate, in addition to a $10 million per claim and annual aggregate product liability insurance policy related to our clinical trials consistent with industry standards. When necessary for our products, we intend to obtain additional product liability insurance. Insurance coverage may be prohibitively expensive, may not fully cover potential liabilities or may not be available in the future. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products. If we were to be sued for any injury caused by or associated with our products or operations, the litigation could consume substantial time and attention of our management, and the resulting liability could exceed our total assets.

If we fail to acquire and develop products or product candidates at all or on commercially reasonable terms, we may be unable to grow our business.

We currently do not have internal discovery capabilities and depend on pharmaceutical and biotechnology companies and other researchers to sell or license products or product candidates to us. To date, three of our product candidates have been derived from technologies discovered by the Vancouver Prostate Centre and licensed to us by UBC. We intend to continue to rely on the Vancouver Prostate Centre, UBC and other research institutions and other biotechnology or pharmaceutical companies as sources of product candidates. We cannot guarantee that the Vancouver Prostate Centre or UBC will continue to develop new product candidate opportunities, that we will continue to have access to such opportunities or that we will be able to purchase or license these product candidates on commercially reasonable terms, if at all. If we are unable to purchase or license new product candidates from the Vancouver Prostate Centre or UBC, we will be required to identify alternative sources of product candidates.

The success of our product pipeline strategy depends on our ability to identify, select and acquire pharmaceutical product candidates. Proposing, negotiating and implementing an economically viable product acquisition or license is a lengthy and complex process. We compete for partnering arrangements and license agreements with pharmaceutical and biotechnology companies and academic research institutions. Our competitors may have stronger relationships with third parties with whom we are interested in collaborating and/or may have more established histories of developing and commercializing products. As a result, our competitors may have a competitive advantage in entering into partnering arrangements with such third parties. In addition, even if we find promising product candidates, and generate interest in a partnering or strategic arrangement to acquire such product candidates, we may not be able to acquire rights to additional product candidates or approved products on terms that we find acceptable, if at all. If we fail to acquire and develop product candidates from others, we may be unable to grow our business.

We expect that any product candidate that we acquire rights to will require additional development efforts prior to commercial sale, including extensive clinical evaluation and approval by the FDA and non-U.S. regulatory authorities. All product candidates are subject to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. Even if the product candidates are approved, we can make no assurance that we would be capable of economically producing the product or that the product would be commercially successful.

We will need to retain additional personnel and expand our other resources in order to promote custirsen in the event we exercise our co-promotion option and to develop our other product candidates. If we fail to effectively expand our operations, including attracting and retaining key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates and our business may be materially adversely affected.

We will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our development and commercialization efforts for our existing and future product candidates. Our success depends on our continued ability to attract, retain and motivate highly qualified personnel, such as management, clinical and preclinical personnel, including our executive officers Scott Cormack, Cindy Jacobs and Susan Wyrick. In addition, although we have entered into employment agreements with each of Mr. Cormack, Dr. Jacobs and Ms. Wyrick such agreements permit the executive to terminate his or her employment with us at any time, subject to providing us with advance written notice.

Should custirsen receive marketing approval in the United States and Canada, or should we exercise our co-promotion option, we would need to hire a substantial number of specialized personnel, including field-based medical affairs representatives. In turn, we would need to increase our administrative headcount to support such expanded development and commercialization operations with respect to our product candidates. Our ability to attract and retain qualified personnel in the future is subject to intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses and our current financial position. The loss of the services of any of our senior management could delay or prevent the development and commercialization of our product candidates, or have other adverse effects on our business for an indefinite term. In particular, if we lose any members of our current senior management team, we may not be able to find suitable replacements in a timely fashion, if at all, and our business may be harmed as a result. If any of such events were to occur, among other things, we may not be able to comply with our contractual obligations to Teva under our Collaboration Agreement or advance our product candidates, which could have a material adverse effect on our business.

We have scientific and clinical advisors who assist us in formulating our development and clinical 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. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We may encounter difficulties in managing our expected growth and in expanding our operations successfully.

As we advance our product candidates custirsen, apatorsen (OGX-427) and OGX-225 through development and clinical trials, we will need to develop or expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. Maintaining additional relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to manage our development efforts effectively, manage our clinical trials effectively, hire, train and integrate additional management, development, administrative and sales and marketing personnel, improve our managerial, development, operational and finance systems, and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure.

Under the Collaboration Agreement, Teva is responsible for the commercialization costs associated with custirsen; however, if we were to exercise our co-promotion option, which we do not anticipate having sufficient funds to do, we would need to expand our marketing and sales capabilities. In addition, as we have primary responsibility for the oversight of the second-line chemotherapy trial in CRPC, we must be able to manage our development responsibilities effectively, which may impose a strain on our administrative and operational infrastructure.

Furthermore, we may acquire additional businesses, products or product candidates that complement or augment our existing business. Integrating any newly acquired business, product or product candidate could be expensive and time-consuming. We may not be able to integrate any acquired business, product or product candidate successfully or operate any acquired business profitably. Our future financial performance will depend, in part, on our ability to manage any future growth effectively and our ability to integrate any acquired businesses. We may not be able to accomplish these tasks, which failure could prevent us from successfully growing our business.

We may be adversely affected if our controls over financial reporting fail or are circumvented.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes Oxley Act of 2002 to report annually on our internal control over financial reporting. If it were to be determined that our internal control over financial reporting is not effective, such shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. This reporting requirement could also make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulation concerning control and procedures could have a material effect on our business, results of operation and financial condition. Any of these events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively affect the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding. The effect of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board and our Board committees and as executive officers.

Risks Related to Our Intellectual Property

Our proprietary rights may not adequately protect our technologies and product candidates.

Our commercial success will depend on our ability to obtain patents and/or regulatory exclusivity and maintain adequate protection for our technologies and product candidates in the United States and other countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and future product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We and our collaborators, including Teva, intend to apply for additional patents covering both our technologies and product candidates, as we deem appropriate. We or our collaborators may, however, fail to apply for patents on important technologies or product candidates in a timely fashion, if at all. Our existing patents and any future patents we or our collaborators obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. In addition, we do not always control the patent prosecution of subject matter that we license from others. Accordingly, we are sometimes unable to exercise a significant degree of control over such intellectual property as we would over our own.

Moreover, the patent positions of biopharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. As a result, the validity and enforceability of our patents cannot be predicted with certainty. In addition, the U.S. Supreme Court has recently revised certain tests regarding granting patents and assessing the validity of patents to make it more difficult to obtain patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our patents or those of our collaborators may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a re-examination proceeding, or during litigation, under the revised criteria. We cannot guarantee that:

- we or our licensors were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' pending patent applications will result in issued patents;
- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaboration partners will provide us with any competitive advantages, or will not be challenged by third parties; and
- we will develop additional proprietary technologies that are patentable, or the patents of others will not have an adverse effect on our business.

The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends on many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents. Our ability or the ability of our collaborators to maintain and solidify our proprietary position for our product candidates will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may issue in the future, or those licensed to us or our collaborators, may be challenged, invalidated, unenforceable or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. Due to the extensive amount of time required for the development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We and our collaborators, including Teva, also rely on trade secrets to protect some of our technology, especially where it is believed that patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our or our collaboration partners' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, non-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

We and our collaborators, including Teva, may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates and products, when and if we have any, in every jurisdiction would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products. These products may compete with our products, when and if we have any, and may not be covered by any of our or our licensors' patent claims or other intellectual property rights.

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

The intellectual property protection for our product candidates depends on third parties.

With respect to custirsen, apatorsen (OGX-427) and OGX-225, we have exclusively licensed from UBC certain issued patents and pending patent applications covering the respective antisense sequences underlying these product candidates and their commercialization and use, and we have licensed from Isis certain issued patents and pending patent applications directed to product compositions and chemical modifications used in product candidates for commercialization, use and the manufacturing thereof, as well as some alternative antisense sequences. We have also received a sublicense from Isis under certain third-party patent portfolios directed to such modifications.

The patents and pending patent applications underlying our licenses do not cover all potential product candidates, modifications and uses. In the case of patents and patent applications licensed from Isis, we do not have and have not had any control over the filing, prosecution or enforcement of these patents or patent applications. We cannot be certain that such prosecution efforts have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. We also cannot be assured that our licensors or their respective licensing partners will agree to enforce any such patent rights at our request or devote sufficient efforts to attain a desirable result. Any failure by our licensors or any of their respective licensing partners to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operation.

We may become involved in disputes with Teva or potential future collaborators over intellectual property ownership, and publications by our research collaborators and scientific advisors could impair our ability to obtain patent protection or protect our proprietary information, which, in either case, could have a significant effect on our business.

Inventions discovered under research, material transfer or other such collaborative agreements, including our Collaboration Agreement with Teva, may become jointly owned by us and the other party to such agreements in some cases and the exclusive property of either party in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention, or whether it is jointly owned, and disputes could arise regarding ownership of those inventions. These disputes could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business if we were not able to protect or license rights to these inventions. In addition, our research collaborators and scientific advisors generally have contractual rights to publish our data and other proprietary information, subject to our prior review. Publications by our research collaborators and scientific advisors containing such information, either with our permission or in contravention of the terms of their agreements with us, may impair our ability to obtain patent protection or protect our proprietary information, which could significantly harm our business.

The patent protection for our product candidates or products may expire before we are able to maximize their commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our product candidates have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, certain of the U.S. patents directed to custirsen and its use that have been licensed from UBC are scheduled to expire in 2020 and 2021. In some of the larger economic territories, such as the United States and Europe, patent term extension/restoration may be available to compensate for time taken during aspects of the product candidate's regulatory review. We cannot, however, be certain that an extension will be granted or, if granted, what the applicable time period or the scope of patent protection afforded during any extended period will be. In addition, even though some regulatory agencies may provide some other exclusivity for a product candidate under its own laws and regulations, we may not be able to qualify the product candidate or obtain the exclusive time period.

If we are unable to obtain patent term extension/restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our U.S. and non-U.S. patents.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents or our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are invalid or unenforceable and that we do not have the right to stop the other party from using the inventions. The U.S. Supreme Court has recently revised certain tests regarding granting patents and assessing the validity of patents to make it more difficult to obtain patents. Some of our issued patents may be subject to challenge and subsequent invalidation under the revised criteria. There is also the risk that, even if the validity or unenforceability of these patents is upheld, the court will narrow the scope of our claim or will refuse to stop the other party on the grounds that such other party's activities do not infringe our rights.

If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity or enforceability of the patents or incur the risk of litigation in the event that the owner asserts that we infringed its patents. The failure to obtain a license to technology or the failure to challenge an issued patent that we may require to discover, develop or commercialize our product candidates may have a material adverse effect on us.

If a third party asserts that we infringed its patents or other proprietary rights, we could face a number of risks that could seriously harm our results of operations, financial condition and competitive position, including:

- patent infringement and other intellectual property claims, which would be costly and time consuming to defend, whether or not the claims have merit, and which could delay the regulatory approval process and divert management's attention from our business;
- substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a competitor's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our technologies or future drugs unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do; and
- if a license is available from a third party, we may have to pay substantial royalties or lump-sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license.

The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates or methods of use either do not infringe the patent claims of the relevant patent, and/or that the patent claims are invalid, and/or that the patent is unenforceable and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

U.S. patent laws as well as the laws of some foreign jurisdictions provide for provisional rights in published patent applications beginning on the date of publication, including the right to obtain reasonable royalties, if a patent subsequently issues and certain other conditions are met.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our licensors' issued patents or our pending applications or our licensors' pending applications, or that we or our licensors were the first to invent the technology.

Patent applications filed by third parties that cover technology similar to ours may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party files a U.S. patent application on an invention similar to ours, we may elect to participate in or be drawn into an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. We cannot predict whether third parties will assert these claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend against these claims, whether they are with or without any merit and whether they

are resolved in favor of or against us or our licensors, we may face costly litigation and diversion of management's attention and resources. As a result of these disputes, we may have to develop costly non-infringing technology, or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, if at all, which could seriously harm our business or financial condition.

If we breach any of the agreements under which we license rights to our product candidates or technology from third parties, we could lose license rights that are important to our business. Certain of our license agreements may not provide an adequate remedy for a breach by the licensor.

We license the development and commercialization rights for most of our product candidates, including custirsen, apatorsen (OGX-427) and OGX-225, and we expect to enter into similar licenses in the future. Under such licenses, we are subject to various obligations such as sublicensing, royalty and milestone payments, annual maintenance fees, limits on sublicensing, insurance obligations and the obligation to use commercially reasonable best efforts to develop and exploit the licensed technology. If we fail to comply with any of these obligations or otherwise breach these agreements, our licensors may have the right to terminate the license in whole or in part or to terminate the exclusive nature of the license. Loss of any of these licenses or the exclusivity rights provided by the licenses could harm our financial condition and results of operations. In addition, certain of our license agreements with UBC eliminate our ability to obtain money damages in respect of certain claims against UBC.

Under the terms of our Collaboration Agreement with Teva, we are required to use commercially reasonable efforts to maintain and not to breach in any material manner certain of our third-party license agreements relating to custirsen. If we, or our third party licensors, breach any of these agreements in a material manner, we may be in breach of the Collaboration Agreement, which may allow Teva to terminate the Collaboration Agreement**.**

We may be subject to damages resulting from claims that we, or our employees or consultants, have wrongfully used or disclosed alleged trade secrets of third parties.

Many of our employees were previously employed, and certain of our consultants are currently employed, at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have not received any claim to date, we may be subject to claims that these employees or consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these current or former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. We may be subject to claims that employees of our partners or licensors of technology licensed by us have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. We may become involved in litigation to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

Risks Related to our Common Stock

The price for our common stock is volatile.

The market prices for our common stock and that of emerging life science companies generally have historically been highly volatile. Future announcements concerning us or our competitors may have a significant effect on the market price of our common stock. The stock markets also experience significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations may also adversely affect the market price of our common stock.

An increase in the market price of our common stock, which is uncertain and unpredictable, may be the sole source of gain from an investment in our common stock. An investment in our common stock may not be appropriate for investors who require dividend

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

If we raise additional capital, the terms of the financing transactions may cause dilution to existing stockholders or contain terms that are not favorable to us.

To date, our sources of cash have been limited primarily to proceeds from the private or public placement of our securities and proceeds from the Collaboration Agreement with Teva. In the future, we may seek to raise additional financing through private placements or public offerings of our equity or debt securities. We cannot be certain that additional funding will be available on acceptable terms, if at all. To the extent that we raise additional financing by issuing equity securities, we may do so at a price per share that represents a discount to the then-current per share trading price of our common stock and our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business.

Additionally, pursuant to our at-the-market equity offering program, we may sell shares of our common stock having aggregate sales proceeds of up to $25,000,000 from time to time through MLV as our sales agent. If we access the at-the-market equity offering program, we will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of our Sales Agreement with MLV, they may sell the shares by methods deemed to be an “at the market” offering as defined in Rule 415 under the Securities Act, including by means of ordinary brokers’ transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and MLV. The sale of additional shares of our common stock pursuant to our Sales Agreement with MLV will have a dilutive impact on our existing stockholders. Sales by us through MLV could cause the market price of our common stock to decline significantly. Sales of our common stock under the Sales Agreement, or the perception that such sales will occur, could encourage short sales by third parties, which could contribute to the further decline of our stock price.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because our stock price and those of other biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

Anti-takeover provisions in our stockholder rights plan, our charter documents and under Delaware law could make a third-party acquisition of us difficult.

We have a stockholder rights plan that may have the effect of discouraging unsolicited takeover proposals. Specifically, the rights issued under the stockholder rights plan could cause significant dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board. In addition, our certificate of incorporation and bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions include the ability of our Board to designate the terms of and issue new series of preferred stock and the ability of our Board to amend our bylaws without stockholder approval. In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation

Law, which generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless certain specific requirements are met as set forth in Section 203. Collectively, these provisions could make a third-party acquisition of us difficult or could discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

Risks Related to Our Industry

The regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA. We have not submitted an application for or received marketing approval for any of our product candidates. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA, non-U.S. regulatory authorities' or other applicable United States and non-U.S. regulatory requirements may, either before or after product approval, if any, subject us to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the drug approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that could cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed safe or effective;
- the FDA may not find the data from preclinical studies and/or clinical trials sufficient;
- the FDA might not approve our third-party manufacturer's processes or facilities;
- the FDA may change its approval policies or adopt new regulations; and
- third-party products may enter the market and change approval requirements.

Even if we obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our product candidates may limit how we manufacture and market our product candidates, which could materially affect our ability to generate revenue.

If any of our product candidates are approved, the approved product and its manufacturer will be subject to continual review. Any regulatory approval that we receive for a product candidate is likely to be subject to limitations on the indicated uses for which the

end product may be marketed, or include requirements for potentially costly post-approval follow-up clinical trials. In addition, if the FDA and/or non-U.S. regulatory authorities approve any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the end product will be subject to extensive regulatory requirements. We and the manufacturers of our products, when and if we have any, will also be required to comply with cGMP regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products, when and if we have any, and these facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA and other non-U.S. regulatory authorities, or if previously unknown problems with our products, when and if we have any, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;
- warning letters;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs.

In addition, the FDA and non-U.S. regulatory authorities may change their policies and additional regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, Canada or abroad. If we are not able to maintain regulatory compliance, we would likely not be permitted to market our future product candidates and we may not achieve or sustain profitability.

There is a high risk that our drug development activities will not result in commercial products.

Our product candidates are in various stages of development and are prone to the risks of failure inherent in drug development. We will need to complete significant additional clinical trials before we can demonstrate that our product candidates are safe and effective to the satisfaction of the FDA and non-U.S. regulatory authorities. Clinical trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process, and successful early clinical trials do not ensure that later clinical trials will be successful. Product candidates in later-stage clinical trials may fail to show desired efficacy and safety traits despite having progressed through initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. In addition, a clinical trial may prove successful with respect to a secondary objective, but fail to demonstrate clinically significant benefits with respect to a primary objective. Failure to satisfy a primary objective in a Phase 3 clinical trial (registration trial) would generally mean that a product candidate would not receive regulatory approval.

If government and third-party payors fail to provide coverage and adequate reimbursement rates for our product candidates, our revenue and potential for profitability will be reduced.

In the United States and elsewhere, our product revenue will depend principally on the reimbursement rates established by third-party payors, including government health administration authorities, managed-care providers, public health insurers, private health insurers and other organizations. These third-party payors are increasingly challenging the price, and examining the cost-effectiveness, of medical products and services. In addition, significant uncertainty exists as to the reimbursement status, if any, of

newly approved drugs, pharmaceutical products or product indications. We may need to conduct post-marketing clinical trials in order to demonstrate the cost-effectiveness of our products, if any. Such clinical trials may require us to commit a significant amount of management time and financial and other resources. If reimbursement of such product is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our revenue could be reduced.

In some countries other than the United States, particularly the countries of the European Union and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, obtaining pricing approval from governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval of a product for an indication. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of one of our product candidates to other available therapies. If reimbursement of such product candidate is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our revenue could be reduced.

Domestic and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare, including drugs. In the United States, there have been, and we expect that there will continue to be, federal and state proposals to implement similar governmental control. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reforms the way Medicare will cover and reimburse pharmaceutical products. The legislation expands Medicare coverage for drug purchases by the elderly and eventually will introduce a new reimbursement methodology based on average sales prices for certain drugs. In addition, the legislation provides authority for limiting the number of outpatient drugs that will be covered in any therapeutic class. As a result of the new legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. The Medicaid program and state healthcare laws and regulations may also be modified to change the scope of covered products and/or reimbursement methodology. Cost control initiatives could decrease the established reimbursement rates that we receive for any products in the future, which would limit our revenue and profitability. Legislation and regulations affecting the pricing of pharmaceutical products, including custirsen, may change at any time, which could further limit or eliminate reimbursement rates for custirsen or other product candidates.

Failure to obtain regulatory approval outside of the United States and Canada would prevent us or Teva from marketing our product candidates abroad.

We intend to market certain of our existing and future product candidates outside of the United States and Canada. In order to market our existing and future product candidates in the European Union and many other non-North American markets, we must obtain separate regulatory approvals. We have had limited interactions with non-North American regulatory authorities. Approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA or other regulatory authorities does not ensure approval by regulatory authorities in other countries, and approval by one or more non-North American regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. The non-North American regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain non-North American regulatory approvals on a timely basis, if at all. We may not be able to file for non-North American regulatory approvals and may not receive necessary approvals to commercialize our existing and future product candidates in any market.

Table of Contents

Item 6. Exhibits

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of OncoGenex Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the company's Current Report on Form 8-K filed with the SEC on May 29, 2013)
10.1	OncoGenex Pharmaceuticals, Inc. 2010 Performance Incentive Plan, as amended and restated (incorporated by reference to Appendix A to the company's Definitive Proxy Statement filed with the SEC on April 22, 2013)
10.2	At-the-Market Issuance Sales Agreement, dated June 18, 2013, by and between OncoGenex Pharmaceuticals, Inc. and MLV & Co. LLC (incorporated by reference to Exhibit 1.1 to the company's Current Report on Form 8-K filed with the SEC on June 18, 2013)
31.1	Certification of President, Chief Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1 *	Certification of President, Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS **	XBRL Instance Document
101.SCH **	XBRL Taxonomy Extension Schema Document
101.CAL **	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF **	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB **	XBRL Taxonomy Extension Label Linkbase Document
101.PRE **	XBRL Taxonomy Extension Presentation Linkbase Document

* The certifications attached as Exhibit 32.1 accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

** These exhibits are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

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.

ONCOGENEX PHARMACEUTICALS, INC.

Date: August 8, 2013

By: /s/ Scott Cormack
Scott Cormack
President, Chief Executive Officer and Principal Financial Officer
(authorized officer and principal financial officer)

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of OncoGenex Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the company's Current Report on Form 8-K filed with the SEC on May 29, 2013)
10.1	OncoGenex Pharmaceuticals, Inc. 2010 Performance Incentive Plan, as amended and restated (incorporated by reference to Appendix A to the company's Definitive Proxy Statement filed with the SEC on April 22, 2013)
10.2	At-the-Market Issuance Sales Agreement, dated June 18, 2013, by and between OncoGenex Pharmaceuticals, Inc. and MLV & Co. LLC (incorporated by reference to Exhibit 1.1 to the company's Current Report on Form 8-K filed with the SEC on June 18, 2013)
31.1	Certification of President, Chief Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1 *	Certification of President, Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS **	XBRL Instance Document
101.SCH **	XBRL Taxonomy Extension Schema Document
101.CAL **	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF **	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB **	XBRL Taxonomy Extension Label Linkbase Document
101.PRE **	XBRL Taxonomy Extension Presentation Linkbase Document

* The certifications attached as Exhibits 32.1 accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

** These exhibits are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934

I, Scott Cormack, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OncoGenex Pharmaceuticals, Inc.;

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

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

4. I am 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. 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 8, 2013

/s/ Scott Cormack

Scott Cormack
President, Chief Executive Officer and
Principal Financial Officer

Exhibit 32.1

Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Scott Cormack, President, Chief Executive Officer and Principal Financial Officer of OncoGenex Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that:

(1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2013 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and

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

Dated: August 8, 2013

/s/ Scott Cormack
Scott Cormack
President, Chief Executive Officer and
Principal Financial Officer