
**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 MARCH 31, 2011

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
(State or Other Jurisdiction of
Incorporation or Organization)

95-4343413
(I.R.S. Employer Identification Number)

1522 217 th 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 definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a 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
Common Stock, \$0.001 par value

Outstanding at May 1, 2011
9,718,251

OncoGenex Pharmaceuticals, Inc.
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PART I. FINANCIAL INFORMATION**Item 1. Consolidated Financial Statements****OncoGenex Pharmaceuticals, Inc.****Consolidated Balance Sheets
(Unaudited)**

(In thousands of U.S. dollars)

	March 31, 2011	December 31, 2010
	\$	\$
ASSETS		
Current		
Cash and cash equivalents ^[note 4]	6,998	23,533
Restricted cash	502	502
Short-term investments ^[note 4]	74,100	61,574
Amounts receivable	1,348	1,224
Prepaid expenses	968	2,485
Total current assets	83,916	89,318
Property and equipment, net	171	87
Other assets	510	513
Total assets	84,597	89,918
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current		
Accounts payable and accrued liabilities	1,166	893
Deferred Collaboration Revenue	10,000	10,000
Current portion of long-term obligations ^[note 6]	1,305	1,314
Warrant liability ^[note 4, note 5]	13,141	15,269
Total current liabilities	25,612	27,476
Deferred Collaboration Revenue, net of current	11,040	11,622
Long-term obligation, less current portion ^[note 6]	6,447	6,695
Total liabilities	43,099	45,793
Commitments and contingencies ^[note 7]		
Shareholders' equity:		
Common shares ^[note 5] :		
\$0.001 par value 25,000,000 shares authorized and 9,718,251 issued and outstanding at March 31, 2011 and 9,693,591 issued and outstanding at December 31, 2010	10	10
Additional paid-in capital	107,940	107,579
Accumulated deficit	(69,114)	(66,069)
Accumulated other comprehensive income	2,662	2,605
Total shareholders' equity	41,498	44,125
Total liabilities and shareholders' equity	84,597	89,918
<i>Subsequent events ^[note 9]</i>		

See accompanying notes.

OncoGenex Pharmaceuticals, Inc.**Consolidated Statements of Loss
(Unaudited)**

(In thousands of U.S. dollars, except per share and share amounts)

	Three months Ended March 31,	
	2011	2010
	\$	\$
COLLABORATION REVENUE	1,199	4,700
EXPENSES		
Research and development	4,853	6,380
General and administrative	1,571	1,350
Total expenses	6,424	7,730
LOSS FROM OPERATIONS	5,225	3,030
OTHER INCOME (EXPENSE)		
Interest income	56	5
Other	(4)	(19)
Gain (loss) on warrants <i>[note 5]</i>	2,128	—
Total other income (expense)	2,180	(14)
Loss for the period before income taxes	3,045	3,044
Income taxes	—	—
Net loss	3,045	3,044
Basic and diluted loss per common share <i>[note 5(e)]</i>	0.31	0.48
Weighted average number of common shares <i>[note 5(e)]</i>	9,713,413	6,333,272

See accompanying notes.

OncoGenex Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows
(Unaudited)
(In thousands of U.S. dollars)

	Three months ended	
	March 31,	
	2011	2010
	\$	\$
OPERATING ACTIVITIES		
Loss for the period	(3,045)	(3,044)
Add items not involving cash		
Depreciation and amortization	19	12
Stock-based compensation [note 5(c)]	271	168
Change in value of warrants [note 5]]	(2,128)	—
Changes in non-cash items		
Amounts receivable	(124)	286
Restricted cash	—	(3,502)
Prepaid expenses	1,519	(1,216)
Accounts payable and accrued liabilities	273	(7,629)
Lease obligation	(247)	(306)
Deferred collaboration revenue	(581)	(1,917)
Cash used in operating activities	(4,043)	(17,148)
FINANCING ACTIVITIES		
Proceeds from issuance of common stock under stock option and employee purchase plans	91	185
Cash provided by financing activities	91	185
INVESTING ACTIVITIES		
Proceeds from sale of investments	16,088	400
Purchase of investments	(28,614)	—
Purchase of property and equipment	(32)	(21)
Cash provided by (used in) investing activities	(12,558)	379
Effect of exchange rate changes on cash and cash equivalents	25	8
Increase (decrease) in cash and cash equivalents during the period	(16,535)	(16,576)
Cash and cash equivalents, beginning of the period	23,533	62,051
Cash and cash equivalents, end of the period	6,998	45,475
Supplemental cash flow information		
Property and equipment acquired under lease obligation	71	—

See accompanying notes.

OncoGenex Pharmaceuticals, Inc.

**Notes to Consolidated Financial Statements
(Unaudited)**

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

OncoGenex Pharmaceuticals, Inc. (the “Company” or “OncoGenex”) is committed to the development and commercialization of new therapies that address treatment resistance in cancer patients. The Company was incorporated in the state of Delaware and, together with its subsidiaries, has a facility in Bothell, Washington and an office in Vancouver, British Columbia (Canada).

The unaudited 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, 2010 has been derived from the audited consolidated financial statements included in the Company’s Annual Report on Form 10-K for the year then ended. The 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, 2010 and filed with the United States Securities and Exchange Commission (“SEC”) on March 10, 2011.

The consolidated financial statements include the accounts of OncoGenex Pharmaceuticals, Inc. and our wholly owned subsidiary, OncoGenex Technologies. All intercompany balances and transactions have been eliminated.

2. ACCOUNTING POLICIES

Recently Adopted Accounting Policies

In April 2010, the FASB issued ASU No. 2010 — 17 — Revenue Recognition — Milestone Method (Topic 605): Milestone Method of Revenue Recognition. This standard provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for certain research and development transactions. Under this new standard, a company can recognize as revenue consideration that is contingent upon achievement of a milestone in the period in which it is achieved, only if the milestone meets all criteria to be considered substantive. This standard was effective for us on a prospective basis beginning in the quarter ended March 31, 2011. The adoption of this standard did not have a significant impact on our financial position or results of operations.

In January 2010, the FASB issued amended guidance on fair value measurements and disclosures. The new guidance requires additional disclosures regarding fair value measurements, amends disclosures about post-retirement benefit plan assets, and provides clarification regarding the level of disaggregation of fair value disclosures by investment class. This guidance is effective for interim and annual reporting periods beginning after December 15, 2009, except for certain Level 3 activity disclosure requirements that will be effective for reporting periods beginning after December 15, 2010. Accordingly, we adopted this amendment in the quarter ended March 31, 2010, while the additional Level 3 requirements were adopted in the quarter ended March 31, 2011.

Recent Accounting Pronouncements

There were no recent accounting pronouncements which the Company expects would have any impact on the consolidated financial position, results of operations or cash flows.

3. COLLABORATION AGREEMENT

On December 20, 2009, the Company, through its wholly-owned subsidiary, OncoGenex Technologies Inc., entered into a Collaboration Agreement with Teva Pharmaceutical Industries Ltd. ("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 associated with cancer treatment resistance, or the Licensed Product. Under the Collaboration Agreement, Teva paid the Company upfront payments in the aggregate amount of \$50 million and has 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.

On the same date, the Company and Teva also entered into a stock purchase agreement, or Stock Purchase Agreement, pursuant to which Teva made an additional \$10 million equity investment in the Company 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 has been included in collaboration revenue.

In connection with the Collaboration Agreement and pursuant to the terms of agreements between the Company and Isis relating to custirsen, the Company paid Isis Pharmaceuticals, Inc., or Isis, \$10 million which was recorded as research and development expense in 2009. The Company also paid approximately \$333,333 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 third-party agreements, the Company anticipates that it 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 third-party agreements, the Company anticipates it will pay royalties to third-parties of 4.88% to 8.00% of net sales, unless the Company's 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 the Company. Minimum royalty rates payable by the Company 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.

Teva has the exclusive worldwide right and license to develop and commercialize products containing custirsen and related compounds. The Company has 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 the Company's co-promotion option, except for start-up costs in advance of commercialization.

Teva and the Company have developed a Clinical Development Plan under which three phase 3 clinical trials will be initiated:

- An ongoing phase 3 clinical trial, referred to as the Prostate Cancer SATURN trial, or SATURN, to evaluate a durable pain palliation benefit for custirsen in combination with docetaxel retreatment as second-line chemotherapy in approximately 300 patients with castrate-resistant prostate cancer, or CRPC.

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- An ongoing phase 3 clinical trial, referred to as the Synergy trial, or SYNERGY, to be conducted in approximately 125 cancer centers to evaluate a survival benefit for custirsen in combination with first-line docetaxel treatment in approximately 800 patients with CRPC.
- A phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with first-line chemotherapy in patients with non-small cell lung cancer, or NSCLC, which is expected to be initiated in 2011 following successful manufacturing of additional custirsen drug product and completion of drug-drug interaction DDI studies. The trial is expected to enroll approximately 950 patients. The study protocol will include two futility assessments and one interim analysis for efficacy. The first-line chemotherapy regimen has been selected as carboplatin and paclitaxel.

Teva will be responsible for conducting any other studies and development work necessary to obtain required regulatory approvals. The Company 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. The Company may terminate its participation in the joint steering committee at any time.

Funding responsibilities for the Clinical Development Plan will be allocated as follows:

- The Company will be required to spend \$30 million in direct and indirect development costs, and
- 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 the Company's patent rights related to custirsen or safety issues or "futility" as defined in the Collaboration Agreement, Teva may terminate the Collaboration Agreement in 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 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 the responsibility of the Company. Either party may terminate the Collaboration Agreement for an uncured material breach by the other party or upon the bankruptcy of either party. If the Collaboration Agreement is terminated by the Company for other than an uncured material breach by Teva, the Company 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 the Company, within 90 days of the change of control, Teva may terminate the joint steering committee in its sole discretion, terminate the co-promotion option in its sole discretion if not then exercised by the Company or if exercised but not yet executed by the Company, or terminate the co-promotion option if in its commercially reasonable opinion co-promotion with the Company's successor would be materially detrimental to Teva's interests.

Upon entering into the Collaboration Agreement, the Company assessed whether withholdings taxes were owed to the Israeli Tax Authority, or ITA, resulting from the Collaboration Agreement. It was the Company's position that withholdings taxes were not owed, and a claim was issued to the ITA accordingly. For accounting purposes, management concluded that the withholdings tax claim was an uncertain tax position, and \$3 million, which represented the potential withholdings tax obligation, once received from Teva was initially recorded as Restricted Cash pending the ITA review of our claim and a corresponding liability of \$3 million was included in Accounts Payable and Accrued Liabilities. In June 2010, the Company received approval from the ITA for our request for a withholdings tax exemption on amounts received from Teva in relation to the Collaboration Agreement. Following receipt of this approval from the ITA the \$3 million was released to the Company from escrow. Subsequently, the Company released the \$3 million liability and recorded a \$3 million income tax recovery in the second quarter of 2010.

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Revenue for the three months ended March 31, 2011 was \$1.2 million, which consists of partial recognition of deferred collaboration revenue representing OncoGenex's contribution to the custirsen phase 3 development plan under our Collaboration Agreement with Teva and custirsen manufacturing costs incurred by OncoGenex in the year ended December 31, 2010 that are reimbursable from Teva. At March 31, 2011, a remaining balance of \$21.0 million of the up-front payment was recorded in deferred collaboration revenue. There was \$4.7 million in revenue recorded in the three months ended March 31, 2010 as a result of the Collaboration Agreement with Teva.

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 the Company's financial instruments including cash and cash equivalents, amounts 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 level listed below:

- Level 1 — Quoted prices in active markets for identical securities;
- Level 2 — Other significant observable 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, the Company obtains estimates for the fair value of financial instruments through third party pricing service providers.

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

The Company invests its 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. Our securities are not collateralized and mature within one year.

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

Financial Instruments

Cash

Significant amounts of cash are held on deposit with a large well established Canadian financial institution.

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Government and Agency Securities

Government Securities U.S. and Canadian Government securities are valued using quoted market prices. Valuation adjustments are not applied. Accordingly, U.S. and Canadian 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.

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)	Level 1	Level 2	Level 3	2011
Assets				
Cash	\$ 2,249	\$ —	\$ —	\$ 2,249
Money market securities	\$ 3,963	\$ —	\$ —	\$ 3,963
Government securities	\$ 5,064	\$ —	\$ —	\$ 5,064
Corporate bonds and commercial paper	\$ —	\$ 70,324	\$ —	\$ 70,324
	\$ 11,276	\$ 70,324	\$ —	\$ 81,600
Liabilities				
Warrants	\$ —	\$ —	\$ 13,141	\$ 13,141

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Marketable securities consist of the following:

(in thousands)	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
2011				
Cash	\$ 2,249	\$ —	\$ —	\$ 2,249
Money market securities	\$ 3,461	\$ —	\$ —	\$ 3,461
Government securities	\$ 1,000	\$ —	\$ —	\$ 1,000
Corporate bonds and commercial paper	\$ 288	\$ —	\$ —	\$ 288
Cash and cash equivalents	\$ 6,998	\$ —	\$ —	\$ 6,998
Money market securities	\$ 502	\$ —	\$ —	\$ 502
Restricted cash	\$ 502	\$ —	\$ —	\$ 502
Government securities	\$ 4,002	\$ 62	\$ —	\$ 4,064
Corporate bonds and commercial paper	\$ 70,076	\$ 8	\$ (48)	\$ 70,036
Short-term investments	\$ 74,078	\$ 70	\$ (48)	\$ 74,100

All securities included in cash, and cash equivalents have 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.

There were no significant realized or unrealized gains or losses on the sales of marketable securities in the three months ended March 31, 2011 and no significant unrealized gains or losses are included in accumulated other comprehensive income as at March 31, 2011. Realized gains and losses are transferred out of accumulated other comprehensive income into interest income using the specific identification method.

All of the marketable securities held as of March 31, 2011 had maturities of one year or less. The Company only invests in A (or equivalent) rated securities with maturities of one year or less. Given the quality of the investment portfolio, its short-term nature, and subsequent proceeds collected on sale of securities that reached maturity, the Company does not believe that there are any other than temporary impairments related to its investments in marketable securities at March 31, 2011.

As of March 31, 2011, the Company recorded a \$13,141,000 warrant liability. The Company reassesses 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 comparable companies from a representative peer group selected based on industry and market capitalization. See note 5(d) in the Notes to Financial Statements for further details on the inputs used in the Black-Scholes pricing model used to recalculate the warrant liability.

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The following table presents the changes in fair value of the Company's total Level 3 financial liabilities for the year ended March 31, 2011:

<u>(In thousands)</u>	<u>Liability at December 31, 2010</u>	<u>Gain (loss) on warrants</u>	<u>Remaining Liability at March 31, 2011</u>
Warrant liability	\$ 15,269	\$ 2,128	\$ 13,141

5. COMMON STOCK

[a] Authorized

25,000,000 authorized common shares, par value of \$0.001, and 5,000,000 preferred shares, par value of \$0.001.

[b] Issued and Outstanding Shares

During the three month period ended March 31, 2011 the Company issued 24,660 common shares upon exercise of stock options (period ended March 31, 2010 — 51,428) to satisfy stock option exercises.

[c] Stock options

2010 Performance Incentive Plan

At the 2010 Annual Meeting of Stockholders of the Company held on June 8, 2010, stockholders of the Company approved the 2010 Performance Incentive Plan. Following the approval of the 2010 Performance Incentive Plan, we are no longer able to issue additional equity awards under any of our other equity compensation plans. As at March 31, 2011 the Company has reserved, pursuant to various plans, 1,003,911 common shares for issuance upon exercise of stock options by employees, directors, officers and consultants of the Company, of which 750,342 are reserved for options currently outstanding, and 253,569 are available for future option grants.

Stock Option Summary

Options vest in accordance with terms as determined by the Board, typically over four years for employee grants and one to three years for Board of Director 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, 2010	744,913	8.73
Option grants	40,500	16.65
Option expirations/cancellations	(2,000)	22.28
Option exercises	(24,660)	3.67
Option forfeitures	(8,411)	11.44
Balance, March 31, 2011	750,342	9.26

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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:

	Three months ended	
	March 31,	
	2011	2010
Risk-free interest rates	2.74%	2.44%
Expected dividend yield	0%	0%
Expected life	7 years	5 years
Expected volatility	75%	73%

The expected life was calculated based on the simplified method as permitted by the SEC's Staff Accounting Bulletin 110, Share-Based Payment. The computation of expected volatility was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. The Company considers the use of these methods of calculating expected term and volatility appropriate because of the lack of sufficient historical exercise data following the reverse takeover of Sonus. The risk-free interest rate was 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 in the following expense categories of the consolidated statements of loss:

(In thousands)	Three Months Ended	
	March 31,	
	2011	2010
	\$	\$
Research and development	121	69
General and administrative	150	99
Total share-based compensation	271	168

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

As at March 31, 2011 and December 31, 2010 the total unrecognized compensation expense related to stock options granted is \$3,081,000 and \$2,962,000 respectively, which is expected to be recognized into expense over a period of approximately four years.

[d] Stock Warrants

At March 31, 2011, 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 three months ended March 31, 2011 or three months ended March 31, 2010.

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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:

	Three months ended	
	March 31,	
	2011	2010
Risk-free interest rates	2.21%	—
Expected dividend yield	0%	—
Expected life	4.6 years	—
Expected volatility	75%	—

[e] Loss per Common Share

(In thousands except shares and per share amounts)	Three Months Ended	
	March 31,	
	2011	2010
Numerator		
Loss attributable to common shareholders as reported	\$ 3,045	\$ 3,044
Denominator		
Weighted average number of common shares outstanding	9,713,413	6,333,272
Basic and diluted loss per common share	\$ 0.31	\$ 0.48

As of March 31, 2011 and December 31, 2010 a total of 2,337,643 and 2,332,214 options and warrants, respectively, have not been included in the calculation of potential common shares as their effect on diluted per share amounts would have been anti-dilutive.

6. RESTRUCTURING ACTIVITIES

On August 21, 2008, Sonus Pharmaceuticals, Inc. (“Sonus”) completed a transaction (“the Arrangement”) with OncoGenex Technologies Inc., (“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 the Company’s current requirements. The Company is currently in the process of evaluating opportunities to exit or sublet portions of the leased space and recorded an initial restructuring charge of \$2,084,000 on August 21, 2008 as part of the purchase price allocation. 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 EITF No. 95-3, “Recognition of Liabilities in Connection with a Purchase Business Combination”. This represents the Company’s best estimate of the liability. Subsequent changes in the liability due to changes in estimates of sublease assumptions are recognized as adjustments to restructuring charges.

In June 2009, the Company revised its sublease income assumptions used to estimate the excess lease facility liability. These assumptions were subsequently revised again in December 2009 and September 2010. These changes in estimate resulted in increases in the value of the excess lease liability of \$494,000, \$3,457,000, and \$4,038,000 and a corresponding expense recorded in June 2009, December 2009, and September 2010, respectively, to reflect these changes in estimate. The estimated value of the liability remaining with respect to excess facilities was \$7,467,000 as of December 31, 2010. In the three months ended March 31, 2011, with respect to excess facilities, \$338,000 was amortized into income resulting in a remaining liability of \$7,129,000 at March 31, 2011.

(In thousands)	Remaining Liability at December 31, 2010	Amortization of excess lease facility	Additional Liability Recorded	Remaining Liability at March 31, 2011
Current portion of excess lease facility	\$ 1,303	\$ 23	\$ —	\$ 1,280
Long-term portion of excess lease facility	\$ 6,164	\$ 315	\$ —	\$ 5,849
Total	\$ 7,467	\$ 338	\$ —	\$ 7,129

7. COMMITMENTS AND CONTINGENCIES

Teva Pharmaceutical Industries Ltd.

Under the Collaboration Agreement, Teva made upfront payments in the aggregate amount of \$50 million, may make up to \$370 million in additional payments upon the achievement of developmental and commercial milestones and may be required in the future to pay royalties at percentage rates ranging from the mid-teens to mid-twenties on net sales. The Company is required to contribute \$30 million in direct and indirect costs towards the Clinical Development Plan. As of March 31, 2011, \$9.0 million of these costs have been incurred by OncoGenex, resulting in a remaining funding responsibility of \$21.0 million which has been recorded under Current and Long-term Deferred Collaboration Revenue as of March 31, 2011. Teva will fund all other expenses under the Clinical Development Plan. See note 3 in the Notes to Financial Statements for further details on our Collaboration Agreement with Teva.

Isis Pharmaceuticals Inc. and University of British Columbia

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

The amendment to the Isis License Agreement provides, among other things, that if the Company is the subject of a 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 the Company 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. As the Company has now licensed the product to Teva and established a royalty rate payable to Isis, no royalty rate adjustments would apply if Teva acquires the Company and is the surviving company. If the \$30 million in advanced reimbursement of development activities has not been spent by OncoGenex prior to the third anniversary of the Collaboration Agreement between OncoGenex and Teva, OncoGenex will pay Isis an amount equal to 30% of any un-spent portion less \$3.5 million.

In addition, we are required to pay to Isis 30% of all Non-Royalty Revenue we receive on custirsen sales. 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, 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 we are, that the applicable amount payable to Isis will be less than 30%.

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Pursuant to license agreements the Company has with the UBC and Isis, the Company is obligated to pay milestone payments of up to CAD \$1.6 million and \$7.75 million, respectively, upon the achievement of specified product development milestones related to OGX-427 and OGX-225 and royalties on future product sales. We paid Isis and UBC \$750,000 and CAD \$100,000, respectively, in 2010 upon the initiation of a phase 2 clinical trial of OGX-427 in patients with CRPC. We do not anticipate making any royalty payments to Isis in 2011.

Unless otherwise terminated, the Isis agreements for custirsen and 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 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.

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 relating to custirsen, OGX-427 and OGX-225. 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.

Bayer HealthCare LLC

On August 7, 2008, Sonus completed an exclusive in-licensing agreement with Bayer HealthCare LLC for the right to develop, commercialize or sublicense a family of compounds known as caspase activators presently in pre-clinical research. Under terms of the agreement, Sonus was granted exclusive rights to develop two core compounds for all prophylactic and therapeutic uses in humans. Additionally, Sonus was granted rights to all other non-core compounds covered under the patents for use in oncology.

Under the terms of the agreement, Bayer received an upfront license fee of \$450,000. OncoGenex will make annual payments to Bayer on the anniversary date (Anniversary Payments), with an initial payment of \$100,000 paid in 2008. The payments increase by \$25,000 each year until the initiation of the first phase 3 clinical trial, at which point the Anniversary Payments reset to \$100,000 each year and increase by \$25,000 until the Company achieves either the first New Drug Application filing in the United States or the European Union. OncoGenex is obligated to pay royalties on net future product sales in addition to aggregate milestone payments of up to \$14,000,000 for clinical development and regulatory milestones. No milestone payments are triggered prior to the initiation of a phase 3 clinical trial. OncoGenex has the option to terminate this contract upon 60 days written notice to Bayer.

Lease Arrangements

The Company has an operating lease agreement for office space in Vancouver, Canada, which expires in September 2014.

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

	CAD
2011	\$ 80
2012	\$ 107
2013	\$ 107
2014	\$ 80
Total	\$ 374

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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 \$497,000, which is included in Other Long Term Assets. In addition, a standby letter of credit was issued in 2010, and \$502,000 was deposited in a restricted money market account as collateral. The Company is currently in the process of evaluating opportunities to exit or sublet portions of the leased space and has recorded a liability in the excess facilities lease charge of \$7,129,000 as at March 31, 2011 (note 6).

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

2011	\$	1,541
2012	\$	2,117
2013	\$	2,180
2014	\$	2,246
2015	\$	2,313
Remainder	\$	4,837
Total	\$	15,234

Consolidated rent expense relating to both the Vancouver, Canada and Bothell, Washington offices for the periods ended March 31, 2011 and 2010 was \$642,000 and \$621,00 respectively.

Guarantees and Indemnifications

OncoGenex indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at our request in such capacity. The term of the indemnification period is equal to the officer's or director's 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 it 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 March 31, 2011.

We have certain 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. COMPREHENSIVE LOSS

(In thousands)	Three Months Ended	
	March 31,	
	2010	2010
	\$	\$
Loss for the period	3,045	3,044
Unrealized gain on cash equivalents and marketable securities	70	—
Unrealized loss on cash equivalents and marketable securities	(48)	(2)
Comprehensive loss	3,023	3,042

9. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to March 31, 2011. Based on our 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, requirements and future clinical trials conducted by us or our collaborators;
- our anticipated future capital requirements and the terms of any capital financing agreements;
- 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. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements:

- uncertainty relating to the timing, feasibility and results of clinical trials;
- dependence on Teva’s ongoing commitment and ability to develop and commercialize custirsen;
- dependence on the development and commercialization of our product candidates, particularly on custirsen;
- the risk that research or previous clinical trial results may not be indicative of results in humans or in future studies;
- uncertainties regarding the safety and effectiveness of our product candidates and technologies;
- the timing, expense and uncertainty associated with the development and regulatory approval process for our product candidates;
- uncertainties regarding our future operating results, and the risk that our product candidates will not obtain the requisite regulatory approvals to commercialize or that the future sales of our product candidates may be less than expected or nil;
- future capital requirements and uncertainty of obtaining additional funding through debt or equity financings on terms acceptable to us;
- acceptance of our products by the medical community;
- the uncertainty associated with exiting or subleasing our excess office and laboratory space;
- our ability to build out our product candidate pipeline through product in-licensing, acquisition activities, or otherwise;

- changes in the treatment landscape, general competitive conditions within the drug development and pharmaceutical industry and new developments or therapies that may not work in combination with our product candidates;
- the potential for product liability issues and related litigation;
- our dependence on key employees;
- proper management of our operations;
- the potential inability to successfully protect and enforce our intellectual property rights;
- the reliance on third parties who license intellectual property rights to us to comply with the terms of such agreements and to enforce, prosecute and defend such intellectual property rights;
- the reliance on third parties to manufacture and supply our product candidates;
- the effect of current, pending or future legislation, regulations and legal actions in the United States, Canada and elsewhere affecting the pharmaceutical and healthcare industries;
- volatility in the value of our common stock; and
- general economic conditions.

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.

MD&A Overview

In Management's Discussion and Analysis of Financial Condition and Results of Operations, we explain the general financial condition and the results of operations for our Company, including:

- an overview of our business;
- results of operations and why those results are different from the prior year; and
- capital resources we currently have and possible sources of additional funding for future capital requirements.

Overview of the Company

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new cancer therapies that address treatment resistance in cancer patients. We have four product candidates in our pipeline, custirsen, OGX-427, OGX-225, and CSP-9222, 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 OGX-427 are clinical-stage assets. In the first quarter of 2011 we decided to cease our previously disclosed efforts to out-license product candidate SN2310 and we do not plan on pursuing any further development efforts for SN2310 in the future.

Our product candidates custirsen, OGX-427 and OGX-225 focus on mechanisms for treating resistance in cancer patients and are designed to address treatment resistance by blocking the production of specific proteins that we believe promote 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, including chemotherapy. We believe this approach will increase survival time and improve the quality of life for cancer patients. Product candidate CSP-9222 is the lead compound from a family of caspase activators that have been in-licensed from Bayer and demonstrate activation of programmed cell death in pre-clinical models.

Product Candidate Custirsen

As discussed above, 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 OGX-427 and OGX-225).

We and Teva have developed a Clinical Development Plan under which two phase 3 clinical trials have been initiated and one additional phase 3 clinical trial will be initiated. We have designed two of the phase 3 clinical trials to evaluate the clinical benefit of custirsen in patients with castrate-resistant prostate cancer, or CRPC, and, together with Teva, we have designed a third phase 3 clinical trial to evaluate the clinical benefit of custirsen in non-small cell lung cancer, or NSCLC, as follows:

- The ongoing phase 3 clinical trial, referred to as the Prostate Cancer SATURN trial, or SATURN, to evaluate a durable pain palliation benefit for custirsen in combination with docetaxel retreatment as second-line chemotherapy in approximately 300 patients with CRPC.
- The ongoing phase clinical trial, referred to as the Synergy trial, or SYNERGY, to be conducted in approximately 125 cancer centers to evaluate a survival benefit for custirsen in combination with first-line docetaxel treatment in approximately 800 patients with CRPC.
- A phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with first-line chemotherapy in patients with NSCLC, which is expected to be initiated in 2011 following successful manufacturing of additional custirsen drug product and completion of DDI studies. The trial is expected to enroll approximately 950 patients. The study protocol will include two futility assessments and one interim analysis for efficacy. The first-line chemotherapy regimen has been selected as carboplatin and paclitaxel.

For detailed information regarding our relationship with Teva and the Collaboration Agreement, refer to the discussion under the heading “Business—License and Collaboration Agreements—Teva Pharmaceutical Industries Ltd.” included in our 2010 Annual Report on Form 10-K filed on March 10, 2011.

Custirsen received Fast Track designations from the U.S. Food and Drug Administration, or FDA, for the treatment of progressive metastatic prostate cancer in combination with docetaxel for both first- and second-line docetaxel treatment. The FDA has agreed on the design of two phase 3 registration trials, each in CRPC, via the special protocol assessment, or SPA, process. The SYNERGY trial design investigates overall survival as the primary endpoint for custirsen in combination with first-line chemotherapy, whereas the other trial design, the SATURN trial, investigates pain palliation as the primary endpoint for custirsen in combination with second-line chemotherapy.

Custirsen has 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 advice corresponded with our development plan regarding the proposed pre-clinical studies and both the study designs and analyses for the phase 3 trials. The Committee for Medicinal Products for Human Use, or CHMP, also agreed that the intended safety database would enable a sufficient qualified risk-benefit assessment for market approval.

Our phase 3 registration trials are designed to build on our phase 2 clinical trials, including:

- A randomized phase 2 trial evaluating the benefit of combining custirsen with first-line docetaxel, the final results of which were published in the September 20, 2010 issue of the Journal of Clinical Oncology. Analyses indicating a survival benefit in patients treated with custirsen in combination with first-line docetaxel compared to docetaxel alone, the latter being the current standard of care for patients with advanced, progressive metastatic prostate cancer requiring initial chemotherapy, are described in our 2010 Annual Report on Form 10-K filed on March 10, 2011 under the heading “Business—Our Product Candidates—Custirsen— Summary of Final Results of Custirsen Phase 2 Clinical Trial in Patients With CRPC Receiving Custirsen and Docetaxel as First-Line Chemotherapy.” Due to the results of the phase 2 trial, the SYNERGY trial will evaluate the survival benefit of custirsen in patients treated with first-line chemotherapy.

- Durable pain palliation, defined as pain palliation of 12 weeks or greater, which has been observed in another phase 2 trial evaluating patients with metastatic CRPC who progressed while receiving, or within six months of completing, first-line docetaxel treatment. Of the patients on this trial who had pain or were on opioids for pain control and were retreated with docetaxel as second-line treatment in combination with custirsen, approximately 50% had durable pain palliation. This is favorable even when compared to the 35% pain responses of three weeks or greater observed in the phase 3 trial, which supported the registration of docetaxel as first-line chemotherapy in patients with CRPC, and when compared to the pain responses for cabazitaxel of 9.2% and for mitoxantrone of 7.7% observed in the Phase 3 TROPIC trial. As of August 13, 2010, the estimated median over survival duration for the custirsen plus mitoxantrone arm was 11.5 months for the custirsen plus docetaxel retreatment arm, the median overall survival was estimated at 15.8 months for the 20 randomized patients and 12.8 months for the 45 combined patients which included 25 additional patients with high serum clusterin levels at enrolment beyond the 20 randomized patients. Due to the results of our phase 2 trial, the SATURN trial is evaluating the durable pain palliation benefit of custirsen in patients treated with second-line docetaxel. We expect the SATURN trial will enroll patients in approximately 50 cancer centers who have previously responded to first-line docetaxel therapy, but who subsequently experienced disease progression involving prostate cancer-related pain despite opioid usage.
- A phase 2 trial evaluating 81 patients with advanced NSCLC who received custirsen in combination with gemcitabine and a platinum chemotherapy (cisplatin or carboplatin) as first-line chemotherapy. The median overall survival was 14.1 months and 54% of patients survived at least one year. Thirty percent of patients who received custirsen with first-line chemotherapy survived at least two years. For comparison, published studies using a platinum-based regimen plus gemcitabine as first-line chemotherapy for advanced NSCLC reported median survivals of 8 to 11 months and one-year survival rates of 33% to 43%. Market approval for Avastin plus paclitaxel and carboplatin chemotherapy for NSCLC was based on results showing a median survival of 12.3 months compared to 10.3 months for patients treated with chemotherapy alone. Survival rates for Avastin plus chemotherapy versus chemotherapy alone were reported as 51% versus 44% at one year and 23% versus 15% at two years, respectively. The protocol for the custirsen phase 3 registration trial in advanced, unresectable NSCLC has yet to be finalized. Teva is expected to initiate this trial in 2011, which will assess overall survival as the primary endpoint.

Product Candidate OGX-427

OGX-427 is a product candidate that, in pre-clinical experiments, inhibits production of Hsp27, a cell survival protein found at elevated levels in many human cancers, including prostate, lung, breast, ovarian, bladder, renal, pancreatic, multiple myeloma and liver cancer. Many anti-cancer therapies are known to further elevate Hsp27 levels. For example, Hsp27 levels increased four-fold in prostate cancer patients after treatment with chemotherapy or hormone therapy. Increased levels of Hsp27 in some human cancers are associated with metastases, poor prognosis and resistance to radiation or chemotherapy.

OGX-427 has been evaluated in a phase 1 trial in patients with breast, prostate, ovarian, or non-small cell lung cancer who have failed potentially curative treatments or for which a curative treatment does not exist. Final results of this phase 1 trial were presented during an oral presentation at the ASCO 2010 annual meeting. The phase 1 trial evaluated 36 patients treated with OGX-427 as a single agent and 12 patients with OGX-427 in combination with docetaxel who had failed up to six prior chemotherapy treatments. OGX-427 as a single agent administered weekly was evaluated at doses from 200 mg up to 1000 mg in five cohorts of approximately six patients in each cohort. Two further cohorts tested OGX-427 at the 800 and 1000 mg doses combined with docetaxel. Patients could receive up to 10 21-day cycles.

OGX-427 was well tolerated both as a monotherapy and in combination with docetaxel. Most adverse events were mild (grade 1 or 2) and mainly occurred during the three “loading doses” given over nine days prior to weekly dosing. The majority of adverse events potentially related to OGX-427 consisted of grade 1 or 2 fever, chills, itching, or flushing (associated with the infusion of OGX-427) and fatigue. Despite evaluating OGX-427 at very high doses, a maximum tolerated dose for OGX-427 was not reached in this trial.

Of particular interest was the decrease at all doses and in all diseases evaluated in the trial for both total CTCs, and CTCs which were positive for Hsp27, Hsp27(+) CTCs. Recent studies have shown that the presence of CTCs in peripheral blood may be of prognostic significance for patients with solid tumors, and patients with values of five tumor cells or less are generally considered to have a more favorable prognosis.

When OGX-427 was used as monotherapy, 3 of 17 evaluable patients had a decrease in measurable disease of 20% or greater. In this heavily pretreated patient population, two of four patients with ovarian cancer had a decrease of 25% or greater in CA-125 (an ovarian tumor marker) and 3 of 15 patients with prostate cancer had a decrease of 30% or greater in PSA (a prostate tumor marker). Hsp27+CTCs decreases were noted in 89% of evaluable patients and were observed at all dose levels and all diseases evaluated. In 9 of 26 (31%) patients with ≥ 5 Hsp27+CTCs at baseline, Hsp27 + CTCs had decreased to five tumor cells or less. In addition, serum Hsp27 protein levels were decreased by 30% or greater over a period of at least six weeks in approximately 25% of patients at the 800 and 1000 mg doses.

When OGX-427 was combined with docetaxel, 5 of 10 patients had a decrease in measurable disease of 20% or greater. Five of nine patients with prostate cancer had a decrease of 30% or greater in PSA. Again, decreases in both total CTCs and Hsp27(+) CTCs were observed. Hsp27+CTCs were decreased in 71% of evaluable patients. In four of seven patients with ≥ 5 Hsp+CTCs at baseline, Hsp+CTCs had decreased to five cells or less. Serum Hsp27 protein levels were decreased by 30% or greater over a time period of at least six weeks in approximately 35% of patients.

An investigator-sponsored phase 1 clinical trial evaluating OGX-427 when administered directly into the bladder in patients with bladder cancer was initiated in August 2009. Our investigators are in the process of accruing patients for this trial, in which we will enroll up to 36 patients. The trial is designed to determine the safety and potential benefit of OGX-427 administered directly into the bladder using a catheter, which is known as intravesical instillation. In addition, the trial will measure the direct effect of OGX-427 on expression of Hsp27 in bladder tumor cells, as well as determine the pharmacokinetics and pharmacodynamics of OGX-427 when delivered by intravesical instillation. This investigator-sponsored trial is funded by the National Cancer Institute of Canada.

In September 2010, we announced the initiation of a separate investigator-sponsored, randomized phase 2 clinical trial evaluating OGX-427 when administered as a monotherapy to patients with CRPC. The randomized, controlled phase 2 trial will enroll up to 72 patients who have minimally symptomatic or asymptomatic advanced prostate cancer and who have not yet received chemotherapy, and is designed to determine the potential benefit of OGX-427 by evaluating the number of patients who are without disease progression at 12 weeks post-trial treatment with or without OGX-427. This phase 2 trial will also measure the direct effect of OGX-427 on PSA levels, time to progression by PSA or measurable disease, numbers of CTCs and other relevant secondary endpoints.

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We expect to initiate a phase 2 clinical trial of OGX-427 in patients with metastatic bladder cancer in the second half of 2011. The proposed trial design is a three-arm, randomized phase 2 in combination with gemcitabine and cisplatin in the first-line metastatic setting. Each arm would enroll approximately 60 patients and the trial would be initiated in sites throughout the United States, Canada and Europe. This trial will complement the phase 2 clinical trial in prostate cancer, and phase 1 clinical trial in superficial bladder cancer.

We are currently evaluating various alternatives, including partnering, which would allow us to expand the OGX-427 development plan beyond the ongoing bladder cancer and CRPC trials and the planned randomized phase 2 bladder cancer trial.

Product Candidates OGX-225, CSP-9222 and SN2310

OGX-225, an inhibitor of insulin growth factor binding proteins 2 and 5, and CSP-9222 are in pre-clinical development. In the first quarter of 2011 we decided to cease our previously disclosed efforts to out-license product candidate SN2310 and we do not plan on pursuing any further development efforts for SN2310 in the future.

Collaboration Revenue

We recorded \$1.2 million of collaboration revenue in connection with our Collaboration Agreement with Teva in the three months ended March 31, 2011, as compared to \$4.7 million in the three months ended March 31, 2010. At March 31, 2011, an aggregate of \$21.0 million of the upfront payment was included in the balance sheet line items Current and Long-term Deferred Collaboration Revenue, which we are amortizing over the expected performance period of our deliverables under the Collaboration Agreement. Management currently expects this performance period to end in the fourth quarter of 2012. Further, we are eligible to receive payments of up to \$370 million upon the achievement of developmental and commercial milestones. At present, we are unable to predict the timing or likelihood of such milestone payments, although we do not expect to receive any milestone payments from Teva in the year ending December 31, 2011. 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 their assessment but believe there may be some lesser payment obligation. See note 3 in the Notes to Financial Statements for further details on our collaboration with Teva.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of costs for milestone payments to third parties, clinical trials, materials and supplies, facilities, personnel, including salaries and benefits, regulatory activities, pre-clinical studies, and allocations of other R&D-related costs. External R&D expenses include fees paid to universities, hospitals and other entities that conduct certain R&D activities and that manufacture our product candidates for use in our clinical trials. Currently, we manage our clinical trials through independent medical investigators at their sites and at hospitals and expect this practice to continue.

Until July 2, 2008, custirsen was being co-developed with Isis and R&D expenses for custirsen were shared 65% by us and 35% by Isis. On July 2, 2008, we and Isis amended the agreement to provide for unilateral development of custirsen by us. In connection with the Collaboration Agreement and pursuant to the terms of agreements between us and Isis relating to custirsen, we paid \$10 million to Isis in the first quarter of 2010, which was included in R&D expenses in 2009. We also paid \$333,333 to UBC in the first quarter of 2010 pursuant to the terms of the license agreement relating to custirsen, which was also included in R&D expenses in 2009.

Under the Collaboration Agreement with Teva, we are required to spend \$30 million towards development of custirsen, which will include our personnel costs for certain development activities. Teva will fund all other expenses incurred pursuant to the Clinical Development Plan. Costs that we incurred totaling \$3.5 million in 2009, \$4.9 million in 2010, and \$0.6 million in the three months ended March 31, 2011 have been applied against our \$30 million funding commitment, resulting in a remaining funding commitment of \$21.0 million at March 31, 2011. We expect aggregate full-time equivalent reimbursement of between \$1.5 and \$2.5 million annually from 2011 to 2012, which will be applied against our funding commitment, or reimbursed to us from Teva on a cash basis. We currently expect that we will incur all remaining costs associated with the Clinical Development Plan by the fourth quarter of 2012.

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, thereby allowing us to complete these clinical trials at a lower cost to us.

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 2011 and into the future, likely significantly, as we further expand development of custirsen, 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 and business consulting, and intellectual property. Other costs include professional fees for legal and auditing services, insurance and facility costs. 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.

Restructuring Activities

On August 21, 2008, Sonus Pharmaceuticals, Inc. ("Sonus") completed a transaction ("the Arrangement") with OncoGenex Technologies Inc., ("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 the Company's current requirements. The Company is currently in the process of evaluating opportunities to exit or sublet portions of the leased space and recorded an initial restructuring charge of \$2,084,000 on August 21, 2008 as part of the purchase price allocation. 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 EITF No. 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination". This represents the Company's best estimate of the liability. Subsequent changes in the liability due to changes in estimates of sublease assumptions are recognized as adjustments to restructuring charges.

In June 2009, the Company revised its sublease income assumptions used to estimate the excess lease facility liability. These assumptions were subsequently revised again in December 2009 and September 2010. These changes in estimate resulted in increases in the value of the excess lease liability of \$494,000, \$3,457,000, and \$4,038,000 and a corresponding expense recorded in June 2009, December 2009, and September 2010, respectively, to reflect these changes in estimate. The estimated value of the liability remaining with respect to excess facilities was \$7,467,000 as of December 31, 2010. In the three months ended March 31, 2011, with respect to excess facilities, \$338,000 was amortized into income resulting in a remaining liability of \$7,129,000 at March 31, 2011.

Results of Operations for the Three Months Ended March 31, 2011 and 2010*Revenue*

Revenue for the three months ended March 31, 2011 decreased to \$1.2 million, from \$4.7 million for the three months ended March 31, 2010. The decrease in 2011 as compared to 2010 was due to lower reimbursement revenue earned through our strategic collaboration with Teva resulting from manufacturing costs now being paid directly by Teva, as well as lower costs associated with clinical trials. Collaboration revenue for 2011 includes recognition of \$0.6 million from the \$30.0 million upfront payment, as well as \$0.6 million earned through collaborative research, which has been reimbursed to us on a cash basis. At March 31, 2011, \$21.0 million of the upfront payment received from Teva in December 2009 was included on our consolidated balance sheet as Current and Long-term Deferred Collaboration Revenue, which we are amortizing over the expected performance period of our deliverables under the Collaboration Agreement. Management currently expects this performance period to end in the fourth quarter of 2012. See Note 3 of Notes to Consolidated Financial Statements included elsewhere in this document for further details on our collaboration with Teva.

Research and Development

Our research and development expenses for our clinical development programs are as follows (in thousands):

	Three months ended	
	March 31,	
	2011	2010
Clinical development programs:		
custirsen	\$ 1,010	\$ 4,703
OGX-427	\$ 2,246	\$ 231
Other research and development	\$ 1,597	\$ 1,446
Total research and development expenses	\$ 4,853	\$ 6,380

Costs for clinical development programs include external direct expenses such as patient treatment costs, clinical trial site costs, clinical research organization costs and contract manufacturing fees incurred for preclinical, clinical, manufacturing and regulatory activities associated with preparing the compounds for submissions of NDAs or similar regulatory filings to the FDA, EMA or other regulatory agencies outside the United States and Europe. Other research and development includes indirect operating costs such as our personnel and occupancy expenses associated with our clinical development programs and other research and development costs associated with the development of our other product candidates. Our internal resources, employees, and infrastructure are not directly tied to any individual research project and are typically deployed across multiple projects. 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. The majority of our costs incurred prior to 2010 were related to the development of custirsen.

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R&D expenses for the three months ended March 31, 2011 decreased to \$4.8 million from \$6.4 million in the three months ended March 31, 2010. The decrease in 2011 as compared to 2010 was due primarily to lower custirsen manufacturing costs, as these costs are now being paid directly by Teva, and lower clinical trial costs associated with the custirsen phase 3 clinical trials, offset by higher manufacturing and clinical trial costs for OGX-427 in 2011. Costs for the custirsen phase 3 clinical trials are applied against the non-refundable upfront payments received from Teva in December 2009, while manufacturing costs are reimbursable from Teva on a cash basis. We expect R&D expenses to increase as we further develop our proprietary product candidates.

General and Administrative Expenses

G&A expenses for the three months ended March 31, 2011 increased to \$1.6 million from \$1.4 million for the three months ended March 31, 2010. The increase in 2011 was due primarily to higher employee expenses, including stock-based compensation expenses, offset by lower severance related charges and legal fees.

Net Interest Income (Expense)

Interest income for the three months ended March 31, 2011 increased to \$56,000 from \$5,000 for the three months ended March 31, 2010 due to higher balances of interest-bearing securities in 2011 as compared to 2010.

Other Income (Expense)

Other expense for the three months ended March 31, 2011 decreased to \$4,000 from \$19,000 in the three months ended March 31, 2010. The expense in both periods relates to foreign exchange losses offset by gains on the sales of equipment.

Gain (loss) on warrants

We recorded a \$2.1 million gain on revaluation of the warrants at March 31, 2011 which is included on our consolidated statement of loss as gain (loss) on warrants. We revalue the warrants at each balance sheet date to fair value. If unexercised, the warrants will expire in October 2015. There was no comparable charge in 2010.

Liquidity and Capital Resources

We have incurred an accumulated deficit of \$69.1 million through March 31, 2011, 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. We have not generated any revenue from product sales to date, and we do not expect to generate product sales revenue for several years, if ever. In the three months ended March 31, 2011, we generated \$1.2 million in collaboration revenue from the Collaboration Agreement with Teva.

All of our operations to date have been funded through the sale of our equity securities, and upfront payments received from Teva. As of March 31, 2011, our cash, cash equivalents, and short-term investments decreased to \$81.1 million in the aggregate from \$85.1 million as of December 31, 2010.

As of March 31, 2011, we do not have any borrowing or credit facilities. Based on our current expectations, we believe our capital resources at March 31, 2011 will be sufficient to fund our currently planned operations into 2014. 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 three months ended March 31, 2011, net cash used in operating activities decreased to \$4.0 million, from \$17.1 million in cash used in operations in the three months ended March 31, 2010. The decrease in cash used in operations is primarily attributable to payments made to Isis and UBC in the first quarter of 2010 resulting from the Collaboration Agreement with Teva as well as decreased costs associated with manufacturing of custirsen drug product and lower upfront payments associated with custirsen clinical trial activities in 2011, offset by increased costs associated with manufacturing OGX-427 clinical supplies in 2011.

Cash Provided by Financing Activities

For the three months ended March 31, 2011, net cash provided by financing activities decreased to \$91 thousand from \$185 thousand in the three months ended March 31, 2010. All net cash provided by financing activities in the three months ended March 31, 2011 and March 31, 2010 was the result of proceeds from the issuance of common shares on stock option exercises.

Cash Used/Provided by Investing Activities

Net cash used in investing activities for the three months ended March 31, 2011 increased to \$12.6 million from \$379 thousand in cash provided by investing activities in three months ended March 31, 2010. Net cash used in or provided by investing activities in the three months ended March 31, 2011 and March 31, 2010 were due to transactions involving marketable securities in the normal course of business.

Operating Capital and Capital Expenditure Requirements

We believe that our cash, cash equivalents and short-term investments will be sufficient to fund our currently planned operations into 2014, including:

- completing the SATURN trial, a phase 3 clinical trial that is evaluating a durable pain palliation benefit for custirsen in combination with docetaxel as second-line chemotherapy in approximately 300 patients with CRPC;
- completing the SYNERGY trial, a phase 3 clinical trial that is evaluating a survival benefit for custirsen in combination with docetaxel as first-line chemotherapy in approximately 800 patients with CRPC;
- completing patient accrual in a phase 3 clinical trial that is evaluating a survival benefit for custirsen in patients with advanced, unresectable NSCLC, which is expected to be initiated in 2011;
- completing an investigator-sponsored phase 2 clinical trial evaluating OGX-427 treatment in patients with prostate cancer; and
- completing a phase 2 clinical trial evaluating OGX-427 in combination with standard first-line chemotherapy in approximately 180 patients with metastatic bladder cancer.

As of March 31, 2011, we have a remaining commitment to fund \$21.0 million towards the three phase 3 trials of custirsen, while Teva is required to fund all additional expenses under the clinical development plan. The final results from the phase 3 trials may be released at a date that is beyond the period for which we currently project we have available cash resources. In addition, if we desire to conduct development activities with respect to our other product candidates beyond those development activities mentioned in the list above, we will 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.

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 and achieving milestones and royalties;
- 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 March 31, 2011.

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented.

Contingencies and Commitments

We previously disclosed certain contractual obligations and contingencies and commitments relevant to the Company 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, 2010, as filed with the SEC on March 10, 2011. There have been no significant 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 2010 Form 10-K. For more information regarding our current contingencies and commitments, see note 7 to the financial statements included above, which is incorporated by reference herein.

Material Changes in Financial Condition

(In thousands)	March 31, 2011	December 31, 2010
	\$	\$
Total assets	84,597	89,918
Total liabilities	43,099	45,793
Shareholders' equity	41,498	44,125

The decrease in assets from December 31, 2010 primarily relates to decreased cash, cash equivalents and marketable securities as these assets have been used to fund operations. The decrease in liabilities from December 31, 2010 relates predominantly to the revaluation of the warrant liability, amortization of restructuring-related liabilities, and the recognition of deferred collaboration revenue.

Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with 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 2010 Form 10-K filed with the SEC on March 10, 2011. Since the date of our 2010 Form 10-K, 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 the 2011 first quarter, 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 our exposure to interest rate changes is monitored. We have very limited interest rate risk due to the few assets or liabilities subject to fluctuations in interests 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.

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 \$100,000 for the quarterly period ended March 31, 2011.

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 the we file or submit under the Exchange Act are accumulated and communicated to our management, including its principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure.

During the quarter ended March 31, 2011, we carried out an evaluation, under the supervision and with the participation of our management, including the principal executive officer and the 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 March 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 a limited operating history, 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 with a limited operating history. We are not profitable and have incurred losses in each year since our inception. 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 only 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.

We are highly dependent on the success of our lead product candidate, custirsen, and we cannot give any assurance that custirsen, or any of our other product candidates, will receive regulatory approval or will be successfully commercialized.

Custirsen has been evaluated in five phase 2 clinical trials, the results of which were previously disclosed. 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 may never receive regulatory approval. 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 initiated two registration trials with custirsen and are intending to initiate a third registration trial in 2011. OGX-427 has been evaluated in humans, although we have very limited safety data and have not yet established efficacy in humans. Additional clinical trials will be required for OGX-427 to establish the safety and efficacy of this product candidate. Neither OGX-225 nor CSP-9222 has been tested in humans. Our pre-clinical testing of these product candidates may not be successful and we may not be able to clinically evaluate them. 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. Any failure to obtain regulatory approval of custirsen or our other product candidates could have a material and adverse effect on our business.

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 that are members of the Joint Steering Committee; and
- possible disagreements with Teva regarding the Collaboration Agreement 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.

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

Positive results from pre-clinical studies and early clinical trials, including those results from the custirsen 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.

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.

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Our clinical trials may be suspended or terminated at any time, including by the FDA, other regulatory authorities, the IRB 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 clinical trials for custirsen or 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 pre-clinical studies or clinical trials, as applicable, beyond those currently planned. The completion or commencement of future pre-clinical 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;
- decrease in Teva's level of focus and efforts to develop custirsen;
- introduction of new product candidates to the market in therapeutic areas similar to those that we are developing our product candidates;
- concurrent evaluation of new investigational product candidates in therapeutic areas similar to those that we are developing 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 an SPA;
- 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 obtain sufficient manufacturing supply of custirsen;
- delay or failure to obtain sufficient supplies of the product candidate for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain the approval of the IRB to conduct a clinical trial at a prospective site.

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

- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- unforeseen safety issues;
- lack of efficacy evidenced during clinical trials;
- termination of our clinical trials by one or more clinical trial sites or investigators;
- 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; 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.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or 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.

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. We are aware of several other companies which are developing therapeutics that seek to promote tumor cell death by inhibiting proteins believed to promote cell survival. 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, which products 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.

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.

We rely on third parties to manufacture and supply our product candidates.

We do not own or operate manufacturing facilities, and we depend on third-party contract manufacturers for production of our product candidates. 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 pre-clinical studies and clinical trials. All API for custirsen has been manufactured for us by Isis or Avecia, and all drug product has been manufactured for us by Formatech, Inc., Pyramid Laboratories, Inc. and Laureate Pharma, Inc., in each case pursuant to a purchase order or short-term contract that has been fulfilled. Avecia is our contract manufacturer for additional quantities of custirsen to complete our phase 3 clinical trials.

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All API for OGX-427 for IND-enabling toxicology studies and initial clinical trials has been manufactured for us by Avecia and all drug product has been manufactured for us by Laureate Pharma, Inc., in each case pursuant to a purchase order or short-term contract which 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. 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 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.

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.

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

Custirsen was administered to 294 patients with various types of cancer in phase 1 and phase 2 clinical trials. Some patients experienced various adverse events, the majority of which are associated with other treatments in the protocol and the disease. The majority of adverse events were mild and the most common adverse events associated with custirsen consisted of flu-like symptoms. The most common serious adverse events associated with custirsen were neutropenia, vomiting, dehydration, pyrexia, pleural effusion and difficulty breathing (also known as “dyspnea”), which occurred in greater than 2% of patients. In addition, we are conducting a phase 1 DDI study, the results of which may affect the development of custirsen in NSCLC.

OGX-427 was administered to 59 patients with various types of cancer in a phase 1 clinical trial. Enrollment is complete in five cohorts with dose-escalation of OGX-427 as monotherapy and in two cohorts in which docetaxel was administered in combination with OGX-427. There was only one dose-limiting toxicity; thus, the maximum tolerated dose was not reached. Of the 46 patients presented at the ASCO 2010 annual meeting, the majority of the adverse events were infusion reactions, which were documented in 72% of patients and increased in incidence with increasing dose. The majority (93%) were grade 1 or 2. Grade 3/4 laboratory events, which occurred in decreasing frequency, were lymphopenia, prolonged PTT, neutropenia, hyponatremia, anemia, elevated creatinine and thrombocytopenia. During monotherapy and when OGX-427 was administered as combination therapy, there was evidence of decreases in tumor markers (CA-125 and PSA), decreases in Hsp27+ circulating tumor cells, and reduction of serum Hsp27 protein levels.

SN2310 was administered to 26 patients with various types of cancer in a phase 1 clinical trial. Data collection for this clinical trial has been completed. Some of the patients experienced adverse events, which were considered unrelated to the study drug and attributed to the underlying disease. Of the adverse events associated with SN2310, most were mild and the most common events were nausea, diarrhea, vomiting and fatigue. Mild to moderate reactions (back/chest pain, flushing) have been observed during infusions. Significant neutropenia has occurred in some patients and was the dose-limiting toxicity observed, sometimes associated with fever or septicemia.

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

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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.

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 the upfront payment we received pursuant to the Collaboration Agreement with Teva. We believe that our existing capital resources and interest on such resources, including the financing we completed in October 2010, will be sufficient to meet our current operating requirements into 2014. If, however, the Collaboration Agreement with Teva were to terminate or if Teva fails to fulfill its obligations under the Collaboration Agreement, or if the trials proceed slower than expected or are initiated later than expected, or if 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;
- whether we experience delays in our pre-clinical and clinical development programs, or slower-than-anticipated product development;
- the scope and results of our pre-clinical studies and clinical trials;
- 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 pre-clinical studies and clinical trials and manufacturing our product candidates to be tested in those studies and trials and the associated costs of those services; and
- 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.

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.

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.

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, 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.

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, and one candidate has been in-licensed from Bayer. 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 our product candidates in the event we exercise our co-promotion option and 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 research, 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, pre-clinical and clinical personnel, including our executive officers Michelle Burris, Scott Cormack, and Cindy Jacobs. In addition, although we have entered into employment agreements with each of Ms. Burris, Mr. Cormack, and Dr. Jacobs, 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, which is unlikely without sufficient funds, 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, OGX-427, OGX-225, and CSP-9222 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 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 external 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 of directors 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, 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, 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. We have entered into an exclusive in-licensing agreement with Bayer for development of caspase activators that are presently being evaluated in pre-clinical studies.

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. In the case of patents and patent applications licensed from Bayer, we did not have any control over the filing of the patents and patent applications before the effective date of the Bayer license, and have had control over the filing and prosecution of these patents and patent applications after the effective date of the Bayer license. Under certain circumstances, we also have the right to enforce patents and patent applications licensed from Bayer. 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. There is also the risk that, even if the validity or unenforceability of these patents is upheld, the court 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, OGX-427, OGX-225 and CSP-9222, 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 breach any of these agreements in a material manner, we would be in breach of the Collaboration Agreement, which would 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 and Other Securities

If we raise additional financing, the terms of such 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, 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.

The price for our common stock is volatile.

The market prices for our common stock and that of emerging growth 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.

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 of directors. 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 of directors to designate the terms of and issue new series of preferred stock and the ability of our board of directors 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 a 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 pre-clinical studies and clinical trials. The number of pre-clinical 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 pre-clinical studies and 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 new 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 the United States would prevent us or Teva from marketing our product candidates abroad.

We intend to market certain of our existing and future product candidates in non-North American markets. 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.

Item 6. Exhibits

Exhibit Number	Description
31.1	Certification of President and Chief Executive 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
31.2	Certification of Chief 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 and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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: May 9, 2011

By: /s/ Michelle Burris
Michelle Burris
Chief Financial Officer
(Principal Financial Officer)

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

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

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

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

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

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

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

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

Date: May 9, 2011

/s/ Scott Cormack
Scott Cormack
President and Chief Executive Officer

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

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

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

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

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

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

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

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

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

Date: May 9, 2011

/s/ Michelle Burris

Michelle Burris
Chief Financial Officer

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 and Chief Executive 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 September 30, 2010 (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: May 9, 2011

/s/ Scott Cormack
Scott Cormack
President and Chief Executive Officer

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

I, Michelle Burris, Chief 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 September 30, 2010 (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: May 9, 2011

/s/ Michelle Burris

Michelle Burris
Chief Financial Officer