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

SEC. 13 Processing Section

MAY 03 2013

FORM 10-K

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

For the fiscal year ended December 31, 2012

Or

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

Commission File Number 033-80623

OncoGenex Pharmaceuticals, Inc.

(Exact name of the registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

95-4343413 (I.R.S. Employer Identification No.)

1522 - 217th Place SE, Suite 100, Bothell, Washington 98021 (Address of principal executive offices, including zip code)

(425) 686-1500

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Table with 2 columns: Title of Each Class, Name of Exchange on Which Registered. Row 1: Common Stock, par value \$0.001 per share, The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [x]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [ ] No [x]

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months... Yes [x] 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... Yes [x] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

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

Large accelerated filer [ ] Non-accelerated filer [ ]

Accelerated filer [x] Smaller reporting company [ ]

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

As of June 30, 2012 the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was \$163,796,958. As of March 7, 2013, 14,658,766 shares of the registrant's Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission not later than April 30, 2013, in connection with the solicitation of proxies for its 2013 Annual Meeting of Stockholders, are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III hereof.

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OncoGenex Pharmaceuticals, Inc.

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## PART I

*References in this Form 10-K to “OncoGenex Pharmaceuticals,” “OncoGenex,” the “Company,” “we,” “us” or “our” refer to OncoGenex Pharmaceuticals, Inc. and its wholly owned subsidiaries. The information in this Annual Report on Form 10-K contains certain forward-looking statements, including statements related to clinical trials, regulatory approvals, markets for our products, new product development, capital requirements and trends in our business that involve risks and uncertainties. Our actual results may differ materially from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as those discussed elsewhere in this Annual Report on Form 10-K.*

### ITEM 1. BUSINESS

#### OVERVIEW OF OUR BUSINESS

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

#### Product Candidates Overview and Recent Developments




Our product candidates custirsen, OGX-427 and OGX-225 focus on mechanisms of treatment resistance in cancer patients and are designed to block 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 cells’ adaptive defenses, thereby rendering the tumor cells more susceptible to attack with a variety of cancer therapies. We believe this approach will increase survival time and improve the quality of life for cancer patients.

#### *Custirsen*

Custirsen is being evaluated in three phase 3 trials in patients with prostate and non-small cell lung cancers. Custirsen is designed to inhibit the production of clusterin, a protein we believe promotes survival of cancer cells when overexpressed in a variety of tumors. We and collaborating investigators have conducted five phase 2 clinical trials to evaluate the ability of custirsen to enhance the effects of therapy in prostate, non-small cell lung and breast cancers. Results have been presented for each of these phase 2 trials. Data from these trials demonstrate the potential benefit of adding custirsen, a second generation antisense molecule, to existing cancer therapies. The SYNERGY phase 3 trial is designed to evaluate a survival benefit for custirsen, in combination with first-line docetaxel chemotherapy, in men with castrate-resistant prostate cancer, or CRCP. The expected timing of results is based on a pre-specified number of death events that is projected to occur in the fourth quarter of 2013, with data results expected to be announced in the first-half of 2014.

In December 2009, we announced that our wholly owned subsidiary, OncoGenex Technologies Inc., or OncoGenex Technologies, entered into a Collaboration and License Agreement dated December 20, 2009, or Collaboration Agreement, with Teva Pharmaceutical Industries Ltd., or Teva, for the development and global commercialization of custirsen (and related compounds targeting clusterin, excluding OGX-427 and OGX-225). On March 6, 2012, OncoGenex Technologies and Teva entered into an amendment to the Collaboration Agreement, or the Collaboration Agreement Amendment. Under the Collaboration Agreement Amendment, OncoGenex Technologies and Teva revised the clinical development plan, or Amended Clinical Development Plan., under which the three phase 3 clinical trials have been initiated:

### Ongoing Phase 3 Custirsen Trials:

Trial	Cancer Indication	Treatment Combination(1)	Status
	Metastatic Castrate Resistant Prostate Cancer—Survival Endpoint	Docetaxel with and without custirsen (~1,000 patients); first-line chemotherapy	<ul style="list-style-type: none"> <li>Phase 3 initiated in the third quarter of 2010</li> <li>Patient accrual complete, survival follow-up ongoing</li> <li>SPA approved by the FDA and EMA in agreement with development plan</li> </ul>
	Metastatic Castrate Resistant Prostate Cancer—Survival Endpoint	Cabazitaxel with and without custirsen (~ 630 patients); second-line chemotherapy	<ul style="list-style-type: none"> <li>Phase 3 initiated in the third quarter of 2012</li> <li>Patient accrual ongoing</li> </ul>
	Advanced Non-Small Cell Lung Cancer—Survival Endpoint	Docetaxel with and without custirsen (~1,100 patients); second-line chemotherapy	<ul style="list-style-type: none"> <li>Phase 3 initiated by Teva in the third quarter of 2012</li> <li>Patient accrual ongoing</li> </ul>

- (1) In all of our prostate cancer clinical trials and in clinical practice for prostate cancer, docetaxel is administered in combination with prednisone.
- The SYNERGY Trial: The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with first-line docetaxel treatment in patients with CRPC. During discussions with the U.S. Food and Drug Administration, or FDA, the FDA informed us that an application supported primarily by the results of SYNERGY alone would be acceptable for submission for market approval. SYNERGY patient enrollment was completed in the fourth quarter of 2012, with over 1,000 men enrolled. The expected timing of results is based on a pre-specified number of death events that is projected to occur in the fourth quarter of 2013, with data results expected to be announced in the first-half of 2014.
  - The AFFINITY Trial: The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with cabazitaxel treatment as second-line chemotherapy in patients with CRPC. We expect to enroll approximately 630 patients in this trial. We initiated this phase 3 clinical trial in August 2012.
  - The ENSPIRIT Trial: The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with docetaxel treatment as second-line chemotherapy in patients with non-small cell lung cancer, or NSCLC. We expect to enroll approximately 1,100 patients in this trial. This trial was initiated by Teva in September 2012. Two formal interim analyses are planned for stopping the trial early based on inadequate evidence of clinical benefit or futility. We will be evaluating both progression-free survival, or PFS, and overall survival, or OS, during the interim analyses. If both endpoints meet the predefined criteria for inadequate PFS clinical benefit and OS futility, the trial would be stopped. The trial will not be stopped early in order to claim efficacy.

For additional 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.”




**OGX-427**

OGX-427 is currently being evaluated in phase 1 and phase 2 clinical trials in patients with bladder and prostate cancers. OGX-427 is our product candidate that is designed to inhibit production of heat shock protein 27, or Hsp27, a cell-survival protein expressed in many types of cancers including prostate, bladder, breast, pancreas and non-small cell lung cancer. Hsp27 expression is stress-induced, including by many anti-cancer therapies. Overexpression of Hsp27 is thought to be an important factor leading to the development of treatment resistance and is associated with metastasis and negative clinical outcomes in patients with various tumor types. We and collaborating investigators have conducted, or are in the process of conducting, two phase 1 and four phase 2 clinical trials to evaluate the ability of OGX-427 to enhance the effects of therapy in patients with prostate and bladder cancers. Preliminary results have been presented for both the ongoing phase 1 and one of the prostate phase 2 trials and final results were presented for the previously completed phase 1 trial. Refer to the discussion below under the headings “Our Product Candidates—OGX-427—Current OGX-427 Development Activities” and “Our Product Candidates—OGX-427—Summary of Results of OGX-427 Clinical Trials” for further details.

In 2013, we initiated the “ORCA” (On-going studies evaluating treatment Resistance in CAncer) program which encompasses clinical studies designed to evaluate whether inhibition of Hsp27 can lead to improved prognosis and treatment outcomes for cancer patients. Our goal is to advance cancer treatment by conducting clinical trials for OGX-427 across multiple cancer indications including, but not limited to, bladder cancer and CRPC. We intend to conduct parallel clinical trials to evaluate OGX-427 in several cancer indications and treatment combinations to accelerate the development of OGX-427. In addition to OncoGenex-sponsored trials, specific investigator-sponsored trials are and will be supported to allow assessment of a broader range of clinical indications for future OncoGenex-sponsored trials for possible market approval.

**Ongoing OGX-427 Trials—The ORCA Program:**



Trial	Cancer Indication	Treatment Combination	Status
 Borealis-1	Metastatic Bladder Cancer	Gemcitabine and cisplatin with and without OGX-427 (~ 180 patients); first line chemotherapy	<ul style="list-style-type: none"> <li>Phase 2 initiated in October 2011</li> <li>Patient accrual ongoing</li> </ul>
 Borealis-1	Metastatic Bladder Cancer	Docetaxel with and without OGX-427 (~ 200 patients); second line chemotherapy	<ul style="list-style-type: none"> <li>Phase 2 is expected to be initiated in the first half of 2013</li> </ul>
BL-01	Superficial and muscle invasive Bladder Cancer	OGX-427 as monotherapy (~ 36 patients)	<ul style="list-style-type: none"> <li>Phase 1 ongoing</li> <li>Preliminary data presented at 2012 ASCO Genitourinary Cancers Symposium</li> </ul>
PR-01	Castrate Resistant Prostate Cancer	Prednisone with and without OGX-427 (74 patients)	<ul style="list-style-type: none"> <li>Phase 2 initiated in third quarter of 2010</li> <li>Patient accrual complete</li> <li>Preliminary data presented at 2012 ESMO Annual Meeting</li> </ul>
 Pacific	Castrate Resistant Prostate Cancer	Zytiga (abiraterone acetate) with and without OGX-427 (~ 80 patients)	<ul style="list-style-type: none"> <li>Phase 2 initiated in December 2012</li> <li>Patient accrual ongoing</li> </ul>

Our current OGX-427 development activities for bladder cancer include the following clinical trials that have been initiated:

- The Borealis-1 Trial: The OncoGenex-sponsored phase 2 clinical trial of OGX-427 in patients with metastatic bladder cancer. Borealis-1 is a three-arm, randomized, placebo-controlled phase 2 trial evaluating OGX-427 in combination with first-line gemcitabine and cisplatin treatment in the metastatic setting. Each arm is currently enrolling approximately 60 patients; the trial has been initiated in sites throughout the United States, Canada and Europe. The trial will be conducted as an event-driven trial such that the final analysis will have 80% power to show a critical hazard ratio of approximately 0.66 to 0.71. This type of phase 2 trial will allow us to better predict the potential size of and success for a phase 3 trial where a survival benefit will be the primary endpoint. This study is ongoing with an enrollment target of approximately 180 patients. We expect to complete patient accrual in the second half of 2013.
- The Borealis-2 Trial: The investigator-sponsored, randomized, controlled Phase 2 study evaluating OGX-427 in patients with advanced or metastatic bladder cancer who have disease progression following initial platinum-based chemotherapy. This study is designed to have adequate power to detect a survival benefit in the docetaxel + OGX-427 arm corresponding to a hazard ratio (docetaxel + OGX-427/ docetaxel) = 0.667. The primary analysis is to be performed at one-sided 0.10 significance level with 90% power to detect this OS difference. We expect to enroll approximately 200 patients to receive either OGX-427 plus docetaxel treatment or docetaxel treatment alone. Patients may also continue weekly OGX-427 infusions as maintenance treatment until disease progression or unacceptable toxicity if they complete all 10 cycles of docetaxel, or are discontinued from docetaxel due to docetaxel toxicity. We expect this trial to be initiated in the first half of 2013.
- The BL-01 Trial: An investigator-sponsored phase 1 clinical trial to evaluate OGX-427 when administered directly into the bladder in patients with bladder cancer. The trial is currently enrolling 36 patients. It is designed to determine the safety and potential benefit of OGX-427 administered 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 clinical trial is being funded by the National Cancer Institute of Canada. Preliminary data were presented at the ASCO GU Symposium in February 2012.

Our current OGX-427 development activities for prostate cancer include the following clinical trials that have been initiated:

- The PR-01 Trial: An investigator-sponsored, randomized phase 2 clinical trial evaluating OGX-427 when administered with prednisone to patients with CRPC. PR-01 has completed enrollment with data collection ongoing. This randomized phase 2 clinical trial enrolled 74 patients who had minimally symptomatic or asymptomatic advanced prostate cancer and who had not yet received chemotherapy. This trial is measuring the direct effect of OGX-427 on prostate-specific antigen, or PSA, levels, time to progression by PSA or measurable disease, numbers of circulating tumor cells, or CTCs, and other relevant secondary endpoints. Preliminary data were presented at several conferences throughout 2012, most recently at the European Society for Medical Oncology, or ESMO, meeting in September 2012.
- The Pacific Trial: An investigator-sponsored, randomized phase 2 study evaluating OGX-427 in men with CRPC who are experiencing a rising PSA while receiving Zytiga (abiraterone acetate). The aim of the study is to determine if adding OGX-427 to Zytiga treatment can reverse or delay treatment resistance. We expect that approximately 80 patients will be enrolled. The trial was initiated in December 2012.

## **OGX-225**

OGX-225 is a product candidate in preclinical development that is designed to inhibit production of both Insulin Growth Factor Binding Protein-2, or IGFBP-2, and Insulin Growth Factor Binding Protein-5, or IGFBP-5. Increased IGFBP-2 or IGFBP-5 production is observed in many human cancers, including prostate, non-small cell lung, breast, ovarian, bladder, pancreatic and colon, as well as acute myeloid leukemia, acute lymphoblastic leukemia, neuroblastoma, glioma and melanoma. Increased IGFBP-2 or IGFBP-5 production is linked to faster rates of cancer progression, treatment resistance and shorter survival duration in humans. We have begun development activities for OGX-225 and we expect to initiate toxicology studies in the second half of 2013.

## **Financial Overview**

In 2012, we recognized \$20.1 million in collaboration revenue attributable to our Collaboration Agreement with Teva. We have devoted substantially all of our resources to the development of our product candidates.

We incurred a loss for the year ended December 31, 2012 of \$21.1 million and had an accumulated deficit at December 31, 2012 of \$101.8 million and \$82.0 million of total assets. We expect to continue to incur increasing additional losses in the future as we continue our research and development activities.

To date, we have funded our operations primarily through private and public placements of equity securities and upfront payments received from our Collaboration Agreement with Teva.

## **Corporate History**

On August 21, 2008, the Company, then named Sonus Pharmaceuticals, Inc., completed its acquisition, or the Arrangement, of OncoGenex Technologies, a Canadian corporation, as contemplated by the Arrangement Agreement between the companies dated May 27, 2008, as amended August 11, 2008 and August 15, 2008. As a result of the Arrangement, OncoGenex Technologies became a wholly owned subsidiary of the Company. As used in this Annual Report on Form 10-K, the term "Sonus" refers to the business of the Company prior to August 21, 2008.

We were incorporated in October 1991 and OncoGenex Technologies was incorporated in May 2000.

## **OUR PRODUCT CANDIDATES**

We have two clinical-stage product candidates, custirsen and OGX-427, and one preclinical-stage product candidate, OGX-225.

### ***Custirsen***

#### **Overview of Custirsen**

Through our clinical trials, we are treating cancer patients with custirsen with the goal of reducing clusterin production. Clusterin is a protein that is over-produced in several types of cancer and in response to many cancer treatments, including hormone ablation therapy, chemotherapy and radiation therapy. Preclinical and other data suggest that clusterin promotes cell survival. Increased clusterin production has been linked to faster rates of cancer progression, treatment resistance and shorter survival duration. Since increased clusterin production is observed in many human cancers, including prostate, non-small cell lung, breast, ovarian, bladder, renal, pancreatic, colon, anaplastic large cell lymphoma and melanoma, we believe that custirsen may have broad market potential to treat many cancer indications and disease stages.

A broad range of preclinical studies conducted by the Vancouver Prostate Centre and others have shown that reducing clusterin production with custirsen: (i) facilitates tumor cell death by sensitizing human prostate, non-small cell lung, breast, ovarian, bladder, renal and melanoma tumor cells to various chemotherapies; and

(ii) sensitizes prostate tumor cells to hormone ablation therapy and sensitizes prostate and non-small cell lung tumor cells to radiation therapy. Preclinical studies conducted by the Vancouver Prostate Centre also indicate that reducing clusterin production with custirsen re-sensitizes docetaxel-resistant prostate tumor cells to docetaxel.

Our phase 1 clinical trials evaluated the safety and established a recommended dose of custirsen in combination with docetaxel (two different schedules), a gemcitabine and a platinum chemotherapy regimen and hormone ablation therapy. Docetaxel, mitoxantrone, cabazitaxel, gemcitabine and platinum (cisplatin and carboplatin) are all examples of chemotherapy agents. Clinical data from our phase 1 trial in prostate cancer patients demonstrated that weekly intravenous administration of custirsen resulted in drug distribution to prostate cancer tissue and over 92% inhibition of its target, clusterin mRNA, in prostate tumor cells in these patients at the 640mg dose, which was the highest dose evaluated in this clinical trial. This dose was determined by the clinical investigators to be well tolerated and therefore was established as the recommended dose.

We have conducted five phase 2 clinical trials to evaluate the ability of custirsen to enhance the effects of therapy in patients with prostate, non-small cell lung and breast cancer. Data from each of the five phase 2 trials demonstrates that adding custirsen to therapy shows potential benefits, including:

- longer survival duration when custirsen was added to first-line docetaxel compared to first-line docetaxel alone in patients with CRPC (randomized phase 2 trial);
- longer survival duration when custirsen was added to either mitoxantrone or docetaxel as second-line chemotherapy compared to survival duration observed in two prior published trials of CRPC patients receiving second-line chemotherapy and comparable survival compared to results observed with cabazitaxel, which is approved for use in the United States. One study evaluated patients with better prognostic risk factors who received docetaxel as second-line chemotherapy; this study, called the BCCA Study, was conducted at the British Columbia Cancer Agency and presented at the American Society of Clinical Oncologists, or ASCO, Genitourinary, or GU, Conference in 2008. The second study was a follow-up evaluation of patients on the TAX 327 Study who later received second-line chemotherapy; results were presented at the ASCO 2007 Prostate Cancer Symposium. (The TAX 327 Study was the key registration study that showed a survival benefit for docetaxel over mitoxantrone for first-line chemotherapy treatment of patients with metastatic CRPC.) A phase 3 trial comparing mitoxantrone to cabazitaxel as second-line chemotherapy for patients with CRPC, referred to as the TROPIC trial, was the key registration study that showed a survival benefit for cabazitaxel over mitoxantrone for second-line chemotherapy treatment of patients with metastatic CRPC;
- decreased on-treatment serum clusterin levels compared to baseline levels of the patient population; preliminary analysis of study data found that lower serum clusterin levels during treatment were predictive of survival;
- increased frequency of pain responses when compared to pain response results with either mitoxantrone or cabazitaxel second-line chemotherapy in the phase 3 TROPIC trial, and increased frequency and duration of pain palliation when custirsen was added to either mitoxantrone or docetaxel as second-line chemotherapy when compared to the frequency and duration of pain palliation observed in the TAX 327 Study for first-line chemotherapy alone in patients with CRPC; and
- longer survival duration when custirsen was added to gemcitabine and a platinum-containing chemotherapy compared to the survival duration reported in prior published results from randomized clinical trials in NSCLC patients receiving gemcitabine and a platinum-containing chemotherapy.

Refer to the discussion below under the heading "Summary of Results of Custirsen Phase 2 Clinical Trials" for further details.

As part of our phase 1 and phase 2 clinical trials, custirsen was administered to 294 patients with various types of cancer. Some of the patients experienced a variety of 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 moderate and severe adverse events associated with custirsen were neutropenia, vomiting, diarrhea and difficulty breathing (also known as “dyspnea”), which occurred in more than 2% of patients.

The U.S. Adopted Name for the custirsen drug product is custirsen sodium, which is the generic name.

#### Current Custirsen Development Activities

As a result of our partnership with Teva, there is committed funding for three phase 3 clinical trials evaluating custirsen. The Amended Clinical Development Plan includes the following clinical trials that have been initiated:

- The SYNERGY Trial: The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with first-line docetaxel treatment in patients with CRPC. The FDA informed us that an application supported primarily by the results of SYNERGY alone would be acceptable for submission for market approval. SYNERGY patient enrollment was completed in the fourth quarter of 2012. Over 1,000 men have now been enrolled in order to show a survival benefit with 90% power based on a hazard ratio of 0.75. The expected timing of results is based on a pre-specified number of death events that is projected to occur in the fourth quarter of 2013, with data results expected to be announced in the first-half of 2014.
- The AFFINITY Trial: The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with cabazitaxel treatment as second-line chemotherapy in patients with CRPC. We expect to enroll approximately 630 patients to show a survival benefit with 85% power based on a hazard ratio of 0.75. We initiated this phase 3 clinical trial in August 2012.
- The ENSPIRIT Trial: The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with docetaxel treatment as second-line chemotherapy in patients with NSCLC. We expect to enroll approximately 1,100 patients in order to show a survival benefit with 90% power based on a hazard ratio of 0.80. This trial was initiated by Teva in September 2012. Two formal interim analyses are planned for stopping the trial early based on inadequate evidence of clinical benefit or futility. We will be evaluating both PFS and OS during the interim analyses. If both endpoints meet the predefined criteria for inadequate PFS clinical benefit and OS futility the trial would be stopped. The trial will not be stopped early in order to claim efficacy.

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

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

#### Summary of Results of Custirsen Phase 2 Clinical Trials

Five phase 2 clinical trials have been conducted to evaluate the ability of custirsen to enhance the effects of therapy in patients with prostate, non-small cell lung and breast cancer. The following is a summary of the clinical trials evaluating custirsen in combination with chemotherapy.

*Summary of Final Results of Phase 2 Clinical Trial in Patients with CRPC Receiving Custirsen and Docetaxel as First-Line Chemotherapy*

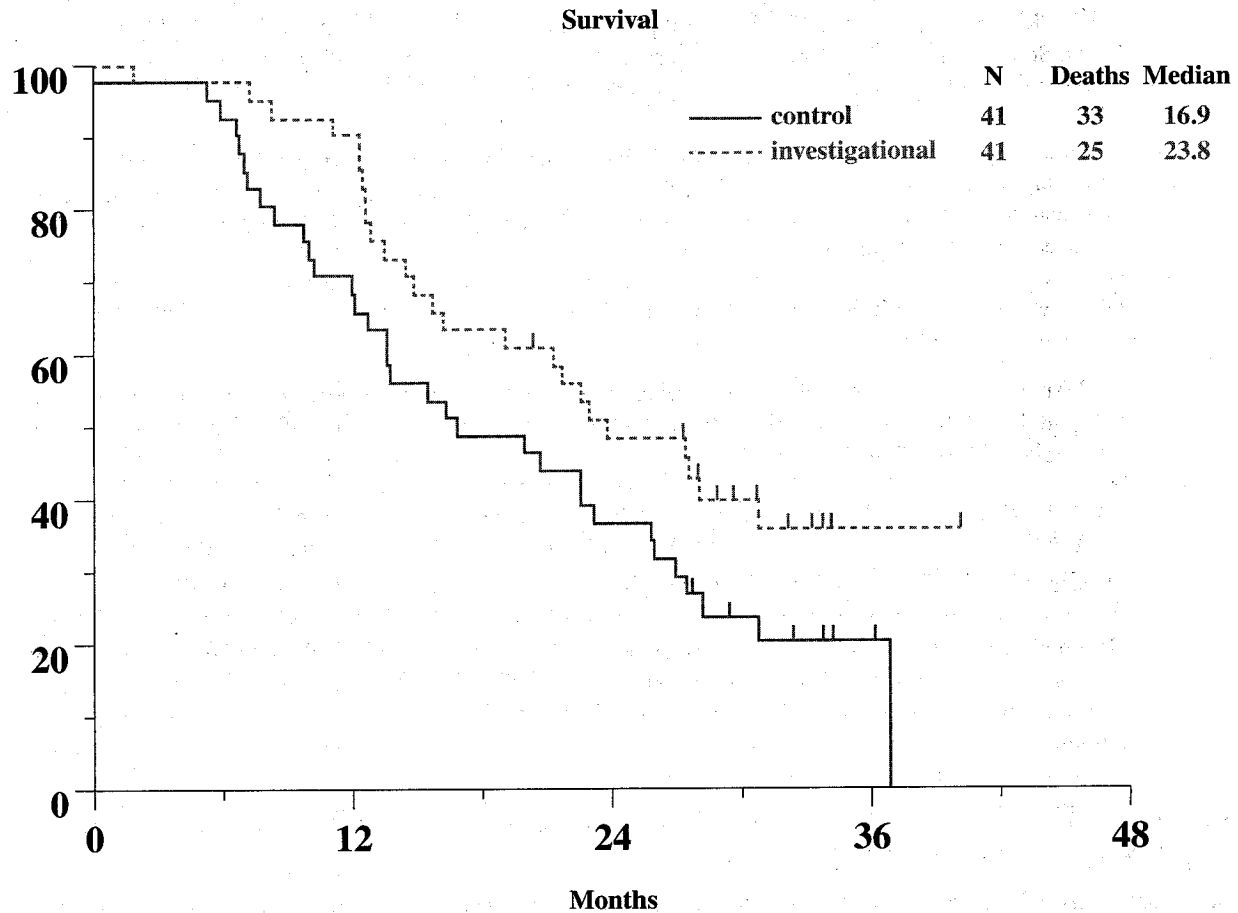
Final results of a randomized phase 2 trial evaluating the benefit of combining custirsen with first-line docetaxel in patients with CRPC were presented during an oral presentation at the ASCO 2009 annual meeting, and were published in the September 20, 2010 issue of the Journal of Clinical Oncology, or JCO. In this trial, patients were randomized to receive either docetaxel or custirsen plus docetaxel.

The trial enrolled 82 patients at 12 sites in Canada and the United States from September 2005 to December 2006. Patients were randomized to one of two treatment arms to receive either 640 mg of custirsen per week by intravenous infusion in combination with docetaxel or docetaxel alone. Patients in both treatment arms received therapy until disease progression, toxicity or the completion of 10 three-week cycles of therapy. Analyses indicated a survival benefit in patients treated with custirsen in combination with docetaxel compared to docetaxel alone, which is the current standard of care for first-line chemotherapy treatment of patients with advanced prostate cancer:

- median overall survival among patients treated with custirsen plus docetaxel was 23.8 months compared to 16.9 months for patients treated with docetaxel alone, indicating a 6.9 month survival advantage in the custirsen arm;
- the unadjusted hazard ratio, or HR, a measure used to compare the death rates between treatment groups, was 0.61, representing a 39% lower rate of death for patients receiving custirsen; and
- a prospectively defined multivariate analysis indicated that the significant predictors of overall survival in this study were treatment arm, performance status and presence of metastases other than in bone or lymph nodes. In the multivariate analysis, patients treated with custirsen had a rate of death 51% lower than patients treated with docetaxel alone (HR=0.49; p=0.012). Additional exploratory analyses found that the lower rate of death was associated with the effect of custirsen treatment even when varying amounts of chemotherapy were administered. In other words, custirsen treatment resulted in a lower rate of death when compared to the control arm for patients receiving six or less cycles of chemotherapy, as well as for patients receiving 10 cycles of chemotherapy.

Study investigators concluded that custirsen treatment was well tolerated in combination with docetaxel. Patients receiving custirsen had an increased incidence of mild fever, chills and elevated creatinine levels (a laboratory measure for reduced kidney function) and a moderate to significant decrease in circulating lymphocytes in the blood (another laboratory measure) without any increase in infection rate compared to patients receiving docetaxel alone. Lymphocytes are a type of white blood cell involved in the body's defense against infections. Based on final results of this randomized phase 2 trial, the phase 3 SYNERGY trial was designed to evaluate the overall survival benefit of custirsen in patients treated with first-line chemotherapy.

The following graph displays the Kaplan-Meier survival curves for patients receiving custirsen in combination with docetaxel (investigational) compared with patients receiving docetaxel alone (control):



*Summary of Results of Phase 2 Clinical Trial in Patients Receiving Custirsen and Docetaxel as Second-Line Chemotherapy*

Data from a Phase 2 clinical study of custirsen in combination with docetaxel retreatment or mitoxantrone as second-line chemotherapy in patients with metastatic CRPC were published in the September 1, 2011 issue of Clinical Cancer Research, or CCR. In this phase 2 trial, patients who were previously treated with a first-line, docetaxel-based chemotherapy regimen and progressed on or within six months of discontinuation of docetaxel treatment were randomized to receive custirsen plus either docetaxel retreatment or mitoxantrone. Initially, 42 patients were randomized, received at least one cycle of custirsen and chemotherapy and were included in the analysis: 20 patients received docetaxel retreatment plus custirsen and 22 patients received mitoxantrone plus custirsen. The protocol was amended to allow additional patients to be enrolled in the docetaxel retreatment arm. Enrollment into the amended protocol was initiated in May 2007 and 25 additional patients were enrolled. All patients received at least one cycle of custirsen and docetaxel retreatment and were included in the analysis. The last survival update was on August 13, 2010. All patients were followed for a minimum of 39 months or until death.

Data from the clinical trial are summarized as follows:

- As of August 13, 2010, the estimated median overall survival duration for the custirsen plus mitoxantrone arm was 11.5 months (95% C.I.: 6.1-15.2 months). For the custirsen plus docetaxel

retreatment arm, the median overall survival was estimated at 15.8 months (95% C.I.:9.9-23.3 months) for the 20 randomized patients and 12.8 months (95% C.I.:9.9-17.0 months) for the combined patient population (n=45) that included 25 additional patients with high serum clusterin levels at enrollment beyond the 20 randomized patients. The median survival duration observed in the phase 3 registration trials for alpharadin, abiraterone acetate, cabazitaxel, and MDV3100 were 14 months, 14.8 months, 15.1 months and 18.4 months, respectively. Patients who participated in these trials had previously received docetaxel as first-line chemotherapy.

- Analyses presented in the CCR manuscript demonstrated that treatment with custirsen in combination with chemotherapy significantly lowered serum clusterin levels as compared to baseline levels, and that average serum clusterin levels during treatment were predictive of survival, with low serum clusterin levels correlating to longer survival.
- Pain responses were observed in 62% of evaluable patients, with 88% of these patients having a durable response of three months or more.
- Pain responses in patients receiving custirsen in addition to docetaxel treatment as second-line therapy were favorable when compared to the pain responses reported for patients in the Phase 3 TROPIC trial that led to the 2010 approval of cabazitaxel in the United States for patients who had previously received treatment with chemotherapy, and the abiraterone acetate Phase 3 trial that led its 2011 approval in the United States for patients who had previously received treatment with chemotherapy. In the TROPIC trial, which evaluated a similar patient population for second-line chemotherapy as was evaluated in our Phase 2 trial (i.e., patients who had progressed while on or soon after first-line docetaxel therapy), the pain response for cabazitaxel was 9.2% and for mitoxantrone was 7.7%. In the abiraterone acetate Phase 3 trial, the proportion of patients with pain palliation among patients with a baseline pain score of four or more and at least one post-baseline pain score was 44% for patients receiving abiraterone and prednisone as compared with 27% for patients receiving prednisone and placebo.

#### *Summary of Preliminary Results of Phase 2 Clinical Trial in Patients with NSCLC Receiving Custirsen and Gemcitabine/Platinum as First-Line Chemotherapy*

Data from a Phase 2 clinical study of custirsen in patients with advanced NSCLC was published in the January 2012 issue of Journal of Thoracic Oncology, or JTO; this study evaluated custirsen in combination with gemcitabine and a platinum chemotherapy (cisplatin or carboplatin) as first-line chemotherapy. In the trial, 81 patients with advanced NSCLC received custirsen in combination with gemcitabine and a platinum chemotherapy as first-line treatment. Eighty-one percent of the patients had stage IV disease at enrollment, and 16% had squamous cell carcinoma. Patients remaining alive have been followed for a median (range) of 41 (38-59) months.

Data from the clinical trial are summarized as follows:

- the median overall survival was 14.1 months; 54% of patients survived at least one year;
- 30% of patients who received custirsen with first-line chemotherapy survived at least two years;
- disease control was achieved in 69% of patients; and
- preliminary analyses have shown that treatment with custirsen in combination with gemcitabine and a platinum chemotherapy significantly lowered serum clusterin levels as compared to baseline levels, and that average serum clusterin levels during treatment were predictive of survival, with low serum clusterin levels correlating to longer survival. Custirsen treatment with chemotherapy decreased serum clusterin levels compared to baseline levels in 95% of patients evaluated. Patients who achieved a minimum median CLU level for the population of  $\leq 38$   $\mu\text{g/mL}$  during treatment had a median survival of 27.1 months compared with 16.1 months for patients who did not have higher CLU levels ( $p=0.02$ ).

*Summary of Preliminary Results of Phase 2 Clinical Trial in Patients with Advanced Breast Cancer Receiving Custirsen and Docetaxel as First- or Second-Line Chemotherapy*

In January 2009, results of a Phase 2 clinical trial in 15 patients with advanced breast cancer were published in the scientific journal CCR; this study evaluated custirsen in combination with docetaxel as first-line or second-line chemotherapy. The authors concluded that the combination of custirsen and docetaxel at 75 mg/m<sup>2</sup> was well tolerated, and some clinical activity was seen in the patients with metastatic breast cancer.

*Summary of Preliminary Results of Phase 2 Clinical Trial in Patients with CRPC Receiving Custirsen and Hormone Ablation Therapy*

This trial was an investigator-sponsored trial that evaluated weekly custirsen with androgen withdrawal therapy for a three-month duration in patients with high-risk, localized prostate carcinoma prior to radical prostatectomy. Results of the trial indicated that custirsen was detectable in prostate tissue for 14 days after the last administration, that clusterin expression was decreased in cells from lymph nodes as well as from prostate specimens, and that patients who received custirsen plus androgen withdrawal therapy had higher levels of apoptosis (cell death) compared with patients who never received androgen withdrawal therapy or who received only androgen withdrawal therapy.

**OGX-427**

Overview of OGX-427

OGX-427 is currently being evaluated in phase 1 and phase 2 clinical trials in patients with bladder and prostate cancer. OGX-427 is our product candidate that is designed to inhibit production of Hsp27, a cell-survival protein expressed in many types of cancers including prostate, bladder, breast, pancreas and non-small cell lung cancer. Hsp27 expression is stress-induced, including by many anti-cancer therapies. For example, Hsp27 levels increased four-fold in prostate cancer patients after treatment with chemotherapy or hormone therapy. Overexpression of Hsp27 is thought to be an important factor leading to the development of treatment resistance and is associated with metastasis and negative clinical outcomes in patients with various tumor types.

A number of preclinical studies conducted by the Vancouver Prostate Centre and others have shown that reducing Hsp27 production induces tumor cell death in prostate, non-small cell lung, bladder and pancreatic cancer cells; the studies also suggest that reducing Hsp27 production sensitizes prostate tumor cells to hormone ablation therapy. These preclinical studies have also shown that inhibiting the production of Hsp27 in human prostate, bladder, lung, breast, ovarian and pancreatic tumor cells sensitizes the cells to chemotherapy.

Our Phase 1 clinical trial evaluated the safety of OGX-427 and established the recommended dose of 1000 mg in combination with docetaxel.

Current OGX-427 Development Activities

In 2013, we initiated the "ORCA" (On-going studies evaluating treatment Resistance in CAncer) program which encompasses clinical studies designed to evaluate whether inhibition of Hsp27 can lead to improved prognosis and treatment outcomes for cancer patients. Our goal is to advance cancer treatment by conducting clinical trials for OGX-427 across multiple cancer indications including, but not limited to, bladder cancer and CRPC. Consistent with the strategy that we have followed for custirsen, we intend to conduct parallel clinical trials to evaluate OGX-427 in several cancer indications and treatment combination to accelerate the development of OGX-427. In addition to OncoGenex-sponsored trials, specific Investigator-sponsored trials are and will be supported to allow assessment of a broader range of clinical indications for future OncoGenex-sponsored trials for possible market approval.



Our current OGX-427 development activities for bladder cancer include the following clinical trials that have been initiated:

- The Borealis-1 Trial: The OncoGenex-sponsored phase 2 clinical trial of OGX-427 in patients with metastatic bladder cancer. Borealis-1 is a three-arm, randomized, placebo-controlled phase 2 trial evaluating OGX-427 in combination with first-line gemcitabine and cisplatin treatment in the metastatic setting. Each arm is currently enrolling approximately 60 patients; the trial has been initiated in sites throughout the United States, Canada and Europe. The trial will be conducted as an event-driven trial such that the final analysis will have 80% power to show a critical hazard ratio of approximately 0.66 to 0.71. This type of phase 2 trial will allow us to better predict the potential size of and success for a phase 3 trial where a survival benefit will be the primary endpoint. This study is ongoing with an enrollment target of approximately 180 patients. We expect to complete patient accrual in the second half of 2013.
- The Borealis-2 Trial: The investigator-sponsored, randomized, controlled Phase 2 study evaluating OGX-427 in patients with advanced or metastatic bladder cancer who have disease progression following initial platinum-based chemotherapy. This study is designed to have adequate power to detect a survival benefit in the docetaxel + OGX-427 arm corresponding to a hazard ratio  $(\text{docetaxel} + \text{OGX-427} / \text{docetaxel}) = 0.667$ . The primary analysis is to be performed at one-sided 0.10 significance level with 90% power to detect this OS difference. We expect to enroll approximately 200 patients to receive either OGX-427 plus docetaxel treatment or docetaxel treatment alone. Patients may also continue weekly OGX-427 infusions as maintenance treatment until disease progression or unacceptable toxicity if they complete all 10 cycles of docetaxel, or are discontinued from docetaxel due to docetaxel toxicity. We expect this trial to be initiated in the first half of 2013.
- The BL-01 Trial: An investigator-sponsored phase 1 clinical trial to evaluate OGX-427 when administered directly into the bladder in patients with bladder cancer. The trial is currently enrolling 36 patients. It is designed to determine the safety and potential benefit of OGX-427 administered into the bladder using 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 clinical trial is being funded by the National Cancer Institute of Canada. Preliminary data were presented at the ASCO GU Symposium in February 2012.

Our current OGX-427 development activities for prostate cancer include the following clinical trials that have been initiated:

- The PR-01 Trial: An investigator-sponsored, randomized phase 2 clinical trial evaluating OGX-427 when administered with prednisone to patients with CRPC. PR-01 has completed enrollment with data collection ongoing. This randomized phase 2 clinical trial enrolled 74 patients who had minimally symptomatic or asymptomatic advanced prostate cancer and who had not yet received chemotherapy. This trial is measuring the direct effect of OGX-427 on PSA, levels, time to progression by PSA or measurable disease, numbers of CTCs and other relevant secondary endpoints. Preliminary data were presented at several conferences throughout 2012, most recently at the ESMO meeting in September 2012.

- The Pacific Trial: An investigator-sponsored, randomized phase 2 study evaluating OGX-427 in men with CRPC who are experiencing a rising PSA while receiving Zytiga (abiraterone acetate). The aim of the study is to determine if adding OGX-427 to Zytiga treatment can reverse or delay treatment resistance. We expect that approximately 80 patients will be enrolled. The trial was initiated in December 2012.

#### Summary of Results of OGX-427 Clinical Trials

Preliminary or final results have been presented for a phase 1 clinical trial in patients with solid tumors, a phase 1 clinical trial in patients with superficial or muscle-invasive bladder cancer, and a randomized phase 2 trial in chemotherapy-naïve patients with metastatic CRPC. The following is a summary of the preliminary or final results from these trials.

#### *Summary of Preliminary results of Ongoing OGX-427 Randomized Phase 2 Clinical Trial in Patients with CRPC*

This randomized, controlled phase 2 trial has completed enrollment of 74 patients who have minimally symptomatic or asymptomatic advanced prostate cancer and who have not yet received chemotherapy. This trial is funded in part by a grant by the Terry Fox Foundation. The trial is designed to determine the potential benefit of OGX-427 by assessing the number of patients without disease progression at 12 weeks post-study treatment with or without OGX-427. Preliminary study results presented at ESMO in September 2012 showed a higher number of patients without disease progression at 12 weeks and greater declines in PSA and CTCs in patients receiving OGX-427 plus prednisone treatment compared to those receiving prednisone alone.

At the time of the presentation at ESMO, 65 patients had been randomized to the CRPC Phase 2 study and had a minimum of 12 weeks in the study; 32 patients had received OGX-427 plus prednisone and 33 patients had received prednisone alone. Results from these 65 patients are as follows:

- in the OGX-427 plus prednisone arm, 71% of patients were progression-free at 12 weeks, compared to 48% in the prednisone alone arm. The primary efficacy endpoint of this study is defined as the proportion of patients without disease progression at 12 weeks where disease progression is based on any of the following parameters: PSA levels, measurable disease, bone lesions, global deterioration or requiring palliative radiation therapy;
- among patients who received OGX-427 plus prednisone, 75% experienced an overall decline in PSA compared to 52% in the prednisone alone arm;
- forty-seven percent of patients who received OGX-427 plus prednisone experienced a greater than or equal to 50% decline in PSA, versus 21% of patients who received prednisone alone;
- CTC declines from greater than or equal to five (unfavorable) to less than five (favorable) occurred in 52% of patients receiving OGX-427 plus prednisone compared to 41% of those treated with prednisone alone;
- among the 33 patients with baseline measurable disease, three out of 16 patients (19%) who received OGX-427 plus prednisone had a partial response compared to two out of 17 (12%) in the prednisone alone arm. In addition, one patient in the OGX-427 treatment arm had a complete response; and
- adverse events reported in both arms were primarily grade 1 or 2.

OGX-427 infusion reactions occurred and were primarily grade 1 or 2 chills, diarrhea, fatigue, nausea, flushing, pyrexia and vomiting. Other adverse events in two or more patients receiving OGX-427 were dizziness, hot flashes, muscular weakness, and hypertension. Grade 3-4 laboratory treatment-emergent adverse events in two or more patients receiving OGX-427 included lymphopenia (12%), hyperglycemia (12%), and elevated creatinine (6%).

*Summary of Preliminary Results of Ongoing OGX-427 Phase 1 Clinical Trial in Patients with Bladder Cancer*

This investigator-sponsored phase 1 trial, which is currently enrolling up to 36 patients, is designed to determine the effects of OGX-427 on Hsp27 expression and tumor response rates when administered into the bladder using intravesical instillation. In addition, the trial will measure the direct effect of delivering OGX-427 by intravesical instillation on expression of Hsp27 in bladder tumor cells. This clinical trial is being primarily funded by the National Cancer Institute of Canada.

Preliminary results from this trial presented at the ASCO 2012 Genitourinary Cancers Symposium in February 2012 demonstrated a trend towards decreased levels of Hsp27 and increased tumor cell death rates after intravesical treatment with OGX-427. Additionally, of the 15 patients treated with OGX-427, 33% had complete responses with no pathologic evidence of disease observed in post-surgical tissue following four doses of OGX-427 administered intravesically over an eight day period. In the OGX-427 treated patients who experienced a complete response, the absence of residual disease made it difficult to fully assess the effect of OGX-427 on Hsp27 expression. Therefore, the analysis was based mainly on the remaining patients who had evaluable tumor tissue. We continue to enroll patients with larger tumors to assess the effect of higher doses of OGX-427 on Hsp27 levels in patients with bladder cancer.

*Summary of Results of OGX-427 Phase 1 Clinical Trial in Patients with Solid Tumors*

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 whom a curative treatment does not exist. Final results of this phase 1 trial were presented in an oral presentation at the ASCO 2010 annual meeting. The phase 1 trial evaluated 42 patients treated with OGX-427 as a single agent and 22 patients treated 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 per cohort. Two further cohorts evaluated OGX-427 at the 800 and 1000 mg doses combined with docetaxel. Patients could receive up to 10 21-day cycles.

When OGX-427 was given as a single agent, a median of two cycles (range of zero to eight) was administered. When OGX-427 was combined with docetaxel, a median of four cycles (range of zero to ten) was administered.

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 most frequently reported adverse events in the OGX-427 monotherapy arms were infusion-related reactions and chills. The most frequently reported adverse events in the OGX-427 plus docetaxel arms were infusion-related reactions, chills, fatigue, diarrhea, pruritus (itching), nausea and back pain. The incidence of laboratory toxicity was determined based on laboratory data. The majority of laboratory toxicities were Grade 1 or Grade 2. The most common laboratory toxicities included: prolongation of time for a patient's blood to clot, or PTT, (95% of patients); low level of lymphocytes in the blood which fight infection, or lymphopenia, (93%); low levels of red blood cells which carry oxygen, or anemia, (90%); low sodium concentration in the blood, or hyponatremia, (52%); low white blood cell count, or leucopenia (49%); high aspartate transaminase level, or AST, a test of liver function, (48%); and low levels of potassium in the blood, or hypokalemia, (48%). Serious adverse events were reported for approximately half the patients. The most common events were disease progression and dyspnea (shortness of breath), reported for 5 subjects each and febrile neutropenia, reported for 4 subjects. Increased blood creatinine (a test of kidney function) and hydronephrosis (obstruction of the urine flow from the kidney due to tumor blockage) were reported for 2 subjects each. All remaining serious adverse events were reported for one subject each.

Thirty patients had baseline and at least one post-baseline assessment of measurable disease. A total of eight of 30 patients (27%) had a decrease in measurable disease from baseline of at least 15%. For patients treated with monotherapy, three patients had tumor reductions and for patients treated with combined therapy with docetaxel, five patients had tumor reductions.



Thirty-three of 36 patients with prostate cancer had at least one post-baseline PSA. Three of 21 in the monotherapy cohorts had reductions in PSA greater than or equal to 30% as did six of 12 in the combination therapy cohorts. Six of seven patients with ovarian cancer had both baseline and post-baseline CA-125 (an ovarian tumor marker) measurements. All were treated with monotherapy. Three patients had a reduction of CA-125.

At all doses and in all diseases evaluated in the trial, decreases were observed in both total CTCs, and in CTCs that were positive for Hsp27, or 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 CTC levels of less than or equal to five tumor cells per 7.5mL of blood are generally considered to have a more favorable prognosis. Hsp27+CTCs decreases were noted in 89% of evaluable patients and were observed at all dose levels and all diseases evaluated. In nine of 26 (31%) patients with greater than or equal to five Hsp+CTCs at baseline, Hsp27+CTCs had decreased to less than or equal to five tumor cells. In addition, in approximately 25% of patients at the 800 and 1000 mg doses, serum Hsp27 protein levels were decreased by 30% or greater over a period of at least six weeks.

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 greater than or equal to five Hsp+CTCs at baseline, Hsp+CTCs had decreased to less than or equal to five cells. In approximately 35% of patients, serum Hsp27 protein levels were decreased by 30% or greater over a time period of at least six weeks.

### **OGX-225**

The development program for our third product candidate, OGX-225, is focused on reducing the production of both IGFBP-2 and IGFBP-5, thereby enhancing treatment sensitivity and delaying tumor progression. Increased IGFBP-2 or IGFBP-5 production is observed in many human cancers and is linked to faster rates of cancer progression, treatment resistance and shorter survival duration. We believe that employing OGX-225 as a monotherapy will inhibit the production of both IGFBP-2 and IGFBP-5 and delay disease progression in cancers that depend on insulin-like growth factor-1, or IGF-1, for proliferation.

Because IGFBP-2 and IGFBP-5 are over-produced in a variety of cancers, OGX-225 may have broad market potential in numerous cancer indications. We expect that the initial opportunity for OGX-225 will be in breast and prostate cancer patients early in the course of cancer recurrence after failed hormone ablation therapy.

We have identified the lead compound and completed numerous preclinical proof of concept studies with OGX-225, which suggest that OGX-225 delays disease progression in prostate and breast cancer model systems. We have begun development activities for OGX-225 and we expect to initiate toxicology studies in the second half of 2013.

### **Second-Generation Antisense Technology**

Custirsen, OGX-427 and OGX-225 are based on second-generation antisense drug chemistry and belong to the drug class known as antisense therapeutics. On a product-by-product basis, we have collaborated with Isis Pharmaceuticals, Inc., or Isis, and selectively licensed technology from Isis to combine Isis' second-generation antisense chemistry with our proprietary gene target sequences to create inhibitors that are designed to down-regulate certain proteins associated with cancer resistance. In contrast to first-generation antisense chemistry, second-generation antisense chemistry has improved target binding affinity, increased resistance to degradation, and improved tissue distribution. These improvements result in slower clearance of the therapies from the body, which allow for less frequent dosing and thereby make treatment easier on patients at a lower associated cost. For example, clinical data from our phase 1 clinical trial evaluating custirsen in combination with neoadjuvant hormone therapy in prostate cancer patients demonstrated that weekly intravenous administration of custirsen resulted in drug distribution to prostate cancer tissue and over 92% inhibition of its target, clusterin mRNA, in

prostate tumor cells in these patients. These data demonstrate that, following systemic administration, custirsen entered tumor cells and effectively inhibited clusterin production.

### Summary of Product Development Programs

#### Ongoing Phase 3 Custirsen Trials:

Cancer Indication and Trial	Treatment Combination(1)	Status
Metastatic Castrate Resistant Prostate Cancer—Survival Endpoint (SYNERGY)	Docetaxel with and without custirsen (~1,000 patients); first line chemotherapy	<ul style="list-style-type: none"> <li>Phase 3 initiated in the third quarter of 2010</li> <li>Patient accrual complete, survival follow-up ongoing</li> <li>SPA approved by the FDA and EMA in agreement with development plan</li> </ul>
Metastatic Castrate Resistant Prostate Cancer—Survival Endpoint (AFFINITY)	Cabazitaxel with and without custirsen (~630 patients); second line chemotherapy	<ul style="list-style-type: none"> <li>Phase 3 initiated in the third quarter of 2012</li> <li>Patient accrual ongoing</li> </ul>
Advanced Non-Small Cell Lung Cancer—Survival Endpoint (ENSPIRIT)	Docetaxel with and without custirsen (~1,100 patients); second-line chemotherapy	<ul style="list-style-type: none"> <li>Phase 3 initiated by Teva in the third quarter of 2012</li> <li>Patient accrual ongoing</li> </ul>

#### Completed Custirsen Trials:

Cancer Indication	Treatment Combination(1)	Status
Metastatic Castrate Resistant Prostate Cancer	Docetaxel with and without custirsen; first line chemotherapy	<ul style="list-style-type: none"> <li>Phase 2 completed</li> <li>Data published in JCO, September 2010</li> </ul>
Metastatic Castrate Resistant Prostate Cancer	Docetaxel or mitoxantrone with and without custirsen; second-line chemotherapy	<ul style="list-style-type: none"> <li>Phase 2 completed</li> <li>Data published in CCR, September 2011</li> </ul>
Advanced Non-Small Cell Lung Cancer	Gemcitabine and cisplatin or carboplatin with and without custirsen; first-line chemotherapy	<ul style="list-style-type: none"> <li>Phase 2 completed</li> <li>Data published in JTO, January 2012</li> </ul>
Localized Prostate Cancer	Custirsen with hormone ablation therapy	<ul style="list-style-type: none"> <li>Phase 2 completed</li> <li>Results presented at ASCO 2008 Genitourinary Cancers Symposium</li> </ul>
Advanced Breast Cancer	Custirsen with docetaxel	<ul style="list-style-type: none"> <li>Phase 2 completed</li> <li>Data published in CCR, January 2009</li> </ul>
Localized Prostate Cancer	Custirsen with hormone ablation therapy	<ul style="list-style-type: none"> <li>Phase 1 completed</li> <li>Data published in Journal of National Cancer Institute, September 2005</li> </ul>
Solid Tumors (prostate, breast, NSCLC, ovarian, renal, bladder, peritoneum)	Custirsen with docetaxel	<ul style="list-style-type: none"> <li>Phase 1 completed</li> <li>Data published in CCR, February 2008</li> </ul>

### Ongoing OGX-427 Trials:

Cancer Indication and Trial	Treatment Combination(1)	Status
Metastatic Bladder Cancer (Borealis-1)	Gemcitabine and cisplatin with and without OGX-427 (~ 180 patients); first line chemotherapy	<ul style="list-style-type: none"><li>Phase 2 initiated in October 2011</li><li>Patient accrual ongoing</li></ul>
Metastatic Bladder Cancer (Borealis-2)	Docetaxel with and without OGX-427 (~ 200 patients); second line chemotherapy	<ul style="list-style-type: none"><li>Phase 2 is expected to be initiated in the first half of 2013</li></ul>
Superficial and muscle invasive Bladder Cancer (BL-01)	OGX-427 as monotherapy (~ 36 patients)	<ul style="list-style-type: none"><li>Phase 1 ongoing</li><li>Preliminary data presented at 2012 ASCO Genitourinary Cancers Symposium</li></ul>
Castrate Resistant Prostate Cancer (PR-01)	Prednisone with and without OGX-427 (74 patients)	<ul style="list-style-type: none"><li>Phase 2 initiated in third quarter of 2010</li><li>Patient accrual complete</li><li>Preliminary data presented at 2012 ESMO Annual Meeting</li></ul>
Castrate Resistant Prostate Cancer (Pacific)	Zytiga (abiraterone acetate) with and without OGX-427 (~ 80 patients)	<ul style="list-style-type: none"><li>Phase 2 initiated in December 2012</li><li>Patient accrual ongoing</li></ul>

### Completed OGX-427 Trial:

Cancer Indication	Treatment Combination	Status
Solid Tumors	OGX-427 with and without chemotherapy	<ul style="list-style-type: none"><li>Phase 1 completed</li><li>Final data presented at 2010 ASCO annual meeting, manuscript in preparation</li></ul>

### OGX-225 Preclinical Studies:

Cancer Indication	Treatment Combination	Status
Solid Tumors	OGX-225 with and without chemotherapy	<ul style="list-style-type: none"><li>Preclinical proof-of-concept studies completed</li><li>Expect to initiate toxicology studies in the second half of 2012</li></ul>

- (1) In all of our prostate cancer clinical trials and in clinical practice for prostate cancer, docetaxel is administered in combination with prednisone.

## OVERVIEW OF MARKET AND TREATMENT

In North America, cancer has recently surpassed heart disease as the leading cause of death in the United States. The American Cancer Society estimated that in 2012 approximately 1,638,910 new patients in the United States will be diagnosed with cancer and that approximately 577,190 patient deaths will be attributable to cancers.

Typically, cancer treatments are given sequentially and can include hormone therapy, surgery, radiation therapy, and chemotherapy. Although a particular therapy may initially be effective, tumor cells often react to therapeutic treatment by increasing the production of proteins that afford them a survival advantage, enabling them to become resistant to therapy, multiply, and spread to additional organs. As a result, many patients progress through multiple different therapies and ultimately die from the disease.

## OUR STRATEGY

Our objective is to develop and commercialize new cancer therapies that address resistance to therapies in cancer patients. Key elements of our strategy include:

- gaining market approval for custirsen by conducting registration trials that demonstrate efficacy and safety, in both prostate and lung cancer, in collaboration with Teva. As a result of the Collaboration Agreement with Teva, committed funding is available for phase 3 trials in patients with CRPC to evaluate custirsen in combination with docetaxel as first-line chemotherapy (SYNERGY), in patients with CRPC to evaluate custirsen in combination with cabazitaxel as second-line chemotherapy (AFFINITY), and in patients with NSCLC to evaluate custirsen in combination with docetaxel as second-line chemotherapy (ENSPIRIT). The SYNERGY trial was initiated in 2010, and both the AFFINITY and ENSPIRIT trials were initiated in the second half of 2012;
- advancing OGX-427 by conducting clinical trials across multiple cancer indications for OGX-427, including, but not limited to, bladder cancer and CRPC. Consistent with the strategy we are following for custirsen, we intend to conduct parallel clinical trials to evaluate OGX-427 in several cancer indications and treatment combinations to accelerate assessment of this product candidate for further development. In—that regard and in addition to Oncogenex-sponsored trials, we expect to support specific investigator-sponsored trials to allow broader assessment of other clinical indications for future Oncogenex-sponsored trials for possible market approval;
- developing and commercializing new cancer therapies to inhibit treatment resistance in cancer patients. We plan to leverage our expertise in development to bring new products to market as soon as possible. We intend to maintain and develop our relationship with the Vancouver Prostate Centre and develop relationships with other research institutions in order to identify additional product candidates; and
- optimizing the development of our product candidates through use of outsourcing and internal expertise. In order to increase efficiency and lower our overhead, we outsource, and plan to continue to outsource, preclinical and manufacturing activities. We have chosen to establish critical product development functions in-house, including clinical trial management and regulatory affairs.

## LICENSE AND COLLABORATION AGREEMENTS

### *Teva Pharmaceutical Industries Ltd.*

#### Custirsen

As discussed above, in December 2009, we, through our wholly owned subsidiary, OncoGenex Technologies, entered into the Collaboration Agreement with Teva for the development and global commercialization of custirsen (and related compounds). Pursuant to the Collaboration Agreement, Teva was granted the exclusive worldwide right and license to develop and commercialize any products containing custirsen and related compounds, which we refer to as the Licensed Products. We have an option to co-promote custirsen in the United States and Canada.

Under the Collaboration Agreement, Teva made upfront payments in the aggregate amount of \$50 million, and will make payments of 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 Licensed Products. Teva also acquired \$10 million of our common stock at a premium under a separate Stock Purchase Agreement. We did not receive any payments from Teva resulting from the achievement of developmental or commercial milestones or royalties in 2012, and we do not expect to receive any such payments from Teva in 2013. As of December 31, 2012 we have spent the entire required \$30 million towards the development of custirsen, which included our personnel costs for certain development activities. Teva will fund all other expenses under the Collaboration Agreement including the three phase 3 clinical trials under the Amended Clinical Development Plan.

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

- The SYNERGY Trial: The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with first-line docetaxel treatment in patients with CRPC. The FDA informed us that an application supported primarily by the results of SYNERGY alone would be acceptable for submission for market approval. SYNERGY patient enrollment was completed in the fourth quarter of 2012. Over 1,000 men have now been enrolled in order to show a survival benefit with 90% power based on a hazard ratio of 0.75. The expected timing of results is based on a pre-specified number of death events that is projected to occur in the fourth quarter of 2013, with data results expected to be announced in the first-half of 2014.
- The AFFINITY Trial: The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with cabazitaxel treatment as second-line chemotherapy in patients with CRPC. We expect to enroll approximately 630 patients to show a survival benefit with 85% power based on a hazard ratio of 0.75. We initiated this phase 3 clinical trial in August 2012.
- The ENSPIRIT Trial: The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with docetaxel treatment as second-line chemotherapy in patients with NSCLC. We expect to enroll approximately 1,100 patients in order to show a survival benefit with 90% power based on a hazard ratio of 0.80. This trial was initiated by Teva in September 2012. Two formal interim analyses are planned for stopping the trial early based on inadequate evidence of clinical benefit or futility. We will be evaluating both PFS and OS during the interim analyses. If both endpoints meet the predefined criteria for inadequate PFS clinical benefit and OS futility the trial would be stopped. The trial will not be stopped early in order to claim efficacy.

Teva will be responsible for conducting any other trials and development work necessary to obtain required regulatory approvals. We may assume some of these activities if assigned by the Joint Steering Committee, but Teva would be responsible for all associated costs. The Joint Steering Committee will oversee the development and regulatory approval of any Licensed Product. Funding responsibilities will be allocated as follows:

- we are required to spend \$30 million in direct and indirect development costs such as full-time equivalent, or FTE, reimbursement for time incurred by OncoGenex personnel for the benefit of the custirsen development plan, such contribution to be funded by a portion of the upfront payment provided by Teva as an advanced reimbursement for the Company Development Expenses, or reimbursed to OncoGenex on a quarterly basis. As of December 31, 2012, we have contributed \$30 million to the development of custirsen; and
- Teva will be required to fund all other expenses.

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

Teva was also granted the first right to file, prosecute and maintain, and enforce at its expense, the patent rights associated with custirsen. If Teva elects, however, not to, or fails to, file, prosecute and maintain, and enforce, the patent rights associated with custirsen, we retain the right to assume responsibility for such activities.

The Collaboration Agreement will remain in effect, on a country-by-country basis, until the expiration of Teva's obligation to pay royalties on sales of the Licensed Product in such country (or earlier termination under its terms). Commencing after the completion of all three phase 3 clinical trials set forth in the Clinical Development Plan, or upon early termination due to a material adverse change in our patent rights related to custirsen or safety issues or "futility," as defined in the Collaboration Agreement, Teva may terminate the Collaboration Agreement in its sole discretion upon three months' advance notice if notice is given prior to regulatory approval of a Licensed Product, and upon six months' advance notice if notice is given after such regulatory approval. If Teva

terminates the Collaboration Agreement for any reason other than an adverse change in custirsen patent rights, safety issues or “futility” determination as previously described, it will remain responsible for paying any remaining costs of all three phase 3 clinical trials, except for specified company development expenses. 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 other than for an uncured material breach by Teva, we will pay Teva a royalty on sales of Licensed Products. The percentage rates of such royalties (which are in the single digits) depend 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 10 years after the first commercial sale of a Licensed Product and certain thresholds related to generic competition.

In the event of a change of control of OncoGenex and within 90 days of such a change of control, Teva may, in its sole discretion, terminate the Joint Steering Committee or terminate the co-promotion option if not then exercised by us or if exercised but not yet executed by us, or terminate the co-promotion option if in its commercially reasonable opinion co-promotion with our successor would be materially detrimental to Teva’s interests.

### ***Isis Pharmaceuticals, Inc.***

#### Custirsen

In November 2001, OncoGenex Technologies entered into an agreement with Isis, referred to as the Original Isis Agreement, to jointly develop and commercialize custirsen. This strategic relationship provided us with access to Isis’ proprietary position in second-generation antisense chemistry for use in custirsen, and Isis’ expertise in developing antisense therapeutics, including its manufacturing expertise, and allowed us to develop custirsen cost efficiently. Under the Original Isis Agreement, we paid 65%, and Isis paid 35%, of the costs and revenue resulting from the development and commercialization of custirsen. On July 2, 2008, we and Isis amended the Original Isis Agreement or the Amended Isis Agreement, pursuant to which we became solely responsible for the costs and development of custirsen, and, in turn, assumed certain financial obligations to Isis, primarily related to sharing revenue received by us from a third party as a result of a licensing transaction.

Under the amended agreement, Isis assigned to OncoGenex Technologies its rights in the patents claiming the composition and therapeutic methods of using custirsen, and granted OncoGenex Technologies a worldwide, nonexclusive license to their know-how and patents covering our core antisense technology and manufacturing technology solely for use with custirsen. The key product related patent that Isis assigned to OncoGenex Technologies was U.S. Patent number 6,900,187 having an expiration date of at least 2021, and the key core antisense technology patents Isis licensed OncoGenex Technologies are U.S. Patent number 7,919,472 having an expiration date of 2026 and its foreign equivalents pending in Australia, Canada, the European Patent Convention and Japan. In addition, Isis agreed that so long as OncoGenex Technologies or its commercialization partner is using commercially reasonable efforts to develop and commercialize custirsen, Isis will not research, develop or commercialize an antisense compound designed to modulate clusterin. The amended agreement will continue until OncoGenex Technologies or its commercialization partner is no longer developing or commercializing custirsen or until Isis terminates the agreement for an uncured failure by OncoGenex Technologies to make a payment required under the agreement.

Licensing revenue that is based on a percentage of net sales of a licensor is defined as Royalty Revenue, while other licensing revenue, with the exception of fair market value of equity and reimbursement of research and development expenses, is defined as Non-Royalty Revenue. We will pay Isis royalties comprised of a base percentage of net sales of custirsen and a percentage of Royalty Revenue we receive in excess of a certain threshold up to a certain cap. The amount of the royalties payable to Isis depends on whether Isis owes royalty payments to third parties pursuant to its license agreements with such parties. Based on the Royalty Revenue we are eligible to receive as a result of the royalty rates established in our collaboration with Teva, our total royalty

obligations to Isis will range between 6.38% and 7.00% of net sales of custirsen by Teva during the period Isis owes royalty payments to third parties, and between 3.88% and 4.50% when those third-party obligations of Isis have expired, which we expect to occur in 2017.

We paid Isis \$10 million in January 2010 as Isis' share of Non-Royalty Revenue received by us in December 2009 in connection with our Collaboration Agreement with Teva. We did not make any further payments to Isis in 2012 under the terms of the Amended Isis Agreement and we do not anticipate making any such payments to Isis in 2013.

In addition, we are required to pay Isis 30% of all Non-Royalty Revenue we receive. 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; 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 discussed above. We cannot provide any assurance 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%. Neither we nor Isis can pursue the development or commercialization of any antisense compound for clusterin outside of the Amended Isis Agreement. This arrangement will continue until custirsen is no longer being developed or commercialized or until the Amended Isis Agreement is earlier terminated due to an uncured material breach.

To facilitate the execution and performance of the Collaboration Agreement, we and Isis agreed to amend the Amended Isis Agreement, which amendment provides that, among other things, if we are the subject of a change of control with a third party, where the surviving entity immediately following such change of control has the right to develop and sell the product, then (i) a milestone payment of \$20 million will be due and payable to Isis 21 days following the first commercial sale of the product in the United States and (ii) unless such surviving entity had previously sublicensed the product and a royalty rate payable to Isis by us has been established, the applicable royalty rate payable to Isis will thereafter be the maximum amount payable under the Amended Isis Agreement. Any non-royalty milestone amounts previously paid will be credited towards the \$20 million milestone if not already paid. As a result of the \$10 million milestone payment paid 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 we have now licensed the product to Teva and established a royalty rate payable to Isis, no royalty rate adjustments would apply if Teva acquires us and is the surviving entity.

OncoGenex Technologies has agreed to indemnify Isis and persons affiliated with Isis against liabilities resulting from the development, manufacture, use, handling, storage, sale or other commercialization or disposition of custirsen caused by OncoGenex Technologies' or its licensees' or sublicensees' gross negligence or willful misconduct, or caused by OncoGenex Technologies' material breach of the Original Isis Agreement, as amended.

#### OGX-427

In January 2005, OncoGenex Technologies entered into a collaboration and license agreement with Isis to jointly identify antisense compounds designed to inhibit the production of proteins encoded by specified gene targets. OncoGenex Technologies is solely responsible for all product development activities for antisense compounds under this collaboration. This relationship provides OncoGenex Technologies with access to Isis' proprietary position in second generation antisense chemistry for use in specified products. OncoGenex Technologies was permitted to designate up to two collaboration gene targets for collaborative research, development and commercialization. In April, 2005, Hsp27 was confirmed as a collaboration gene target, and we and Isis jointly designed and screened antisense compounds for this gene target. OncoGenex Technologies' right to designate a second collaboration gene target expired on January 5, 2007.

Under the terms of the agreement, in the event that OncoGenex Technologies abandons OGX-427, Isis may elect to unilaterally continue development of OGX-427, in which case it must provide Isis with a worldwide license or

sublicense (as the case may be) of its relevant technology solely to develop and commercialize OGX-427 in exchange for a royalty on Isis' sales of OGX-427.

In consideration for the grant of rights related to OGX-427, on May 5, 2005 OncoGenex Technologies issued Isis a promissory note, which was converted into shares of OncoGenex Technologies that were subsequently exchanged in the Arrangement for 53,200 shares of OncoGenex Pharmaceuticals common stock. Under the terms of the agreement, OncoGenex Technologies may be obligated to make certain milestone payments to Isis contingent upon the occurrence of certain clinical development and regulatory events related to OGX-427. It is also obligated to pay to Isis certain milestone payments, as well as certain low to mid single-digit royalties on net sales for OGX-427, with the amount of royalties depending on whether third-party royalty payments are owed. We paid Isis USD\$0.8 million in 2010 upon the initiation of a phase 2 clinical trial of OGX-427 in patients with CRPC. We did not make any royalty payments to Isis under the terms of the agreement in 2012 and do not anticipate making any royalty payments to Isis under the terms of the agreement in 2013.

OncoGenex Technologies has agreed to indemnify Isis and certain persons affiliated with Isis against liabilities caused by its and its licensees' and sublicensees' gross negligence or willful misconduct, its material breach of the collaboration and license agreement, and the manufacture, use, handling, storage, sale or other disposition of OGX-427 that is sold by OncoGenex Technologies or its affiliates, agents or sublicensees.

The term of the collaboration and license agreement will continue for each product until the later of 10 years after the date of the first commercial sale of OGX-427 and the expiration of the last to expire of any patents required to be licensed in order to use or sell OGX-427, unless OncoGenex Technologies abandons OGX-427 and Isis does not elect to unilaterally continue development of OGX-427.

### ***University of British Columbia***

#### **Custirsen**

Efforts conducted at the Vancouver Prostate Centre are owned and managed by the University of British Columbia, or UBC. Under a license agreement entered into in November 2001, as amended, UBC granted to OncoGenex Technologies an exclusive, worldwide license to commercialize its existing intellectual property and any improvements related to clusterin. This technology, combined with Isis' second-generation antisense chemistry, is our product candidate custirsen. In connection with entering into the license agreement, we issued to UBC shares of OncoGenex Technologies that were exchanged in the Arrangement for 15,243 shares of our common stock. OncoGenex Technologies agreed to pay UBC low single digit royalties on milestones and the revenue from sales of custirsen. OncoGenex Technologies is obligated to pay UBC CAD\$2,000 in annual maintenance fees. In January 2010, we paid UBC CAD\$0.3 million as a result of upfront payments we received from Teva in December 2009 in connection with our Collaboration Agreement. The occurrence and receipt of future milestone payments and the generation of royalty revenue are uncertain. We did not make any royalty payments to UBC under the terms of the agreement in 2012 and do not anticipate making any such payments to UBC in 2013.

OncoGenex Technologies agreed to use its commercially reasonable efforts to develop and exploit the licensed technology and any improvements. OncoGenex Technologies also agreed to promote, market and sell any resulting products and to cause the market demand for such products to be satisfied. OncoGenex Technologies is permitted to sublicense the technology, subject to certain consent and other requirements. OncoGenex Technologies directs patent prosecution and is responsible for all fees and costs related to the preparation, filing, prosecution and maintenance of the patent rights underlying the license agreement. OncoGenex Technologies indemnifies UBC and certain of UBC's affiliates against liability arising out of the exercise of any rights granted pursuant to the agreement. The term of the agreement will expire on the later of 20 years from its effective date and the expiration of the last patent licensed under the agreement. Subject to patent term extensions, the current granted patent for custirsen expires in the United States in 2021 and would expire in all other jurisdictions by



2020. OncoGenex Technologies has additional patent applications pending that, if issued and not invalidated, may extend the expiration date of the last-to-expire patents. OncoGenex Technologies may also file additional patent applications related to clusterin that could potentially extend the expiration date of the last to expire patent in this area.

#### OGX-427

Under a license agreement entered into in April 2005, as amended, UBC granted to OncoGenex Technologies an exclusive, worldwide license to commercialize its existing intellectual property and any improvements related to Hsp27. This technology, combined with Isis' second-generation antisense chemistry, is our product candidate OGX-427. In connection with entering into the license agreement, OncoGenex Technologies issued to UBC shares that were exchanged in the Arrangement for 6,533 shares of our common stock. OncoGenex Technologies also agreed to pay UBC low single digit royalties on the revenue from sales of OGX-427, which royalty rate may be reduced in the event that OncoGenex Technologies must pay additional royalties under patent licenses entered into with third parties in order to manufacture, use or sell OGX-427. OncoGenex Technologies may be obligated to make milestone payments to UBC contingent upon the occurrence of certain clinical development and regulatory events related to OGX-427. OncoGenex Technologies is obligated to pay UBC CAD\$2,000 in annual maintenance fees. We paid UBC CAD\$0.1 million in 2010 in relation to the initiation of a phase 2 trial of OGX-427 in patients with CRPC. The occurrence and receipt of upfront and milestone payments and the generation of royalty revenue are uncertain. We did not make any royalty payments to UBC under the terms of the agreement in 2012 and do not anticipate making any such payments to UBC in 2013.

Subject to certain exceptions, OncoGenex Technologies agreed to use its commercially reasonable efforts to (i) develop and exploit the licensed technology and any improvements and (ii) promote, market and sell any resulting products. OncoGenex Technologies is permitted to sublicense the technology, subject to certain consent and other requirements. OncoGenex Technologies directs patent prosecution and is responsible for all fees and costs related to the preparation, filing, prosecution and maintenance of the patent rights underlying the license agreement. OncoGenex Technologies indemnifies UBC and certain of UBC's affiliates against liability arising out of the exercise of any rights granted pursuant to the agreement. The term of the agreement will expire on the later of 20 years from its effective date and the expiration of the last patent licensed under the agreement. Depending on the outcome of the pending patent applications in the licensed patent family, and subject to any applicable patent term extensions, a patent issuing from this family would expire in all jurisdictions by 2023. OncoGenex Technologies may also file additional patent applications related to Hsp27 that could potentially extend the expiration date of the last to expire patent in this area.

#### OGX-225

Pursuant to the terms of our third-party license agreement relating to OGX-225, we will owe payments upon the completion of product development milestones, as well as low to mid single digit royalties on product sales. We did not make any milestone or royalty payments to third parties under the terms of the agreement in 2012 and do not anticipate making any such payments during 2013.

We are also obligated to pay annual license fees to third parties with respect to these product candidates. These amounts are disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations," which is incorporated herein by reference.

### ***Summary of Milestone Obligations by Product Candidate***

The following table sets forth the milestones that we may be required to pay to third parties under the license and collaboration agreements described above. As described above, we will also be required to pay certain revenue-based royalties with respect to each of our product candidates.

<u>Milestone Obligations to Third Parties</u>	<u>Amount Payable</u>
Custirsen	31% of non-royalty revenue
OGX-427	Up to \$4,997,000 (1)(2)(3)
OGX-225	Up to \$4,346,000 (2)(3)

- (1) Additional milestone payments may be required for product approvals outside the field of oncology.
- (2) Payable in connection with initiating certain clinical trials and obtaining certain market approvals.
- (3) Certain milestone payments are payable in Canadian dollars, which are translated based on the December 31, 2012 exchange rate of US\$1.00 = CAD\$0.9949, and rounded to the nearest \$1,000.

### **GOVERNMENT REGULATIONS**

#### ***Drug Approval Process***

Regulation by government authorities in the United States and other countries is a significant factor in our ongoing research and development activities and in the production and marketing of our products. In order to undertake clinical trials and to produce and market products for human use, mandatory procedures and safety standards established by the FDA in the United States and by comparable agencies in other countries must be followed.

The standard process before a pharmaceutical agent may be marketed includes the following steps:

- preclinical studies, including laboratory evaluation and animal studies to test for initial safety and efficacy;
- submission to national health authorities of an IND or Clinical Trials Application, or CTA, or equivalent dossier, which must be accepted by each national health authority before human clinical trials may commence in that country;
- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug in its intended population and use(s);
- submission to appropriate national and/or regional regulatory health authorities of a New Drug Application or NDA, or equivalent marketing authorization application, which application is not automatically accepted for review; and
- approval by appropriate regulatory health authorities of the marketing authorization application prior to any commercial sale or shipment of the drug in each country or jurisdiction.

As part of the regulatory health authority approval for each product, the drug-manufacturing establishment is subject to inspection by the FDA and must comply with current Good Manufacturing Practices, or cGMP, requirements applicable to the production of pharmaceutical drug products. The facilities, procedures and operations of manufacturers must be determined to be adequate by the FDA before product approval.

Preclinical studies include laboratory evaluation of the active drug substance and its formulation in animals to assess the potential safety and efficacy of the drug and its formulation. Prior to initiating the first clinical testing of a new drug product candidate, the results of the preclinical studies are submitted to regulatory health authorities as part of an IND or CTA, and must be accepted before the proposed clinical trial(s) can begin.

Clinical trials for cancer therapeutics involve the administration of the investigational drug to patients with a defined disease state, under the supervision of a qualified principal investigator.

Clinical trials are conducted in accordance with protocols that detail the parameters to be used to monitor safety and efficacy. Each protocol is submitted to regulatory health authorities as part of the IND or CTA in each country where clinical trials are to be conducted. Each clinical trial is approved and monitored by independent Institutional Review Boards, or IRB, or Ethics Committees who consider ethical factors, informed consent documents, the safety of human subjects and the possible liability of the institutions conducting a clinical trial. The IRB or Ethics Committee may require changes in the clinical trials protocol, which may delay initiation or completion of the trial.

Clinical trials typically are conducted in three sequential phases, although the phases may overlap. In phase 1, the initial introduction of the drug to humans, the drug is tested for safety and clinical pharmacology. Phase 2 trials involve more detailed evaluation of the safety and efficacy of the drug in patients with a defined disease. Phase 3 trials consist of large-scale evaluations of safety and efficacy of the investigational drug compared to accepted standard therapy in a defined disease.

The process of completing clinical testing and obtaining regulatory approval for a new product takes a number of years and requires the expenditure of substantial resources. The FDA, or another regulatory authority, may not grant approval on a timely basis, if at all. We may encounter difficulties in securing regulatory approval or unanticipated costs, which may delay or preclude the commercialization of our product candidates. For instance, regulatory authorities may conclude that the data submitted in a marketing authorization application, such as a NDA, are not adequate to support approval of a pharmaceutical agent and may require further clinical and preclinical testing, re-submission of the application, and further review. Even after initial approval has been obtained, an indication may be limited or conditioned on the provision of further studies to support an approved indication, and further studies will be required to gain approval for the use of a product for clinical indications other than those for which the product was approved initially. Also, regulatory authorities require post-marketing surveillance programs to monitor the drug product's side effects.

Marketing of pharmaceutical products outside of the United States is subject to regulatory requirements that vary from country to country. In the European Union, the general trend has been towards coordination of common standards for clinical testing of new drug products. Centralized approval in the European Union is coordinated through the EMA.

The level of regulation outside the United States and the European Union varies widely. The time required to obtain regulatory approval from regulatory agencies in each country may be longer or shorter than that required for FDA or EMA approval. In addition, in certain markets, reimbursement is subject to governmentally mandated prices.

## **CONTRACT RESEARCH AGREEMENTS**

Consistent with our strategy to outsource certain product development activities, we have established contract research agreements for preclinical, manufacturing and some data management services. We choose which business or institution to use for these services based on their expertise, capacity and reputation and the cost of the service.

We also provide quantities of our product candidates to academic research institutions to investigate the mechanism of action and evaluate novel combinations of product candidates with other cancer therapies in various cancer indications. These collaborations expand our research activities for product candidates with modest contribution from us.

## **RESEARCH AND DEVELOPMENT EXPENDITURES**

For the years ended December 31, 2012, 2011, and 2010, our expenditures for research and development activities were \$40.0 million, \$21.6 million, and \$18.5 million, respectively. Such research and development expenses primarily related to the advancement of our product candidates custirsen and OGX-427.

## **MANUFACTURING**

We do not own facilities for the manufacture of materials for clinical or commercial use. We rely and expect to continue to rely on contract manufacturers to manufacture our product candidates in accordance with cGMP, for use in clinical trials, as well as for process development as required. We will ultimately depend on contract manufacturers for the manufacture of our products, when and if we have any, for commercial sale.

To date, all active pharmaceutical ingredient, or API, and drug product for custirsen and OGX-427 has been manufactured by third parties on a purchase order basis, under cGMP. If our product candidates are approved for commercial sale in the future, we may be required to contract with larger contract manufacturers that can meet higher commercial drug quantities.

## **INTELLECTUAL PROPERTY**

Our success depends in part on our ability and that of our collaborators to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to prevent others from infringing on the proprietary rights of our product candidates, and to operate without infringing on the proprietary rights of others.

## **PATENTS**

We have a license from UBC and ISIS to use, make, have made, or make improvements upon custirsen, OGX-427 and OGX-225. In addition, Isis has assigned a three-member patent family related to clusterin antisense to OncoGenex Technologies, and we have a pending family of applications on an OGX-427 formulation.

As discussed above, certain intellectual property rights relating to custirsen have been sublicensed exclusively to Teva, which has subsequently assumed direct control of the prosecution of those rights as custirsen is developed.

We have been granted non-exclusive rights to all intellectual property owned, licensed or otherwise controlled by Isis as of the date of our agreements with Isis that relate to second-generation antisense chemistry and that are required for our product candidates (such as custirsen, OGX-427 and OGX-225). Isis is generally restricted from engaging in research, development and commercialization of antisense compounds related to clusterin, Hsp27, IGFBP-5 and IGFBP-2, other than as provided in the collaboration and license agreement related to each target. Isis directs patent prosecution and is responsible for all fees and costs related to the preparation, filing, prosecution and maintenance of these patent rights, which extend to numerous jurisdictions throughout the world. Individual patents have terms of protection depending on the laws of the countries in which the applications are made.

We direct patent prosecution, and are responsible for all fees and costs related to the preparation, filing, prosecution and maintenance of the patent rights for intellectual property under license from UBC covering OGX-427 and OGX-225. We file patent applications for this intellectual property in the United States, Canada, Europe (through the European Patent Office), Japan and other jurisdictions.

Composition of matter patents covering custirsen and OGX-427 have been issued in the United States and certain other jurisdictions. Additional patent applications covering all of these products, as well as other technologies, are pending in the United States and certain other countries.

Generally, patents issued in the United States are effective for 20 years from the earliest non-provisional filing date, if the application from which the patent issues was filed on or after June 8, 1995 (otherwise the term is the longer of 17 years from the issue date and 20 years from the earliest non-provisional filing date). The duration of patent terms for non-U.S. patents is typically 20 years from the earliest corresponding national or international filing date. Our licensed UBC patent estate, based on those patents and applications existing now and expected by us to issue, will expire in years ranging from 2020 to 2024, which dates do not include extensions that may be available. Patent term extensions, specifically to make up for regulatory delays, are available in the United States,

Europe and Japan. Although we believe that some or all of our product candidates will meet the criteria for patent term extensions, we can provide no assurance that we will obtain such extensions.

We also rely on unpatented trade secrets, proprietary know-how and continuing technological innovation, which we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants in our drug development research. We can provide no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets or know-how will not otherwise become known or be independently discovered by competitors. Further, we can provide no assurance that we will be able to protect our trade secrets or that others will not independently develop substantially equivalent proprietary information and techniques.

## **TRADEMARKS**

We own two trademarks registered in the United States and Canada: OncoGenex™ and Bringing Hope to Life™. We no longer use the trademark Bringing Hope to Life™ in our business and the registration of Bringing Hope to Life™ will expire in the United States in 2014 and in Canada in 2021.

We can provide no assurance that our registered or unregistered trademarks or trade names will not infringe upon third-party rights or will be acceptable to regulatory agencies.

## **COMPETITION**

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. Several therapies have been recently approved by the FDA, and we expect more to be approved in the future.

Many oncology drugs in clinical trials are being developed for the four primary indications: lung, breast, colorectal, and prostate cancers. Certain of these drugs are designed, like custirsen, OGX-427, and OGX-225, to interfere with mechanisms potentially involved with treatment resistance. If new drugs targeting mechanisms of treatment resistance are approved for sale for the indications that we are evaluating in advance of our product candidates or even after their commercialization, the market's interest in our product candidates may be reduced. We are aware of several other companies developing therapeutic products, whether antisense or otherwise, which seek to promote tumor cell death by inhibiting proteins believed to promote cell survival. Our competitors may seek to identify gene sequences, protein targets or antisense chemistry different from ours, and outside the scope of our intellectual property protection, to develop antisense therapeutics that serve the same function as our product candidates. Our competitors may also seek to use mechanisms other than antisense to inhibit the proteins that our product candidates are designed to inhibit.

Some of our product candidates' development plans include pursuing prostate cancer indications. Substantial advancements in the treatment of prostate cancer have occurred in the past two years and new products from our competitors have been approved for marketing on the basis of showing a survival advantage. Many of our existing and potential competitors have substantially greater financial resources and expertise than we do in manufacturing and developing products, conducting clinical trials, obtaining regulatory approvals and marketing. These entities also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products and technologies complementary to our programs. Standard treatments vary considerably by cancer indication, and new drugs may be more effective in treating one cancer indication than another. In addition, cancer is a difficult disease to treat and it is likely that no one therapeutic will replace all other therapies in any particular indication. Therapeutic strategies for treating cancer are increasingly focused on combining a number of drugs in order to yield the best results. Since custirsen and OGX-427 are intended to be

used in multiple cancer indications and target the tumors' adaptive survival mechanisms, these drugs may potentially be synergistic with many new and currently marketed therapies. Our ability to compete successfully will depend largely on our ability and, where applicable, the ability of our collaborators to:

- maintain or establish development programs in combination with new agents that may replace or diminish the markets for which we are currently developing our product candidates;
- establish that our product candidates are well tolerated and result in a clinical benefit when administered to cancer patients;
- establish that our product candidates address significant unmet needs for patients, resulting in prioritization of our product candidates over other treatment options;
- advance the development of our lead programs, including the enrollment of patients for our clinical trials;
- gain regulatory approval for our product candidates in their respective first indications as well as expand into additional indications;
- commercialize our lead product candidates successfully, which includes convincing physicians, insurers and other third-party payors of the advantages of our products over current therapies, when and if they have advantages;
- obtain intellectual property protection and protect the exclusivity for our product candidates and products, when and if we have any; and
- acquire other product candidates to expand our pipeline.

## **EMPLOYEES**

We have a total of 44 employees, of whom 29 are engaged in research and development functions, including clinical development, regulatory affairs and manufacturing, and 15 are engaged in general and administrative functions, including accounting and finance, administration, and corporate communications. Four of our 44 employees are employed on a part-time basis.

All of our employees have entered into non-disclosure agreements regarding our intellectual property, trade secrets and other confidential information. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced any work stoppages. We believe that we maintain satisfactory relations with our employees.

From time to time, we also use outside consultants to provide advice on our clinical development plans, research programs, administration and potential acquisitions of new technologies.

## **FINANCIAL INFORMATION**

We manage our operations and allocate resources as a single reporting segment. Financial information regarding our operations, assets and liabilities, including our total revenue and net loss for the years ended December 31, 2012, 2011 and 2010 and our total assets as of December 31, 2012 and 2011, is included in our Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

## **COMPANY INFORMATION**

We were incorporated in California in October 1991 and subsequently reorganized as a Delaware corporation in March 1995. Our principal executive offices are located at 1522-217th Place SE, Suite 100, Bothell, Washington 98021, and our telephone number is (425) 686-1500.

On August 21, 2008, pursuant to the Arrangement, OncoGenex Technologies became our wholly owned subsidiary. OncoGenex Technologies was incorporated under the federal laws of Canada in May 2000.

OncoGenex, Inc., a former subsidiary of OncoGenex Technologies, was incorporated under the laws of Washington in August 2005 and was dissolved pursuant to the Articles of Dissolution filed on July 1, 2009.

#### **AVAILABLE INFORMATION**

We maintain a website at <http://www.oncogenex.com>. The information contained on or accessible through our website is not part of this Annual Report on Form 10-K. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or Exchange Act, are available free of charge on our website as soon as reasonably practicable after we electronically file such reports with, or furnish those reports to, the SEC. Any information we filed with the SEC may be accessed and copied at the SEC's Public Reference Room at 100 F Street NE, Washington, DC 20549. Information may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at <http://www.sec.gov>.

## 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 Annual Report on Form 10-K, before deciding to invest in our common stock. If any of the following risks materialize, our business, financial condition, results of operation and future prospects will likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.*

#### Risks Related to Our Business

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

We are a clinical-stage biopharmaceutical company, are not profitable, have incurred losses in each year since our inception and do not expect to become profitable in the foreseeable future. We have never had any products available for commercial sale and we have not generated any revenue from product sales nor do we anticipate that we will generate revenue from product sales in the foreseeable future. Our 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.

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

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

- limited number of, and competition for, suitable patients with the particular types of cancer required for enrollment in our clinical trials;
- limited number of, and competition for, suitable sites to conduct clinical trials;
- introduction of new product candidates to the market in therapeutic areas similar to those that we are developing for our product candidates;
- concurrent evaluation of new investigational product candidates in therapeutic areas similar to those that we are developing for our product candidates;
- delay or failure to obtain the FDA's or non-U.S. regulatory agencies' approval or agreement to commence a clinical trial, including our phase 3 or registration clinical trials or amendment of those trials under a special protocol assessment;



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

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

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

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

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 one ongoing registration trial with custirsen in patients with CRPC, referred to as the SYNERGY trial. In the second half of 2012, we initiated an additional registration trial in patients with NSCLC, referred to as the ENSPIRIT trial, and a second trial, referred to as the AFFINITY trial, in combination with cabazitaxel as second-line chemotherapy in patients with CRPC. OGX-427 has been evaluated

in humans, although we have 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. We intend to conduct parallel clinical trials to evaluate OGX-427 in several cancer indications and treatment combination to accelerate the development of OGX-427. 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. OGX-225 has not been tested in humans. Our preclinical 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

- Teva may elect to terminate the ongoing clinical trials and cease development of custirsen;
- regulatory authorities may withdraw their approval of the product;

- we may be required to recall the product, change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- a product may become less competitive and product sales may decrease; and
- our reputation may suffer.

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

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

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

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

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

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

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

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

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

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

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

will be delayed and our costs will be increased. If these clinical trials generate safety concerns or lack of efficacy, our business would be adversely affected.

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

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

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

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

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

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

Our business strategy relies in part on potentially partnering successful product candidates with larger companies to complement our internal development and commercialization efforts. While we have successfully entered into a Collaboration Agreement with Teva with respect to custirsen, it may be difficult for us to find third parties that are willing to enter into a collaboration on acceptable economic terms, if at all, with respect to our other product candidates. We also will be competing with many other companies as we seek partners for our other product candidates and may not be able to compete successfully against those companies. If we are not able to enter into collaboration arrangements for our other product candidates and custirsen does not achieve regulatory approval or is delayed, we would be required to undertake and fund further development, clinical trials, manufacturing and commercialization activities solely at our own expense and risk. If we are unable to finance and/or successfully execute those expensive activities, our business could be materially and adversely affected, and we may be forced to discontinue clinical development of these product candidates.

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

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

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

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

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

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

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

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

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

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

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

We will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our development and commercialization efforts for our existing and future product candidates. Our success depends on our continued ability to attract, retain and motivate highly qualified personnel, such as management, clinical and preclinical personnel, including our executive officers Scott Cormack, and Cindy Jacobs. In addition, although we have entered into employment agreements with each of 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, 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 and OGX-225 through development and clinical trials, we will need to develop or expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. Maintaining additional relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to manage our development efforts effectively, manage our clinical trials effectively, hire, train and integrate additional management, development, administrative and sales and marketing personnel, improve our managerial, development, operational and finance systems, and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure.

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

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

***We may be adversely affected if our controls over 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 and our Board committees and as executive officers.

### **Risks Related to Our Intellectual Property**

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

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

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

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

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

The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends on many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents. Our ability or the ability of our collaborators to maintain and solidify our proprietary position for our

product candidates will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may issue in the future, or those licensed to us or our collaborators, may be challenged, invalidated, unenforceable or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. Due to the extensive amount of time required for the development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

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

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

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

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

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

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

The patents and pending patent applications underlying our licenses do not cover all potential product candidates, modifications and uses. In the case of patents and patent applications licensed from Isis, we do not have and have not had any control over the filing, prosecution or enforcement of these patents or patent applications. We cannot be certain that such prosecution efforts have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. We also cannot be assured that our licensors or their respective licensing partners will agree to enforce any such patent rights at our request or devote sufficient efforts

to attain a desirable result. Any failure by our licensors or any of their respective licensing partners to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **Risks Related to our Common Stock and Other Securities**

***The price for our common stock is volatile.***

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

An increase in the market price of our common stock, which is uncertain and unpredictable, may be the sole source of gain from an investment in our common stock. An investment in our common stock may not be appropriate for investors who require dividend income. We have never declared or paid cash dividends on our

capital stock and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for stockholders for the foreseeable future. Accordingly, an investment in our common stock may not be appropriate for investors who require dividend income.

***If we raise additional 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, we may do so at a price per share that represents a discount to the then-current per share trading price of our common stock and our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business.

***We are at risk of securities class action litigation.***

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

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

We have a stockholder rights plan that may have the effect of discouraging unsolicited takeover proposals. Specifically, the rights issued under the stockholder rights plan could cause significant dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board. In addition, our certificate of incorporation and bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions include the ability of our Board to designate the terms of and issue new series of preferred stock and the ability of our Board to amend our bylaws without stockholder approval. In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless certain specific requirements are met as set forth in Section 203. Collectively, these provisions could make a third-party acquisition of us difficult or could discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

## **Risks Related to Our Industry**

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

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive

approval of 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 preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

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

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

If any of our product candidates are approved, the approved product and its manufacturer will be subject to continual review. Any regulatory approval that we receive for a product candidate is likely to be subject to limitations on the indicated uses for which the end product may be marketed, or include requirements for potentially costly post-approval follow-up clinical trials. In addition, if the FDA and/or non-U.S. regulatory authorities approve any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the end product will be subject to extensive regulatory requirements. We and the manufacturers of our products, when and if we have any, will also be required to comply with cGMP regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products, when and if we have any, and these facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA and



other non-U.S. regulatory authorities, or if previously unknown problems with our products, when and if we have any, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

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

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

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

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

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

In the United States and elsewhere, our product revenue will depend principally on the reimbursement rates established by third-party payors, including government health administration authorities, managed-care providers, public health insurers, private health insurers and other organizations. These third-party payors are increasingly challenging the price, and examining the cost-effectiveness, of medical products and services. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved drugs, pharmaceutical products or product indications. We may need to conduct post-marketing clinical trials in order to demonstrate the cost-effectiveness of our products, if any. Such clinical trials may require us to commit a significant amount of management time and financial and other resources. If reimbursement of such product is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our revenue could be reduced.

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

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

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

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

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

We have business offices located in Bothell, Washington and Vancouver, British Columbia. Prior to the Arrangement, Sonus entered into a non-cancellable lease agreement for laboratory and office space in Bothell, Washington, and moved into this facility on December 14, 2007. The lease covers approximately 42,600 square feet of laboratory and office space in a single facility, is currently at an annual rent of approximately \$2.1 million, and has a 10-year term with two five-year renewal options.

We lease approximately 4,857 square feet in Vancouver, British Columbia, currently at an annual rent of approximately CND \$0.1 million, which lease expires in September 2014 and includes a five-year renewal option.

We believe that the facilities we currently lease are sufficient for our anticipated near-term needs.

### **ITEM 3. LEGAL PROCEEDINGS**

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We are not currently a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on the results of our operations or financial position. There are no material proceedings to which any director, officer or any of our affiliates, any owner of record or beneficially of more than five percent of any class of our voting securities, or any associate of any such director, officer, our affiliates, or security holder, is a party adverse to us or our consolidated subsidiary or has a material interest adverse thereto.

### **ITEM 4. MINE SAFETY DISCLOSURE**

Not applicable.

## PART II

### ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock first began trading on the Nasdaq National Market under the symbol "SNUS" on October 12, 1995. Following the completion of the Arrangement discussed elsewhere in this Annual Report on Form 10-K, our common stock commenced trading on the Nasdaq Capital Market under the stock symbol "OGXT", effective August 21, 2008.

No cash dividends have been paid on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future. As of February 15, 2013, there were approximately 112 stockholders of record and there were approximately 7,220 beneficial stockholders of our common stock. The high and low sales prices of our common stock as reported by the NASDAQ Capital Market for the periods indicated are as follows:

<u>OncoGenex Pharmaceuticals, Inc.</u>	<u>HIGH</u>	<u>LOW</u>
YEAR ENDED DECEMBER 31, 2011:		
First quarter .....	\$17.44	\$14.77
Second quarter .....	18.99	15.27
Third quarter .....	17.75	8.63
Fourth quarter .....	12.74	9.07
YEAR ENDED DECEMBER 31, 2012:		
First quarter .....	\$17.48	\$11.33
Second quarter .....	13.72	11.84
Third quarter .....	14.99	13.20
Fourth quarter .....	14.54	11.51

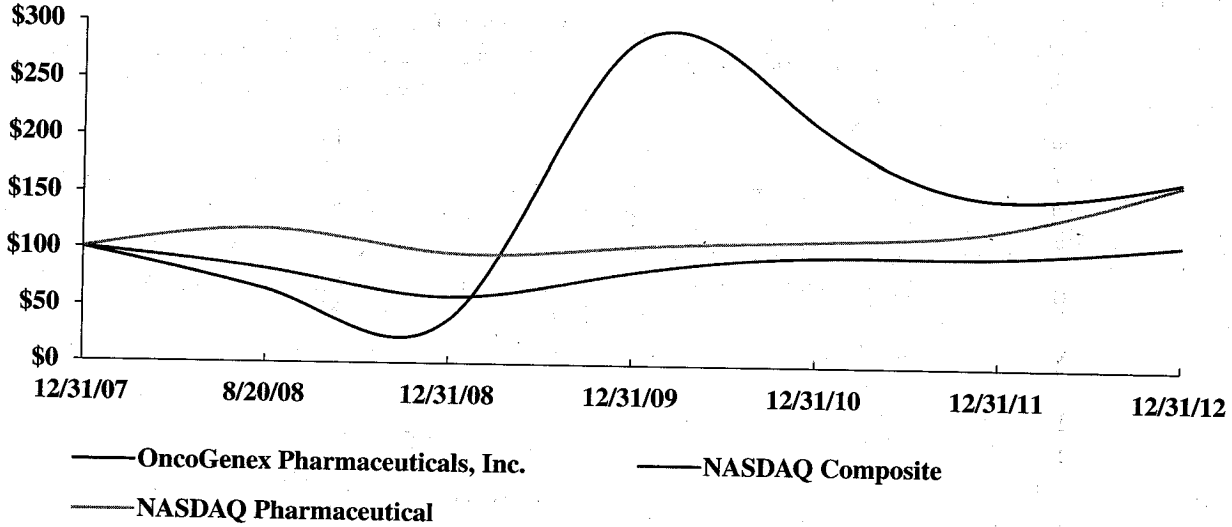
The information required by this item regarding equity compensation plan information is set forth in Part III, Item 12 of this Annual Report on Form 10-K. No purchases of equity securities during the year ended December 31, 2012 were made by us or on our behalf and we did not sell any unregistered securities during such year.

#### Stock Performance Graph

The following performance graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filings. The graph compares the cumulative five-year total return provided to stockholders on our common stock relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index. An investment of \$100 (with reinvestment of all dividends into additional shares of the same class of equity securities at the frequency with which dividends are paid on such securities during the applicable year) is assumed to have been made in our common stock and in each of the indexes on December 31, 2006 and its relative performance is tracked through December 31, 2012. All amounts reflected in the graph are presented after having given effect to the one-for-eighteen reverse stock split effected in connection with the Arrangement.

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***  
 Among OncoGenex Pharmaceuticals, Inc., the NASDAQ Composite Index,  
 and the NASDAQ Pharmaceutical Index



\*\$100 invested on 12/31/07 in stock or index, including reinvestment of dividends.  
 Fiscal year ending December 31.

	<u>12/31/07</u>	<u>8/20/08</u>	<u>12/31/08</u>	<u>12/31/09</u>	<u>12/31/10</u>	<u>12/31/11</u>	<u>12/31/12</u>
<b>OncoGenex Pharmaceuticals, Inc.</b>	<b>100.00</b>	<b>64.34</b>	<b>38.31</b>	<b>284.55</b>	<b>214.43</b>	<b>149.94</b>	<b>167.56</b>
<b>NASDAQ Composite</b>	<b>100.00</b>	<b>82.69</b>	<b>59.03</b>	<b>82.25</b>	<b>97.32</b>	<b>98.63</b>	<b>110.78</b>
<b>NASDAQ Pharmaceutical</b>	<b>100.00</b>	<b>117.99</b>	<b>97.45</b>	<b>104.75</b>	<b>111.47</b>	<b>123.06</b>	<b>164.89</b>

(1) August 20, 2008 represents the day before the date of the completion of the Arrangement.

## ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The data set forth below should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Consolidated Financial Statements and Notes thereto appearing at Item 8 of this Annual Report on Form 10-K. The selected consolidated statements of loss data for the years ended December 31, 2012, 2011 and 2010 and consolidated balance sheet data as of December 31, 2012 and 2011 set forth below have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected statements of loss data for the years ended December 31, 2009 and December 31, 2008 and the balance sheet data as of December 31, 2010, 2009 and 2008 set forth below have been derived from the audited consolidated financial statements for such years not included in this Annual Report on Form 10-K.

In connection with the Arrangement, OncoGenex Technologies was considered to be the acquiring company for accounting purposes. Accordingly, the assets and liabilities of Sonus were recorded, as of the effective time of the Arrangement, at their respective fair values and added to those of OncoGenex Technologies. The results of the operations and balance sheet data for the year ended December 31, 2008 reflect the results of only OncoGenex Technologies for the time period of January 1, 2008 through August 20, 2008 and the results of the combined company from August 21, 2008 through December 31, 2008. The historical results presented are not necessarily indicative of future results.

	December 31,				
	2012	2011	2010	2009	2008
	(in thousands except share and per share amounts)				
<b>Statements of Loss Data:</b>					
Collaboration revenue .....	\$ 20,095	\$ 5,496	\$ 13,616	\$ 25,539	\$ —
Total expenses .....	\$ 46,082	\$ 27,783	\$ 28,361	\$ 28,121	\$ 11,112
Net loss .....	\$ (21,098)	\$ (14,673)	\$ (12,584)	\$ (5,476)	\$ (4,204)
Redeemable convertible preferred share accretion .....	\$ —	\$ —	\$ —	\$ —	\$ 1,973
Net loss attributable to common stockholders .....	\$ (21,098)	\$ (14,673)	\$ (12,584)	\$ (5,476)	\$ (6,177)
Basic and diluted loss per common share .....	\$ (1.56)	\$ (1.51)	\$ (1.79)	\$ (0.95)	\$ (3.38)
Shares used in calculation of net loss per share					
Basic and diluted .....	13,522,723	9,729,340	7,030,903	5,766,850	1,829,276

	December 31,				
	2012	2011	2010	2009	2008
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments .....	\$ 75,383	\$ 64,927	\$ 85,107	\$ 64,568	\$ 12,419
Total assets .....	\$ 82,016	\$ 68,015	\$ 89,918	\$ 68,980	\$ 14,790
Current liabilities .....	\$ 11,556	\$ 30,786	\$ 27,476	\$ 25,781	\$ 2,884
Total liabilities .....	\$ 15,809	\$ 37,125	\$ 45,793	\$ 46,021	\$ 4,083
Additional paid-in capital .....	\$ 165,395	\$ 108,986	\$ 107,579	\$ 73,798	\$ 56,070
Accumulated deficit .....	\$ (101,840)	\$ (80,742)	\$ (66,069)	\$ (53,485)	\$ (48,009)
Stockholder's equity .....	\$ 66,207	\$ 30,890	\$ 44,125	\$ 22,959	\$ 10,707

## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

### **Forward-Looking Statements**

This Annual Report on Form 10-K 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 Annual Report on Form 10-K or in documents incorporated by reference into this Annual Report on Form 10-K. 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 trial conducted by us or our collaborators;
- anticipated regulatory filings, requirements and future clinical trials conducted by us or our collaborators;
- timing and amount of future contractual payments, product revenue and operating expenses;
- market acceptance of our products and the estimated potential size of these markets; and
- our anticipated future capital requirements and the terms of any capital financing agreements.

These forward-looking statements are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. Factors that might cause such a difference include those discussed in Item 1A "Risk Factors," as well as those discussed elsewhere in the Annual Report on Form 10-K.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K 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 Annual Report on Form 10-K or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

### **Overview**

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

Our product candidates custirsen, OGX-427 and OGX-225 focus on mechanisms of treatment resistance in cancer patients and are designed to block 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. We believe this approach will increase survival time and improve the quality of life for cancer patients.

#### *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 an Amended Clinical Development Plan under which the following three phase 3 clinical trials have been initiated:

- **The SYNERGY Trial:** The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with first-line docetaxel treatment in patients with castrate resistant prostate cancer, or CRPC. During discussions with the U.S. Food and Drug Administration, or FDA, the FDA informed us that an application supported primarily by the results of SYNERGY alone would be acceptable for submission for market approval. SYNERGY patient enrollment was completed in the fourth quarter of 2012. Over 1,000 men have now been enrolled in order to show a survival benefit with 90% power based on a hazard ratio of 0.75. The expected timing of results is based on a pre-specified number of death events that is projected to occur in the fourth quarter of 2013, with data results expected to be announced in the first-half of 2014.
- **The AFFINITY Trial:** The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with cabazitaxel treatment as second-line chemotherapy in patients with CRPC. We expect to enroll approximately 630 patients to show a survival benefit with 85% power based on a hazard ratio of 0.75. We initiated this phase 3 clinical trial in August 2012.
- **The ENSPIRIT Trial:** The phase 3 clinical trial to evaluate a survival benefit for custirsen in combination with docetaxel treatment as second-line chemotherapy in patients with non-small cell lung cancer, or NSCLC. We expect to enroll approximately 1,100 patients in order to show a survival benefit with 90% power based on a hazard ratio of 0.80. This trial was initiated by Teva in September 2012. Two formal interim analyses are planned for stopping the trial early based on inadequate evidence of clinical benefit or futility. We will be evaluating both PFS and OS during the interim analyses. If both endpoints meet the predefined criteria for inadequate PFS clinical benefit and OS futility the trial would be stopped. The trial will not be stopped early in order to claim efficacy.

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."

Custirsen received Fast Track designation from the FDA for the treatment of progressive metastatic prostate cancer in combination with docetaxel. The FDA has also agreed on the design of the SYNERGY trial through the special protocol assessment process.

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



We and collaborating investigators have conducted five phase 2 clinical trials to evaluate the ability of custirsen to enhance the effects of therapy in patients with prostate, non-small cell lung and breast cancers. Results have been presented for each of these phase 2 trials. Our phase 3 registration trials have been designed based on our phase 2 clinical trials. Data from these phase 2 studies demonstrate the potential benefit of adding custirsen, a second generation antisense molecule, to existing cancer therapies. Refer to the discussion above under the headings “Our Product Candidates—Custirsen— Current Custirsen Development Activities” and “Our Product Candidates—Custirsen—Summary of Results of Custirsen Phase 2 Clinical Trials” for further details.

#### *Product Candidate OGX-427*

OGX-427 is our product candidate that is designed to inhibit production of heat shock protein 27, or Hsp27, a cell-survival protein expressed in many types of cancers including bladder, prostate, breast and non-small cell lung cancer. Hsp27 expression is stress-induced, including by many anti-cancer therapies. For example, Hsp27 levels increased four-fold in prostate cancer patients after treatment with chemotherapy or hormone therapy. Overexpression of Hsp27 is thought to be an important factor leading to the development of treatment resistance and is associated with metastasis, negative clinical outcomes in patients with various tumor types.

In 2013, we initiated the “ORCA” (On-going studies evaluating treatment Resistance in CANcer) program which encompasses clinical studies designed to evaluate whether inhibition of Hsp27 can lead to improved prognosis and treatment outcomes for cancer patients. Our goal is to advance cancer treatment by conducting clinical trials for OGX-427 across multiple cancer indications including, but not limited to bladder cancer and CRPC. Consistent with the strategy that we have followed for custirsen, we intend to conduct parallel clinical trials to evaluate OGX-427 in several cancer indications and treatment combination to accelerate the development of OGX-427. In addition to OncoGenex-sponsored trials, specific Investigator-sponsored trials will be supported to allow assessment of a broader range of clinical indications for future OncoGenex-sponsored trials for possible market approval.



Our current OGX-427 development activities for bladder cancer include the following clinical trials that have been initiated:

- The BL-01 Trial: An investigator-sponsored phase 1 clinical trial to evaluate OGX-427 when administered directly into the bladder in patients with bladder cancer. The trial is currently enrolling 36 patients. It is designed to determine the safety and potential benefit of OGX-427 administered into the bladder using 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 clinical trial is being funded by the National Cancer Institute of Canada. Preliminary data were presented at the ASCO GU Symposium in February 2012.
- The Borealis-1 Trial: An OncoGenex-sponsored phase 2 clinical trial of OGX-427 in patients with metastatic bladder cancer. Borealis-1 is a three-arm, randomized, placebo-controlled phase 2 trial evaluating OGX-427 in combination with first-line gemcitabine and cisplatin treatment in the metastatic setting. Each arm is currently enrolling approximately 60 patients; the trial has been initiated in sites throughout the United States, Canada and Europe. The trial will be conducted as an event-driven trial such that the final analysis will have 80% power to show a critical hazard ratio of

approximately 0.66 to 0.71. This type of phase 2 trial will allow us to better predict the potential size of and success for a phase 3 trial where a survival benefit will be the primary endpoint. This study is ongoing with an enrollment target of approximately 180 patients. We expect to complete patient accrual in the second half of 2013.

- The Borealis-2 Trial: The investigator-sponsored, randomized, controlled Phase 2 study evaluating OGX-427 in patients with advanced or metastatic bladder cancer who have disease progression following initial platinum-based chemotherapy. This study is designed to have adequate power to detect a survival benefit in the docetaxel + OGX-427 arm corresponding to a hazard ratio (docetaxel + OGX-427/ docetaxel) = 0.667. The primary analysis is to be performed at one-sided 0.10 significance level with 90% power to detect this OS difference. We expect to enroll approximately 200 patients to receive either OGX-427 plus docetaxel treatment or docetaxel treatment alone. Patients may also continue weekly OGX-427 infusions as maintenance treatment until disease progression or unacceptable toxicity if they complete all 10 cycles of docetaxel, or are discontinued from docetaxel due to docetaxel toxicity. We expect this trial to be initiated in the first half of 2013.

Our current OGX-427 development activities for prostate cancer include the following clinical trials that have been initiated:

- The PR-01 Trial: An investigator-sponsored phase 2 clinical trial evaluating OGX-427 when administered with prednisone to patients with CRPC. PR-01 has completed enrollment with data collection ongoing. This randomized, controlled phase 2 clinical trial enrolled 74 patients who had minimally symptomatic or asymptomatic advanced prostate cancer and who had not yet received chemotherapy. This trial is measuring the direct effect of OGX-427 on prostate-specific antigen, or PSA, levels, time to progression by PSA or measurable disease, numbers of circulating tumor cells, or CTCs, and other relevant secondary endpoints. Preliminary data were presented at several conferences throughout 2012, most recently at the European Society for Medical Oncology, or ESMO, meeting in September 2012.
- The Pacific Trial: An investigator-sponsored, randomized phase 2 study evaluating OGX-427 in men with CRPC who are experiencing a rising PSA while receiving Zytiga (abiraterone acetate). The aim of the study is to determine if adding OGX-427 to Zytiga treatment can reverse or delay treatment resistance. Approximately 80 patients will be enrolled. The trial was initiated in December 2012.

Additional phase 2 investigator-sponsored studies evaluating OGX-427 in other malignancies are under development. Further details of these studies will be provided when the trials are initiated. Results of these studies may direct future company-sponsored trials in indications that show promising clinical benefits.

Refer to the discussion above under the headings "Our Product Candidates—OGX-427—Summary of Results of OGX-427 Clinical Trials" for further details.

#### *Product Candidates OGX-225*

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

#### **Collaboration Revenue**

We recorded \$20.1 million of collaboration revenue in connection with our Collaboration Agreement with Teva in the year ended December 31, 2012, as compared to \$5.5 million in the year ended December 31, 2011. At December 31, 2012, the \$30 million upfront collaboration payment was fully expended resulting in a Current Deferred Collaboration Revenue balance of zero. Teva is required to fund all additional expenses under the

Amended Clinical Development Plan. We are eligible to receive payments of up to \$370 million upon the achievement of developmental and commercial milestones set forth in the Collaboration Agreement. At present, we are unable to predict the timing or likelihood of such milestone payments, although we did not receive any payments from Teva resulting from the achievement of developmental or commercial milestones or royalties in 2012, and we do not expect to receive any such payments from Teva in 2013. Moreover, Isis has disclosed in its Securities and Exchange Commission, or SEC, filings that it is entitled to receive 30% of the up to \$370 million in milestone payments we may receive from Teva as part of the Collaboration Agreement. We disagree with their assessment but believe there may be some lesser payment obligation. See Note 4 of Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for further details on our collaboration with Teva.

### **Research and Development Expenses**

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

Currently, we manage our clinical trials through contract research organizations and independent medical investigators at their sites and at hospitals and expect this practice to continue. Through our clinical development programs, we are developing each of our product candidates in parallel for multiple disease indications. Due to the number of ongoing projects and our ability to utilize resources across several projects, we do not record or maintain information regarding the indirect operating costs incurred for our research and development programs on a program-specific basis. In addition, we believe that allocating costs on the basis of time incurred by our employees does not accurately reflect the actual costs of a project.

As of December 31, 2012, we had spent the entire \$30 million related to the development of custirsen, as required under the Collaboration Agreement. Teva is required to fund all additional expenses under the Amended Clinical Development Plan. We expect aggregate full-time equivalent reimbursement of between \$1.2 and \$2.0 million annually from 2013 to 2014, which will be reimbursed to us from Teva.

A majority of our expenditures to date have been related to the development of custirsen. 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 \$0.3 million 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.

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 2013 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. While we believe that G&A resources are sufficient to carry on existing development activities we anticipate that G&A expenses will increase in the future as we continue to expand our operating activities.

## **Excess Lease Liability**

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 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 and occupancy assumptions are recognized as adjustments to the related liability with an offset to restructuring (gain)/loss in future periods.

In December 2012, we decided to expand our occupancy of the Bothell facility and revised our assumptions used to estimate the excess lease facility liability. As of December 31, 2012 the estimated value of the liability was \$4.6 million compared with \$7.0 million as of December 31, 2011. The change in the estimated liability resulted from \$0.7 million amortized into income through research and development expense and a reduction of the liability of \$1.7 million recorded in the fourth quarter of 2012 related to the updated assumptions related to occupancy of the Bothell facility.

## **Results of Operations**

Years Ended December 31, 2012, 2011 and 2010

### *Revenue*

Revenue for the year ended December 31, 2012 increased to \$20.1 million, from \$5.5 million for the year ended December 31, 2011. Revenue was \$13.6 million for the year ended December 31, 2010. The increase in 2012 compared to 2011 was due to an increase in revenue earned through our strategic collaboration with Teva, as a result of the clinical development activities associated with the AFFINITY trial which was initiated in August 2012. Revenue for 2012 includes recognition of \$18.3 million from the \$30.0 million upfront payment, as well as \$1.8 million earned through collaborative research. See Note 4 of Notes to Consolidated Financial Statements included elsewhere in the Annual Report on Form 10-K for further details on our collaboration with Teva. The decrease in 2011 compared to 2010 was due to lower reimbursement revenue earned through our strategic collaboration with Teva resulting from manufacturing costs being paid directly by Teva and lower clinical trial costs associated with the SATURN trial.

### *Research and Development Expenses*

R&D expenses for the year ended December 31, 2012 increased to \$40.0 million from \$21.6 million in the year ended December 31, 2011. R&D expenses for the year ended December 31, 2010 were \$18.5 million. The increase in 2012 as compared to 2011 was due primarily to higher clinical study expenses associated with the startup of the AFFINITY trial, increased patient enrollment in our clinical trial evaluating OGX-427 in combination with initial chemotherapy in patients with metastatic bladder cancer and associated manufacturing

costs and increased employee expenses, including stock-based compensation expense. These increases were partially offset by lower preclinical expenses. The increase in 2011 as compared to 2010 was due primarily to higher OGX-427 clinical trial and manufacturing costs, higher employee expenses, including stock based compensation. These increases were largely offset by lower custirsen manufacturing costs, as these costs are being paid directly by Teva. Certain costs for the custirsen phase 3 clinical trials are applied against the non-refundable upfront payments received from Teva in December 2009, while costs unassociated with the AFFINITY trial, such as manufacturing costs and compensation for work performed by our employees on the SYNERGY trial are reimbursed from Teva. We expect R&D expenses to increase as we further develop custirsen and our proprietary product candidates.

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

	Year ended December 31,		
	2012	2011	2010
Clinical development programs:			
custirsen .....	\$18,163	\$ 4,301	\$12,341
OGX-427 .....	\$12,971	\$ 9,597	\$ 821
Other research and development .....	\$ 8,814	\$ 7,655	\$ 5,321
Total research and development expenses .....	<b>\$39,948</b>	<b>\$21,553</b>	<b>\$18,483</b>

#### *General and Administrative Expenses*

G&A expenses for the years ended December 31, 2012, 2011 and 2010 increased to \$7.8 million from \$6.2 million and from \$5.8 million, respectively. The increase in 2012 as compared to 2011 was due primarily to higher employee expenses, including stock-based compensation expenses and infrastructure related costs. The increase in 2011 compared with 2010 was due primarily to higher employee expenses, including stock-based compensation expenses.

#### *Restructuring Gain (Expense)*

Restructuring gain for the year ended December 31, 2012 was \$1.7 million, as compared with zero in 2011. Restructuring expense was \$4.0 million in the year ended December 31, 2010. In December 2012, we decided to expand our occupancy of the Bothell facility and revised our assumptions used to estimate the value of the excess lease facility liability. This change in estimate resulted in a decrease in the value of our excess lease liability and a \$1.7 million restructuring gain recorded in the fourth quarter of 2012 to reflect this change in estimate. In September 2010, we revised our sublease income assumptions used to estimate the value of the excess lease facility liability. This change in estimate resulted in an increase in the value of our excess lease liability and a \$4.0 million restructuring expense was recorded in the third quarter of 2010 to reflect this change in estimate.

#### *Revaluation of Warrants*

We recorded a \$4.5 million gain on revaluation of the warrants for the year ended December 31, 2012, which is included on our consolidated statement of loss as a gain on warrants. A \$7.4 million gain on revaluation of the warrants was recorded for the year ended December 31, 2011. We revalue the warrants at each balance sheet date to fair value. If unexercised, the warrants will expire in October 2015.

#### *Interest Income*

Interest income for the year ended December 31, 2012, 2011 and 2010 increased to \$0.3 million from \$0.2 million and \$0.1 million, respectively. The increase in both years was due to higher average balances of interest-bearing securities.

### *Other Income*

Other income for the year ended December 31, 2012 increased to \$0.1 million, from \$6,000 for the years ended December 31, 2011 and 2010. The income earned in the year ended December 31, 2012 relates primarily to a gain from a barter transaction, while income earned in December 31, 2011 and 2010 relate to gains on foreign exchange.

### *Income Tax Recovery*

An income tax recovery of \$3.0 million was recorded in the second quarter of 2010, as we received approval from the Israeli Tax Authority, or ITA, for its request for a withholdings tax exemption on amounts received from Teva in relation to the collaboration. Under the Collaboration Agreement, Teva paid us \$50 million in upfront payments, of which \$20 million was for an upfront milestone payment and subject to possible withholding taxes by the ITA. Prior to the receipt of the approval, Teva was granted a temporary exemption for a transfer of \$17 million of the \$20 million upfront milestone payment. This temporary exemption was conditioned upon Teva's depositing \$3 million, which represented 15% of the upfront milestone payment paid according to the Collaboration Agreement, in a trust account in favor of the ITA until a final decision would be made by the ITA regarding the request. Accordingly, prior to the receipt of the approval, we had recorded a \$3 million liability recognizing this amount as an uncertain tax position. Following this approval from the ITA, this liability was released, and we recorded a \$3 million income tax recovery. See Note 4 of Notes to Consolidated Financial Statements for further details on our collaboration with Teva.

### **Liquidity and Capital Resources**

We have incurred an accumulated deficit of \$101.8 million through December 31, 2012, 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 year ended December 31, 2012, we generated \$20.1 million in collaboration revenue from the Collaboration Agreement with Teva.

In March 2012 we completed a public offering of 4,789,750 shares of our common stock at a purchase price of \$12.00 per share. The total net proceeds to us from the public offering and exercise of the overallotment option, after deducting underwriting discounts and commissions and other offering expenses from the sale of the shares, were approximately \$53.8 million.

All of our operations to date have been funded through the sale of our equity securities and payments received from Teva. As of December 31, 2012, our cash, cash equivalents, and short-term investments increased to \$75.4 million in the aggregate from \$64.9 million as of December 31, 2011.

Based on our current expectations, we believe our capital resources at December 31, 2012 will be sufficient to fund our currently planned operations into 2015. Our currently planned operations are set forth below under the heading "Operating Capital and Capital Expenditure Requirements."

### **Cash Flows**

#### *Operating Activities*

For the year ended December 31, 2012, cash used in operating activities increased to \$43.5 million, from \$20.3 million in the year ended December 31, 2011. The increase in cash used in operations is primarily attributable to our cuspisens phase 3 clinical trial costs associated with the AFFINITY trial, OGX-427 clinical trial and manufacturing costs and higher employee expenses.

For the year ended December 31, 2010, cash used in operating activities was \$26.8 million. The decrease in 2011 compared with 2010 was attributable primarily to payments made to Isis and UBC in the first quarter of 2010 resulting from the Collaboration Agreement with Teva and lower custirsen manufacturing costs, as these costs are now being paid directly by Teva, partially offset by higher OGX-427 clinical and manufacturing costs in 2011.

#### *Financing Activities*

For the year ended December 31, 2012, net cash provided by financing activities increased to \$54.2 million from \$0.2 million for the year ended December 31, 2011. Net cash provided by financing activities in for the year ended December 31, 2012 was primarily attributable to the net proceeds we received from the public offering of our common stock that closed in March 2012 as well as proceeds from stock option exercises. Net cash provided by financing activities in the year ended December 31, 2011 was the result of proceeds from stock option exercises.

Net cash provided by financing activities in the year ended December 31, 2010 was \$47.5 million, resulting from net proceeds we received from the issuance of common shares pursuant to the financing we completed in October 2010 and proceeds from stock option exercises.

#### *Investing Activities*

Net cash used in investing activities for the year ended December 31, 2012 was \$21.2 million compared with net cash provided by investing activities of \$25.1 million for the year ended December 31, 2011. Net cash used in investing activities in the year ended December 31, 2010 was \$59.1 million. Net cash used in and provided by investing activities in all years was 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 meet our anticipated cash needs, including for working capital purposes, capital expenditures, and various contractual obligations for at least the next 12 months. We also believe that our cash, cash equivalents, short-term investments and receivables from Teva will be sufficient to fund our currently planned operations into 2015 including:

- 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. SYNERGY patient enrollment was completed in the fourth quarter of 2012. Over 1,000 men have now been enrolled;
- completing patient enrollment in the AFFINITY trial, a phase 3 clinical trial that is evaluating a survival benefit for custirsen in combination with cabazitaxel as second-line chemotherapy in approximately 630 patients with CRPC, which was initiated in August 2012;
- enrolling patients in the ENSPIRIT trial, a phase 3 clinical trial that is evaluating a survival benefit for custirsen in combination with docetaxel as second-line chemotherapy in approximately 1,100 patients with NSCLC, which was initiated in September 2012 and is being conducted by our partner Teva;
- completing patient enrollment in the Borealis-1 Oncogenex-sponsored phase 2 clinical trial evaluating OGX-427 in combination with standard first-line chemotherapy in approximately 180 patients with metastatic bladder cancer called the Borealis-1 trial;
- initiating the Borealis-2 trial, an investigator-sponsored, randomized, controlled Phase 2 study evaluating OGX-427 in patients with advanced or metastatic bladder cancer who have disease progression following initial platinum-based chemotherapy first line treatment;

- completing the BL-01 trial, an investigator-sponsored phase 1 clinical trial evaluating OGX-427 when administered directly into the bladder in patients with superficial or muscle-invasive bladder cancer;
- completing the PR-01 trial, an investigator-sponsored phase 2 clinical trial evaluating OGX-427 treatment in combination with prednisone in patients with prostate cancer who have not received chemotherapy;
- enrolling patients in the Pacific trial, a phase 2 clinical trial evaluating OGX-427 treatment in combination with Zytiga in patients with prostate cancer; and
- initiating other additional clinical trials evaluating OGX-427; and
- initiating OGX-225 toxicology studies.

As of December 31, 2012, we had contributed \$30 million to the development of custirsen, as required under the Collaboration Agreement. Teva is required to fund all additional expenses under the Amended Clinical Development Plan. While we currently have sufficient operating capital to fund our currently planned operations through the expected release of final data from the SYNERGY trial, the final results from the AFFINITY and ENSPIRIT 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 were to conduct development activities with respect to our other product candidates beyond those development activities mentioned in the list above, including activities with respect to OGX-225, we would require additional funding to support such operations. If we need to extend our cash availability, or to conduct any such currently unplanned development activities, we would seek such necessary funding through the licensing or sale of certain of our product candidates, by executing a partnership or collaboration agreement, or through private or public offerings of our equity or debt.

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

- timing, costs and results of clinical trials, preclinical development and regulatory approvals;
- success of custirsen including 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.

### Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2012:

<u>(In thousands of U.S. dollars)</u>	<u>Total</u>	<u>1 year</u>	<u>2-3 years</u>	<u>4-5 years</u>	<u>Thereafter</u>
Bothell office operating lease (1) .....	\$11,576	2,180	\$4,559	\$4,837	—
Vancouver office operating lease (2) .....	188	107	81	—	—
UBC license maintenance fees (3) .....	40	8	16	16	—
Leased equipment .....	36	33	3	—	—
Total .....	\$11,840	2,328	\$4,659	\$4,853	—



- (1) This operating lease, which commenced in 2007, is for a 10-year term and includes two five-year option renewals.
- (2) This operating lease expires in 2014.
- (3) We are obligated to pay an annual license maintenance fee of CAD\$8,000 to UBC, which has been converted to US dollars based on the December 31, 2012 exchange rate of US\$1.00 = CAD\$0.9949, and rounded to the nearest \$1,000.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet financing arrangements at December 31, 2012.

### **Inflation**

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

### **Material Changes in Financial Condition**

<u>(in thousands)</u>	<u>December 31, 2012</u>	<u>December 31, 2011</u>
Total Assets .....	\$82,016	\$68,015
Total Liabilities .....	\$15,809	\$37,125
Total Equity .....	\$66,207	\$30,890

The increase in assets at December 31, 2012 from December 31, 2011 primarily relates to net proceeds received from the public offering of our common stock that closed in March 2012. The decrease in liabilities at December 31, 2012 from December 31, 2011 relates predominantly to the recognition of deferred collaboration revenue, revaluation of the warrant liability and amortization of restructuring-related liabilities. The increase in equity relates primarily to the issuance of common stock from the March 2012 public offering, partially offset by the net loss for the period.

### **Critical Accounting Policies and Estimates**

#### *Use of Estimates*

The preparation of consolidated financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and notes thereto. Actual results could differ from those estimates. Estimates and assumptions principally relate to estimates of the fair value of our warrant liability and excess lease facility liability, estimates of the initial fair value and forfeiture rates of stock options issued to employees and consultants and clinical trial and manufacturing accruals.

#### *Cash Equivalents*

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents, which we consider as available for sale and are carried at market value with unrealized gains and losses, if any, reported as accumulated other comprehensive income or loss, which is a separate component of shareholders' equity.

#### *Short-Term Investments*

Short-term investments consist of financial instruments purchased with an original maturity of greater than three months and less than one year. We consider our short-term investments as available-for-sale and they are carried at market value with unrealized gains and losses except other than temporary losses, if any, reported as accumulated other comprehensive income or loss, which is a separate component of shareholders' equity.

Realized gains and losses on the sale of these securities are recognized in net income or loss. The cost of investments sold is based on the specific identification method.

#### *Fair value of financial instruments*

The fair value of our cash equivalents and marketable securities is based on quoted market prices and trade data for comparable securities. We determine the fair value of its warrant liability based on the Black-Scholes pricing model and using considerable judgment, including estimating stock price volatility and expected warrant life. Other financial instruments including amounts receivable, accounts payable and accrued liabilities, are carried at cost, which we believe approximates fair value because of the short-term maturities of these instruments.

#### *Intellectual Property*

The costs of acquiring intellectual property rights to be used in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where we have not identified an alternative future use for the acquired rights, and are capitalized in situations where it has identified an alternative future use. No costs associated with acquiring intellectual property rights have been capitalized to date. Costs of maintaining intellectual property rights are expensed as incurred.

#### *Revenue Recognition*

Revenue recognized to date is attributable solely to the upfront payment we received in the fourth quarter of 2009 pursuant to our Collaboration Agreement with Teva, as well as cash reimbursements from Teva for certain costs incurred by us under the Clinical Development Plan we and Teva developed under which three phase 3 clinical trials have been initiated. Under the Collaboration Agreement, we and Teva share certain custirsen-related development costs. We have spent the required \$30 million in direct and indirect development costs, such as full-time equivalent (FTE) reimbursement for time incurred by our personnel for the benefit of the custirsen development plan. On a quarterly basis Teva will fund all other expenses under the Clinical Development Plan. Our policy is to account for these reimbursements as Collaboration Revenue. For a summary description of the Collaboration Agreement, see Note 4 to Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

The Collaboration Agreement contains multiple elements and deliverables, and requires evaluation pursuant to ASC 605-25, *Multiple-Element Arrangements*, or ASC 605-25. We evaluated the facts and circumstances of the Collaboration Agreement to determine whether it had obligations constituting deliverables under ASC 605-25. We concluded that it had multiple deliverables under the Collaboration Agreement, including deliverables relating to the grant of a technology license, and performance of manufacturing, regulatory and clinical development services in the U.S. and Canada, and estimated that the period in which we would perform those deliverables began in the fourth quarter of 2009 and will be completed in the fourth quarter of 2012. Because we were able to establish vendor specific objective evidence, or VSOE, of the fair value of the maintenance, regulatory, and clinical services, we concluded that these deliverables should be accounted as separate units of accounting under ASC 605-25. In establishing VSOE for the manufacturing, regulatory, and clinical development services, management relied on rates charged by other service providers providing similar development services.

We have now recognized the entire \$30 million allocated to the manufacturing, regulatory and clinical development services element as revenue on a proportional performance basis, as we incurred direct and indirect development costs under the Collaboration Agreement. As the direct and indirect costs associated with the Clinical Development plan were incurred and the associated revenue was recognized, the Current Deferred Collaboration Revenue balance was reduced to zero as at December 31, 2012.

Because management was not able to reliably estimate the fair value of the technology license, it used the residual value approach to determine the amount of revenue to recognize. Based on this approach, we recognized \$22 million in 2009 relating to this element.

Under the Collaboration Agreement, we are entitled to receive up to \$370 million upon the achievement of developmental and commercial milestones. Management evaluated the nature of the events triggering these contingent payments and concluded that these events constituted substantive milestones. This conclusion was based primarily on the facts that each triggering event represents a specific outcome that can be achieved only through successful performance by us of one or more of our deliverables, and that achievement of each triggering event was subject to inherent risk and uncertainty and would result in additional payments becoming due to us. Management concluded that each of these milestones was substantive, based primarily on the facts that the payments they trigger are non-refundable, that achievement of the milestone entails risk and was not reasonably assured at inception of the Collaboration Agreement, that substantial effort is required to complete each milestone, that the amount of each milestone payment is reasonable in relation to the value created in achieving the milestone, that a substantial amount of time is expected to pass between the upfront payment and the potential milestone payments, and that the milestone payments, once received, relate solely to past performance. Based on the foregoing, we will recognize any revenue from these milestone payments under the substantive milestone method in the period in which the underlying triggering event occurs.

Under the Collaboration Agreement, we are also entitled to receive percentage royalties on sales of custirsen ranging from the mid-teens to the mid-twenties. We will recognize any revenue from these events based on the revenue recognition criteria set forth in ASC 605, Revenue Recognition. Based on those criteria, we consider these potential payments to be contingent revenue, and will recognize them as revenue in the period in which the applicable contingency is resolved.

#### *Barter Transaction*

During 2012, we entered into a barter transaction, exchanging laboratory capital assets with a zero net book value for barter credits on future preclinical research services on OGX-427. Such credits are estimated to be redeemed over the one year period that the preclinical research services are expected to be rendered by the vendor.

The credits were recorded at the fair value of the laboratory capital assets exchanged, in accordance with ASC 845, "Nonmonetary Transactions" resulting in other income on this exchange of \$0.2 million which was recorded in our Consolidated Statement of Loss in the year ended December 31, 2012

#### *Property and Equipment*

Property and equipment assets are recorded at cost less accumulated depreciation. Depreciation expense on assets acquired under capital lease is recorded within depreciation expense. Depreciation is provided on a straight-line basis over the following periods:

Computer equipment	3 years
Furniture and fixtures	5 years
Leasehold improvements and equipment under capital lease	Over the term of the lease

#### *Income Taxes*

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the differences between the carrying values of assets and liabilities and their respective income tax bases and for operating losses and tax credit carry forwards. A valuation allowance is provided for the portion of deferred tax assets that is more likely than not to be unrealized. Deferred tax assets and liabilities are measured using the enacted tax rates and laws.

#### *Scientific Research and Development Tax Credits*

The benefits of tax credits for scientific research and development expenditures are recognized in the year the qualifying expenditure is made provided there is reasonable assurance of recoverability. The tax credits recorded

are based on management's estimates of amounts expected to be recovered and are subject to audit by taxation authorities. The non-refundable tax credit reduces the tax provision; however, no reduction to the tax provision has been recorded to date as we record a full valuation allowance. All qualifying expenditures are eligible for non-refundable tax credits only.

#### *Therapeutic Discovery Research Grants*

The Internal Revenue Service's therapeutic discovery tax credit program, created under the Patient Protection and Affordable Care Act of 2010, provides tax credits or grants representing up to 50 percent of eligible-qualified investments in therapeutic discovery projects during tax years 2009 and 2010. We applied for and received funds under this program to support the company's custirsen and OGX-427 development projects. The benefits of research grants under the Internal Revenue Service's therapeutic discovery tax credit program were recognized in the year the qualifying expenditure was approved. The research grants reduced R&D expenditures in 2010.

#### *Research and Development Costs*

Research and development costs are expensed as incurred, net of related refundable investment tax credits; with the exception of non-refundable advanced payments for goods or services to be used in future research and development, which are capitalized in accordance with ASC 730, "Research and Development" and included within Prepaid Expenses or Other Assets depending on when the assets will be utilized.

Clinical trial expenses are a component of research and development costs. These expenses include fees paid to clinical research organizations, clinical trial site costs and patient treatment costs. We use an accrual basis of accounting, based upon estimates of the amount of service completed. In the event payments differ from the amount of service completed, prepaid expense or accrued liabilities amounts are adjusted on the balance sheet. These expenses are based on estimates of the work performed under service agreements, milestones achieved, patient enrollment and experience with similar contracts. We monitor each of these factors to the extent possible and adjust estimates accordingly.

#### *Stock-Based Compensation*

Effective January 1, 2006, we adopted the fair value recognition provisions of the ASC 718, "Stock Compensation", using the modified prospective method with respect to options granted to employees and directors. Under this transition method, compensation cost is recognized in the financial statements beginning with the effective date for all share-based payments granted after January 1, 2006 and for all awards granted prior to but not yet vested as of January 1, 2006. The expense is amortized on a straight-line basis over the graded vesting period.

#### *Restricted Stock Awards*

We grant restricted stock awards that generally vest and are expensed over a four-year period. In 2012, we also granted restricted stock awards that vest in conjunction with certain performance conditions to certain executive officers and key employees. At each reporting date, we evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon management's assessment of accomplishing each performance provision or the occurrence of other events which may have caused the awards to accelerate and vest.

#### *Segment Information*

We follow the requirements of ASC 280, "Segment Reporting." We have one operating segment, dedicated to the development and commercialization of new cancer therapies, with operations located in Canada and the United States.

### *Comprehensive Income (Loss)*

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) consists of unrealized gains and losses on our available-for-sale marketable securities. We have reported the components of comprehensive loss in the statement of shareholders' equity.

### *Loss per Common Share*

Basic loss per common share is computed using the weighted average number of common shares outstanding during the period. Diluted loss per common share is computed in accordance with the treasury stock method. The effect of potentially issuable common shares from outstanding stock options is anti-dilutive for all periods presented.

### *Warrants*

We account for warrants pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, the warrants require the issuance of registered securities upon exercise and therefore do not sufficiently preclude an implied right to net cash settlement. We classify warrants on the consolidated balance sheet as a liability which is revalued at each balance sheet date subsequent to the initial issuance. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment, including estimating stock price volatility and expected warrant life. The computation of expected volatility was based on the historical volatility of shares of the Company's common stock for a period that coincides with the expected life of the warrants. A small change in the estimates used may have a relatively large change in the estimated valuation. We use the Black-Scholes pricing model to value the warrants. Changes in the fair market value of the warrants are reflected in the consolidated statement of loss as gain (loss) on revaluation of warrants.

### *Reclassifications*

Certain prior period balances have been reclassified to conform to the current period presentation. The expenses associated with adjustments to sublease income assumptions relating to our Bothell facility (please see Note 7 to Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K) were reclassified during the third quarter of 2010 from research and development expenses to restructuring expenses. This reclassification on the statements of loss was made in all prior periods presented for comparability purposes. This reclassification had no effect on net loss attributable to common shareholders, shareholders' equity, total assets and total liabilities, or the major categories of the cash flow statement.

### *Foreign currency translation*

Our functional and reporting currency is the U.S. dollar. Revenues and expenses denominated in other than U.S. dollars are translated at average monthly rates.

The functional currency of our other foreign operation is the U.S. dollar. For this foreign operation, assets and liabilities denominated in other than U.S. dollars are translated at the period-end rates for monetary assets and liabilities and historical rates for non-monetary assets and liabilities. Revenues and expenses denominated in other than U.S. dollars are translated at average monthly rates. Gains and losses from this translation are recognized in the current consolidated statement of operations.

### **Recently Adopted Accounting Policies**

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

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

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

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

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

### **Interest Rate Risk**

Interest rate risk is the risk that the fair values and future cash flows of financial instruments will fluctuate because of the changes in market interest rates. We invest our cash in a variety of financial instruments, primarily in short-term bank deposits, money market funds, and domestic and foreign commercial paper and government securities. These investments are denominated in U.S. dollars, and we monitor our exposure to interest rate changes 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. We have estimated the effect on our portfolio of a hypothetical increase in interest rates by one percent to be a reduction of \$0.3 million in the fair value of our investments as of December 31, 2012.

### **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 \$0.3 million for the year ended December 31, 2012.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of **OncoGenex Pharmaceuticals, Inc.**

We have audited the accompanying consolidated balance sheets of **OncoGenex Pharmaceuticals, Inc.** (the "Company") as of December 31, 2012 and 2011, and the related consolidated statements of loss and comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of **OncoGenex Pharmaceuticals, Inc.** at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), **OncoGenex Pharmaceuticals, Inc.**'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 7, 2013 expressed an unqualified opinion thereon.

Vancouver, Canada  
March 7, 2013

/s/ ERNST & YOUNG LLP  
Chartered Accountants



REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of **OncoGenex Pharmaceuticals, Inc.**

We have audited **OncoGenex Pharmaceuticals, Inc.**'s (the "Company") internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO" criteria). The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying "Management's Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, OncoGenex Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of the Company as of December 31, 2012 and 2011, and the related consolidated statements of loss and comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2012 and our report dated March 7, 2013 expressed an unqualified opinion thereon.

Vancouver, Canada  
March 7, 2013

/s/ ERNST & YOUNG LLP  
Chartered Accountants

**OncoGenex Pharmaceuticals, Inc.**

**Consolidated Balance Sheets**

(In thousands of U.S. dollars)

	<u>December 31,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
	<u>\$</u>	<u>\$</u>
<b>ASSETS</b>		
<b>Current</b>		
Cash and cash equivalents <i>[note 5]</i> .....	18,075	28,517
Short-term investments <i>[note 5]</i> .....	57,308	36,410
Interest receivable .....	327	363
Amounts receivable .....	714	449
Prepaid expenses .....	3,755	1,210
<b>Total current assets</b> .....	<b>80,179</b>	<b>66,949</b>
Restricted cash <i>[note 5]</i> .....	314	377
Property and equipment, net <i>[note 6]</i> .....	371	180
Other assets <i>[note 8]</i> .....	1,152	509
<b>Total assets</b> .....	<b>82,016</b>	<b>68,015</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current</b>		
Accounts payable and accrued liabilities .....	7,050	3,217
Deferred collaboration revenue <i>[note 4]</i> .....	—	18,271
Current portion of long-term obligations <i>[note 7]</i> .....	1,084	1,417
Warrant liability <i>[note 5 and note 11]</i> .....	3,422	7,881
<b>Total current liabilities</b> .....	<b>11,556</b>	<b>30,786</b>
Long-term obligations, less current portion <i>[note 7]</i> .....	4,253	6,339
<b>Total liabilities</b> .....	<b>15,809</b>	<b>37,125</b>
Commitments and contingencies <i>[note 13]</i>		
<b>Shareholders' equity:</b>		
Common shares <i>[note 11]</i> :		
\$0.001 par value 25,000,000 shares authorized and 14,656,916 and 9,749,819 issued and outstanding at December 31, 2012 and 2011, respectively .....	15	10
Additional paid-in capital .....	165,395	108,986
Accumulated deficit .....	(101,840)	(80,742)
Accumulated other comprehensive income .....	2,637	2,636
<b>Total shareholders' equity</b> .....	<b>66,207</b>	<b>30,890</b>
<b>Total liabilities and shareholders' equity</b> .....	<b>82,016</b>	<b>68,015</b>
<i>Subsequent events [note 15]</i>		

See accompanying notes.

**OncoGenex Pharmaceuticals, Inc.**

**Consolidated Statements of Loss and Comprehensive loss**

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

	<b>2012</b>	<b>Years Ended December 31, 2011</b>	<b>2010</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>COLLABORATION REVENUE (note 2 and 4)</b> .....	20,095	5,496	13,616
<b>EXPENSES</b>			
Research and development .....	39,948	21,553	18,483
General and administrative .....	7,791	6,230	5,840
Restructuring (gain) expense [note 7] .....	(1,657)	—	4,038
<b>Total Operating expenses</b> .....	<b>46,082</b>	<b>27,783</b>	<b>28,361</b>
<b>OTHER INCOME (EXPENSE)</b>			
Interest income .....	292	220	86
Other .....	138	6	6
Warrant issuance costs .....	—	—	(1,027)
Gain on warrants .....	4,459	7,388	96
<b>Total other income (expense)</b> .....	<b>4,889</b>	<b>7,614</b>	<b>(839)</b>
<b>Loss for the period before taxes</b> .....	<b>(21,098)</b>	<b>(14,673)</b>	<b>(15,584)</b>
Income tax recovery [note 10] .....	—	—	(3,000)
<b>Net loss attributable to common shareholders</b> .....	<b>(21,098)</b>	<b>(14,673)</b>	<b>(12,584)</b>
<b>OTHER COMPREHENSIVE INCOME (LOSS)</b>			
Net unrealized income (loss) on securities .....	1	31	(35)
<b>Total other comprehensive income (loss)</b> .....	<b>1</b>	<b>31</b>	<b>(35)</b>
<b>Total comprehensive loss attributable to common shareholders</b> .....	<b>(21,097)</b>	<b>(14,642)</b>	<b>(12,619)</b>
Basic and diluted net loss per common share [note 11[h]] .....	(1.56)	(1.51)	(1.79)
Weighted average number of common shares [note 11[h]] .....	13,522,723	9,729,340	7,030,903

See accompanying notes.

**OncoGenex Pharmaceuticals, Inc.**

**Consolidated Statements of Shareholders' Equity**

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

	<u>Number of Common Shares</u>	<u>Common Shares and Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated deficit</u>	<u>Total Shareholders' Equity</u>
<b>Balance, December 31, 2009</b> .....	<b><u>6,324,033</u></b>	<b><u>73,804</u></b>	<b><u>2,640</u></b>	<b><u>(53,485)</u></b>	<b><u>22,959</u></b>
Stock-based compensation expense .....		642			642
Shares issued in October 2010 financing ...	3,174,602	32,319			32,319
Stock option exercises .....	194,956	824			824
Net unrealized loss on marketable securities .....			(35)		(35)
Loss for the period .....				<u>(12,584)</u>	<u>(12,584)</u>
<b>Balance, December 31, 2010</b> .....	<b><u>9,693,591</u></b>	<b><u>107,589</u></b>	<b><u>2,605</u></b>	<b><u>(66,069)</u></b>	<b><u>44,125</u></b>
Stock-based compensation expense .....		1,188			1,188
Shares issued in October 2010 financing					
Stock option exercises .....	56,228	219			219
Net unrealized gain on marketable securities .....			31		31
Loss for the period .....				<u>(14,673)</u>	<u>(14,673)</u>
<b>Balance, December 31, 2011</b> .....	<b><u>9,749,819</u></b>	<b><u>108,996</u></b>	<b><u>2,636</u></b>	<b><u>(80,742)</u></b>	<b><u>30,890</u></b>
Stock-based compensation expense .....		2,175			2,175
Shares issued in March 2012 financing ....	4,789,750	53,777			53,777
Stock option exercises .....	117,347	462			462
Net unrealized gain on marketable securities .....			1		1
Loss for the period .....				<u>(21,098)</u>	<u>(21,098)</u>
<b>Balance, December 31, 2012</b> .....	<b><u>14,656,916</u></b>	<b><u>165,410</u></b>	<b><u>2,637</u></b>	<b><u>(101,840)</u></b>	<b><u>66,207</u></b>

**OncoGenex Pharmaceuticals, Inc.**  
**Consolidated Statements of Cash Flows**

(In thousands of U.S. dollars)

	2012 \$	Years ended December 31, 2011 \$	2010 \$
<b>OPERATING ACTIVITIES</b>			
Loss for the period	(21,098)	(14,673)	(12,584)
Adjustments to reconcile net loss to net cash used in operating activities:			
Warrant issuance costs	—	—	1,027
Gain on warrants	(4,459)	(7,388)	(96)
Depreciation	100	75	52
Stock-based compensation [note 11[c]]	2,175	1,188	642
Restructuring (gain) expense [note 7]	(1,657)	—	4,038
Gain on non-monetary transaction	(151)	—	—
Changes in operating assets and liabilities:			
Interest receivable	36	211	(494)
Amounts receivable	(265)	201	2,379
Restricted cash	63	125	(502)
Prepaid expenses	(2,394)	1,275	(1,763)
Other Assets	(643)	3	(4)
Accounts payable and accrued liabilities	3,833	2,324	(13,560)
Lease obligation [note 7]	(762)	(253)	(1,069)
Deferred collaboration revenue [note 4]	(18,271)	(3,351)	(4,906)
<b>Cash used in operating activities</b>	<b>(43,493)</b>	<b>(20,263)</b>	<b>(26,840)</b>
<b>FINANCING ACTIVITIES</b>			
Proceeds from exercise of stock options	462	219	824
Issuance of warrants, net of warrant issuance costs	—	—	14,338
Issuance of common shares, net of share issue costs	53,777	—	32,319
<b>Cash provided by financing activities</b>	<b>54,239</b>	<b>219</b>	<b>47,481</b>
<b>INVESTING ACTIVITIES</b>			
Purchase of investments	(110,443)	(75,147)	(93,018)
Proceeds from sale of investments	89,546	100,294	33,960
Purchase of property and equipment	(291)	(79)	(68)
<b>Cash provided by (used in) investing activities</b>	<b>(21,188)</b>	<b>25,068</b>	<b>(59,126)</b>
Effect of exchange rate changes on cash	—	(40)	(33)
Increase (decrease) in cash and cash equivalents during the period	(10,442)	4,984	(38,518)
Cash and cash equivalents, beginning of the period	28,517	23,533	62,051
<b>Cash and cash equivalents, end of the period</b>	<b>18,075</b>	<b>28,517</b>	<b>23,533</b>
<b>Supplemental cash flow information</b>			
Property and equipment acquired under lease obligation	—	89	—

See accompanying notes.

## **OncoGenex Pharmaceuticals, Inc.**

### **Notes to Consolidated Financial Statements**

#### **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 is headquartered in Bothell, Washington and has a subsidiary in Vancouver, British Columbia.

##### **Basis of Presentation**

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The consolidated financial statements include the accounts of OncoGenex Pharmaceuticals, Inc. and its wholly owned subsidiary OncoGenex Technologies Inc.

##### **Liquidity**

The Company has historically experienced recurring losses from operations that have generated an accumulated deficit of \$101.8 million through December 31, 2012. At December 31, 2012, the Company had cash, cash equivalents and short-term investments of \$75.4 million.

#### **2. ACCOUNTING POLICIES**

##### **Significant Accounting Policies**

###### *Use of Estimates*

The preparation of consolidated financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and notes thereto. Actual results could differ from these estimates. Estimates and assumptions principally relate to estimates of the fair value of its warrant liability and excess lease facility liability, the initial fair value and forfeiture rates of stock options issued to employees and consultants and clinical trial and manufacturing accruals.

###### *Cash Equivalents*

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents, which it considers as available for sale and carries at market value, with unrealized gains and losses, if any, reported as accumulated other comprehensive income or loss, which is a separate component of shareholders' equity.

###### *Short-Term Investments*

Short-term investments consist of financial instruments purchased with an original maturity of greater than three months and less than one year. The Company considers its short-term investments as available-for-sale and carries them at market value, with unrealized gains and losses except other than temporary losses, if any, reported as accumulated other comprehensive income or loss, which is a separate component of shareholders' equity. Realized gains and losses on the sale of these securities are recognized in net income or loss. The cost of investments sold is based on the specific identification method.

### *Fair value of financial instruments*

The fair value of the Company's cash equivalents and marketable securities is based on quoted market prices and trade data for comparable securities. The Company determines the fair value of its warrant liability based on the Black-Scholes pricing model and using considerable judgment, including estimating stock price volatility and expected warrant life. Other financial instruments including amounts receivable, accounts payable and accrued liabilities, are carried at cost, which the Company believes approximates fair value because of the short-term maturities of these instruments.

### *Intellectual Property*

The costs of acquiring intellectual property rights to be used in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where the Company has not identified an alternative future use for the acquired rights, and are capitalized in situations where it has identified an alternative future use. No costs associated with acquiring intellectual property rights have been capitalized to date. Costs of maintaining intellectual property rights are expensed as incurred.

### *Revenue Recognition*

Revenue recognized to date is attributable solely to the upfront payment the Company received in the fourth quarter of 2009 pursuant to its Collaboration Agreement with Teva, as well as cash reimbursements from Teva for certain costs incurred by the Company under the Clinical Development Plan the Company and Teva developed under which three phase 3 clinical trials are initiated. Under the Collaboration Agreement, the Company and Teva share certain ustirsen-related development costs. The Company has spent the required \$30 million in direct and indirect development costs, such as full-time equivalent (FTE) reimbursement for time incurred by its personnel for the benefit of the ustirsen development plan. On a quarterly basis Teva will reimburse all development expenses incurred in accordance with the Clinical Development Plan. The Company's policy is to account for these reimbursements as Collaboration Revenue. For a summary description of the Collaboration Agreement, see Note 4 to Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

The Collaboration Agreement contains multiple elements and deliverables, and requires evaluation pursuant to ASC 605-25, *Multiple-Element Arrangements*, or ASC 605-25. The Company evaluated the facts and circumstances of the Collaboration Agreement to determine whether it had obligations constituting deliverables under ASC 605-25. The Company concluded that it had multiple deliverables under the Collaboration Agreement, including deliverables relating to the grant of a technology license, and performance of manufacturing, regulatory and clinical development services in the U.S. and Canada, and estimated that the period in which it would perform those deliverables began in the fourth quarter of 2009 and will be completed in the fourth quarter of 2012. Because the Company has been able to establish vendor specific objective evidence, or VSOE, of the fair value of the manufacturing, regulatory, and clinical services, the Company concluded that these deliverables should be accounted as separate units of accounting under ASC 605-25. In establishing VSOE for the manufacturing, regulatory, and clinical development services, management relied on rates charged by other service providers providing similar development services.

The Company has now recognized the entire \$30 million allocated to the manufacturing, regulatory and clinical development services element as revenue on a proportional performance basis, as it incurred direct and indirect development costs under the Collaboration Agreement. As the direct and indirect costs associated with the Clinical Development plan were incurred and the associated revenue was recognized, the Current Deferred Collaboration Revenue balance was reduced to zero as at December 31, 2012.

Because the Company was not able to reliably estimate the fair value of the technology license, it used the residual value approach to determine the amount of revenue to recognize. Based on this approach, the Company recognized \$22 million in 2009 relating to this element.

Under the Collaboration Agreement, the Company is entitled to receive up to \$370 million upon the achievement of developmental and commercial milestones. The Company evaluated the nature of the events triggering these contingent payments and concluded that these events constituted substantive milestones. This conclusion was based primarily on the facts that each triggering event represents a specific outcome that can be achieved only through successful performance by the Company of one or more of its deliverables, and that achievement of each triggering event was subject to inherent risk and uncertainty and would result in additional payments becoming due to the it. The Company concluded that each of these milestones was substantive, based primarily on the facts that the payments they trigger are non-refundable, that achievement of the milestone entails risk and was not reasonably assured at inception of the Collaboration Agreement, that substantial effort is required to complete each milestone, that the amount of each milestone payment is reasonable in relation to the value created in achieving the milestone, that a substantial amount of time is expected to pass between the upfront payment and the potential milestone payments, and that the milestone payments, once received, relate solely to past performance. Based on the foregoing, the Company will recognize any revenue from these milestone payments under the substantive milestone method in the period in which the underlying triggering event occurs.

Under the Collaboration Agreement, the Company is also entitled to receive percentage royalties on sales of custirsen ranging from the mid-teens to the mid-twenties. The Company will recognize any revenue from these events based on the revenue recognition criteria set forth in ASC 605, Revenue Recognition. Based on those criteria, the Company considers these potential payments to be contingent revenue, and will recognize them as revenue in the period in which the applicable contingency is resolved.

*Barter Transactions*

During 2012, the Company entered into a barter transaction, exchanging laboratory capital assets with a zero net book value for barter credits on future preclinical research services on OGX-427. Such credits are estimated to be redeemed over the one year period that the preclinical research services are expected to be rendered by the vendor.

The credits were recorded at the fair value of the laboratory capital assets exchanged, in accordance with ASC 845, “Nonmonetary Transactions” resulting in other income of \$0.2 million which was recorded in the Company’s Consolidated Statement of Loss in the year ended December 31, 2012.

*Property and Equipment*

Property and equipment assets are recorded at cost less accumulated depreciation. Depreciation expense on assets acquired under capital lease is recorded within depreciation expense. Depreciation is provided on a straight-line basis over the following periods:

Computer equipment .....	3 years
Furniture and fixtures .....	5 years
Leasehold improvements and equipment under capital lease .....	Over the term of the lease

*Income Taxes*

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the differences between the carrying values of assets and liabilities and their respective income tax bases and for operating losses and tax credit carry forwards. A valuation allowance is provided for the portion of deferred tax assets that is more likely than not to be unrealized. Deferred tax assets and liabilities are measured using the enacted tax rates and laws.

*Scientific Research and Development Tax Credits*

The benefits of tax credits for scientific research and development expenditures are recognized in the year the qualifying expenditure is made provided there is reasonable assurance of recoverability. The tax credits recorded



are based on the Company's estimates of amounts expected to be recovered and are subject to audit by taxation authorities. The non-refundable tax credit reduces the tax provision; however, no reduction to the tax provision has been recorded to date as the Company records a full valuation allowance. All qualifying expenditures are eligible for non-refundable tax credits only.

#### *Therapeutic Discovery Research Grants*

The Internal Revenue Service's therapeutic discovery tax credit program, created under the Patient Protection and Affordable Care Act of 2010, provides tax credits or grants representing up to 50 percent of eligible qualified investments in therapeutic discovery projects during tax years 2009 and 2010. The Company applied for and received funds under this program to support cistus and OGX-427 development projects. The benefits of research grants under the Internal Revenue Service's therapeutic discovery tax credit program were recognized in the year the qualifying expenditure was approved. The research grants reduced R&D expenditures in 2010.

#### *Research and Development Costs*

Research and development costs are expensed as incurred, net of related refundable investment tax credits, with the exception of non-refundable advanced payments for goods or services to be used in future research and development, which are capitalized in accordance with ASC 730, "Research and Development" and included within Prepaid Expenses.

Clinical trial expenses are a component of research and development costs. These expenses include fees paid to contract research organizations and investigators and other service providers, which conduct certain product development activities on the Company's behalf. The Company uses an accrual basis of accounting, based upon estimates of the amount of service completed. In the event payments differ from the amount of service completed, prepaid expense or accrued liabilities amounts are adjusted on the balance sheet. These expenses are based on estimates of the work performed under service agreements, milestones achieved, patient enrollment and experience with similar contracts. The Company monitors each of these factors to the extent possible and adjusts estimates accordingly.

#### *Stock-Based Compensation*

Effective January 1, 2006, the Company adopted the fair value recognition provisions of the ASC 718, "Stock Compensation", using the modified prospective method with respect to options granted to employees and directors. Under this transition method, compensation cost is recognized in the financial statements beginning with the effective date for all share-based payments granted after January 1, 2006 and for all awards granted prior to but not yet vested as of January 1, 2006. The expense is amortized on a straight-line basis over the graded vesting period.

#### *Restricted Stock Awards*

The Company grants restricted stock awards that generally vest and are expensed over a four-year period. In 2012, the Company also granted restricted stock awards that vest in conjunction with certain performance conditions to certain executive officers and key employees. At each reporting date, the Company evaluates whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon the Company's assessment of accomplishing each performance provision or the occurrence of other events that may have caused the awards to accelerate and vest.

#### *Segment Information*

The Company follows the requirements of ASC 280, "Segment Reporting." The Company has one operating segment, dedicated to the development and commercialization of new cancer therapies, with operations located in Canada and the United States.

### *Comprehensive Income (Loss)*

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) consists of unrealized gains and losses on the Company's available-for-sale marketable securities. The Company has reported the components of comprehensive loss in the statement of shareholders' equity.

### *Loss per Common Share*

Basic loss per common share is computed using the weighted average number of common shares outstanding during the period. Diluted loss per common share is computed in accordance with the treasury stock method. The effect of potentially issuable common shares from outstanding stock options is anti-dilutive for all periods presented.

### *Warrants*

The Company accounts for warrants pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, the warrants require the issuance of registered securities upon exercise and therefore do not sufficiently preclude an implied right to net cash settlement. The Company classifies warrants on the consolidated balance sheet as a liability which is revalued at each balance sheet date subsequent to the initial issuance. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment, including estimating stock price volatility and expected warrant life. The computation of expected volatility was based on the historical volatility of shares of the Company's common stock for a period that coincides with the expected life of the warrants. A small change in the estimates used may have a relatively large change in the estimated valuation. The Company uses the Black-Scholes pricing model to value the warrants. Changes in the fair market value of the warrants are reflected in the consolidated statement of loss as gain (loss) on revaluation of warrants.

### *Reclassifications*

Certain prior period balances have been reclassified to conform to the current period presentation. The expenses associated with adjustments to sublease income assumptions relating to the Company's Bothell facility (please see Note 7 to Notes to Consolidated Financial Statements) were reclassified during the third quarter of 2010 from research and development expenses to restructuring expenses. This reclassification on the statements of loss was made in all prior periods presented for comparability purposes. This reclassification had no effect on net loss attributable to common shareholders, shareholders' equity, total assets and total liabilities, or the major categories of the cash flow statement.

### *Foreign Currency Translation*

The Company's functional and reporting currency is the U.S. dollar. Revenues and expenses denominated in other than U.S. dollars are translated at average monthly rates.

The functional currency of the Company's foreign subsidiary is the U.S. dollar. For this foreign operation, assets and liabilities denominated in other than U.S. dollars are translated at the period-end rates for monetary assets and liabilities and historical rates for non-monetary assets and liabilities. Revenues and expenses denominated in other than U.S. dollars are translated at average monthly rates. Gains and losses from this translation are recognized in the current consolidated statement of operations.

### **Recently Adopted Accounting Policies**

In December 2011, the FASB issued ASU No. 2011-12, "Comprehensive Income." This ASU defers the effective date for amendments to the presentation of reclassification of items out of accumulated other

comprehensive income in ASU No. 2011-05. The amendments are being made to allow the FASB time to redeliberate whether to present on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income for all periods presented. While the FASB is considering the operational concerns about the presentation requirements for reclassification adjustments and the needs of financial statement users for additional information about reclassification adjustments, entities should continue to report reclassifications out of accumulated other comprehensive income consistent with the presentation requirements in effect before Update 2011-05.

All other requirements in ASU 2011-05 are not affected by this ASU, including the requirement to report comprehensive income either in a single continuous financial statement or in two separate but consecutive financial statements. Public entities are required to apply these requirements for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company adopted this standard beginning in the quarter ended March 31, 2012. The adoption of this standard did not have a significant impact on the Company's financial position or results of operations.

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

### **3. FINANCIAL INSTRUMENTS AND RISK**

For certain of the Company's financial instruments, including cash and cash equivalents, amounts receivable and accounts payable carrying values approximate fair value due to their short-term nature. The Company's cash equivalents and short-term investments are recorded at fair value.

Financial risk is the risk to the Company's results of operations that arises from fluctuations in interest rates and foreign exchange rates and the degree of volatility of these rates as well as credit risk associated with the financial stability of the issuers of the financial instruments. Foreign exchange rate risk arises as a portion of the Company's investments which finance operations and a portion of the Company's expenses are denominated in other than U.S. dollars.

The Company invests its excess cash in accordance with investment guidelines, which limit the credit exposure to any one financial institution or corporation other than securities issued by the U.S. government. The Company only invests in A (or equivalent) rated securities with maturities of one year or less. These securities generally mature within one year or less and in some cases are not collateralized. At December 31, 2012 the average days to maturity of the Company's portfolio of cash equivalents and marketable securities was 121 days (December 31, 2011—131 days). The Company does not use derivative instruments to hedge against any of these financial risks.

### **4. COLLABORATION AGREEMENT**

On December 20, 2009, the Company, through its wholly-owned subsidiary, OncoGenex Technologies, entered into a Collaboration Agreement with Teva Pharmaceutical Industries Ltd., or Teva, for the development and global commercialization of custirsen (and related compounds), a pharmaceutical compound designed to inhibit the production of clusterin, a protein the Company believes is 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, acquired \$10 million of the Company's common stock at a premium under a separate Stock Purchase Agreement and agreed to pay up to \$370 million upon the achievement of developmental and commercial milestones and royalties at percentage rates ranging from the mid-teens to mid-twenties on net sales, depending on aggregate annual net sales of the Licensed Product. We did not receive any payments from Teva resulting from the achievement of developmental or commercial milestones or royalties in 2012, and we do not expect to receive any such payments from Teva in 2013.

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

In connection with the Collaboration Agreement and pursuant to the terms of agreements between the Company and Isis Pharmaceuticals, Inc., or Isis, relating to custirsen, the Company paid Isis \$10 million which was recorded as research and development expense in 2009. The Company also paid approximately \$0.3 million to the University of British Columbia, or UBC, pursuant to the terms of their license agreement relating to custirsen, which has been recorded as research and development expense in 2009. Pursuant to the terms of the agreements, 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 these 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. The Company did not make any royalty payments to Isis in 2012 and does not anticipate making any such payments to Isis in 2013. 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.

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

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

Teva will be responsible for conducting any other 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 is required to spend \$30 million in direct and indirect development costs such as full-time equivalent, or FTE, reimbursement for time incurred by OncoGenex personnel for the benefit of the custirsen development plan, such contribution to be funded by the upfront payment provided by Teva as an advanced reimbursement for the Company Development Expenses. As of December 31, 2012, The Company has spent the entire \$30 million related to the development of custirsen, 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 at its sole discretion upon three months' notice if notice is given prior to regulatory approval of a Licensed Product and upon six months' notice if notice is given after such regulatory approval. If Teva terminates the Collaboration Agreement for any reasons other than an adverse change in custirsen patent rights, safety issues or "futility" determination as previously described, it will remain responsible for paying for any remaining costs of all three phase 3 clinical trials, except for specified development expenses that are the responsibility of the Company. Either party may terminate the Collaboration Agreement for an uncured material breach by the other party, unless such breach is not curable, in which case the agreement may not be terminated unless the other party fails to use commercially reasonable efforts to prevent a similar subsequent breach. Either party also may terminate the Collaboration Agreement upon the bankruptcy of either party. If the Collaboration Agreement is terminated by 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 at its sole discretion, terminate the co-promotion option at its sole discretion if the option has not been 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 withholding 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 the Company's 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 its 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.

Revenue for the year ended December 31, 2012 was \$20.1 million, which consists of full recognition of the remaining balance 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 and certain other preclinical and clinical trial costs incurred by OncoGenex in the year ended December 31, 2012 that

are reimbursable from Teva. There was \$5.5 million in revenue in the year ended December 31, 2011 as a result of the Collaboration Agreement with Teva.

#### *Amendment to Isis and UBC License Agreements*

To facilitate the execution and performance of the Collaboration Agreement, the Company 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. The \$30 million in advanced reimbursement of development activities has been fully spent by OncoGenex prior to the third anniversary of the Collaboration Agreement between OncoGenex and Teva. As a result, the Company does not owe any payment to Isis related to the \$30 million advance reimbursement from Teva.

## **5. 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 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 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. These 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 large well established U.S. and Canadian financial institutions.

*U.S. Government and Agency Securities*

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

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

*Corporate and Other Debt*

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

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

<u>December 31, 2012</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Assets</b>				
Cash .....	\$ 2,440	\$ —	\$ —	\$ 2,440
Money market securities .....	15,949	—	—	15,949
Corporate bonds and commercial paper .....	—	57,308	—	\$57,308
<b>Total assets .....</b>	<b>\$18,389</b>	<b>\$57,308</b>	<b>\$ —</b>	<b>\$75,697</b>
<b>Liabilities</b>				
Warrants .....	\$ —	\$ —	\$3,422	\$ 3,422
 <u>December 31, 2011</u>	 <u>Level 1</u>	 <u>Level 2</u>	 <u>Level 3</u>	 <u>Total</u>
<b>Assets</b>				
Cash .....	\$ 5,725	\$ —	\$ —	\$ 5,725
Money market securities .....	21,163	—	—	21,163
Corporate bonds and commercial paper .....	—	38,416	—	38,416
<b>Total assets .....</b>	<b>\$26,888</b>	<b>\$38,416</b>	<b>\$ —</b>	<b>\$65,304</b>
<b>Liabilities</b>				
Warrants .....	\$ —	\$ —	\$7,881	\$ 7,881

Marketable securities consist of the following (in thousands):

<u>December 31, 2012</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Cash .....	\$ 2,440	\$—	\$—	\$ 2,440
Money market securities .....	15,635	—	—	15,635
Corporate bonds and commercial paper .....	—	—	—	—
<b>Total cash and cash equivalents .....</b>	<b>\$18,075</b>	<b>\$—</b>	<b>\$—</b>	<b>\$18,075</b>
Money market securities .....	314	—	—	314
<b>Total restricted cash .....</b>	<b>\$ 314</b>	<b>\$—</b>	<b>\$—</b>	<b>\$ 314</b>
U.S. government securities .....	—	—	—	—
U.S. agency securities .....	—	—	—	—
Corporate bonds and commercial paper .....	57,312	4	(8)	57,308
<b>Total short-term investments .....</b>	<b>\$57,312</b>	<b>\$ 4</b>	<b>\$ (8)</b>	<b>\$57,308</b>

<u>December 31, 2011</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Cash .....	\$ 5,725	\$—	\$—	\$ 5,725
Money market securities .....	20,786	—	—	20,786
Corporate bonds and commercial paper .....	2,006	—	—	2,006
<b>Total cash and cash equivalents .....</b>	<b>\$28,517</b>	<b>\$—</b>	<b>\$—</b>	<b>\$28,517</b>
Money market securities .....	377	—	—	377
<b>Total restricted cash .....</b>	<b>\$ 377</b>	<b>\$—</b>	<b>\$—</b>	<b>\$ 377</b>
Corporate bonds and commercial paper .....	36,414	7	(11)	36,410
<b>Total short-term investments .....</b>	<b>\$36,414</b>	<b>\$ 7</b>	<b>\$(11)</b>	<b>\$36,410</b>

The Company's gross realized gains and losses on sales of available-for-sale securities were not material for the years ended December 31, 2012 and 2011.

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.

All of the marketable securities held as of December 31, 2012 and December 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. The Company does not believe that there are any other than temporary impairments related to its investment in marketable securities at December 31, 2012, given the quality of the investment portfolio, its short-term nature, and subsequent proceeds collected on sale of securities that reached maturity.

As of December 31, 2012, the Company recorded a \$3.4 million 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 shares of the Company's common stock for a period that coincides with the expected life of the warrants. A small change in the estimates used may have a relatively large change in the estimated valuation.

The following table presents the changes in fair value of the Company's total Level 3 financial liabilities for the year ended December 31, 2012 (in thousands). Further, there have been no transfers of assets or liabilities to or from level 3.

	<u>Liability at December 31, 2011</u>	<u>Gain on warrants</u>	<u>Liability at December 31, 2012</u>
Warrant liability .....	\$7,881	\$4,459	\$3,422



## 6. PROPERTY AND EQUIPMENT

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

	Cost \$	Accumulated Depreciation \$	Net Book Value \$
<b>December 31, 2012</b>			
Computer equipment .....	489	366	123
Furniture and fixtures .....	154	125	29
Leasehold improvements .....	55	49	6
Equipment under capital lease .....	106	64	42
Construction in Progress .....	171	—	171
<b>Total property and equipment .....</b>	<b>975</b>	<b>604</b>	<b>371</b>
<b>December 31, 2011</b>			
Computer equipment .....	369	311	58
Furniture and fixtures .....	154	113	41
Leasehold improvements .....	55	46	9
Equipment under capital lease .....	106	34	72
Construction in Progress .....	—	—	—
<b>Total property and equipment .....</b>	<b>684</b>	<b>504</b>	<b>180</b>

## 7. EXCESS LEASE LIABILITY

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 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 and occupancy assumptions are recognized as adjustments to the related liability with an offset to restructuring (gain)/loss in future periods.

In December 2012, the Company decided to expand its occupancy of the Bothell facility and revised its assumptions used to estimate the excess lease facility liability. As of December 31, 2012 the estimated value of the liability was \$4.6 million compared with \$7.0 million as of December 31, 2011. The change in the estimated liability resulted from \$0.7 million amortized into income through research and development expense and a reduction of the liability of \$1.7 million recorded in the fourth quarter as a result of the updated assumptions related to occupancy of the Bothell facility.

<u>(In thousands)</u>	<u>Liability at December 31, 2011</u>	<u>Amortization of excess lease facility</u>	<u>Reduction of Liability</u>	<u>Liability at December 31, 2012</u>
Current portion of excess lease facility .....	\$1,388	\$ 41	\$ (379)	\$1,050
Long-term portion of excess lease facility .....	5,651	(837)	(1,278)	3,536
<b>Total .....</b>	<b>\$7,039</b>	<b>\$(796)</b>	<b>\$(1,657)</b>	<b>\$4,586</b>

## 8. OTHER ASSETS

Other assets include prepaid amounts related to clinical trials that will not be utilized in the next 12 months and deposits paid for office space in accordance with the terms of the operating lease agreements.

## 9. BARTER TRANSACTION

During 2012, the Company entered into a barter transaction, exchanging laboratory capital assets with a zero net book value for barter credits on future preclinical research services on OGX-427. Such credits are to be redeemed over a 1 year period, beginning September 2012, for preclinical research services to be rendered by the vendor.

The credits were recorded at the fair value of the laboratory capital assets exchanged, in accordance with ASC 845, "Nonmonetary Transactions" resulting in other income on this exchange of \$0.2 million, which was recorded in the Company's Consolidated Statement of Loss, in 2012.

## 10. INCOME TAX

[a] The reconciliation of income tax attributable to operations computed at the statutory tax rate to income tax expense is as follows. OncoGenex Technologies, a Canadian corporation, which is subject to combined Canadian federal and provincial statutory tax rates for December 31, 2012, 2011, and 2010 of 25.0%, 26.5%, and 28.5%, respectively. Following the reverse takeover by OncoGenex Technologies of Sonus Pharmaceuticals, Inc. (which subsequently changed its name to OncoGenex Pharmaceuticals, Inc.) in 2008, OncoGenex Technologies became a wholly owned subsidiary of the Company, which is a Delaware incorporated company subject to US Federal Statutory rates of 34% for all three years presented.

For the purposes of estimating the tax rate in effect at the time that deferred tax assets and liabilities are expected to reverse, management uses the furthest out available future tax rate in the applicable jurisdictions. For the years ended December 31, 2012, 2011 and 2010 the future Canadian enacted rates the Company used were 25%, 25%, and 25%, respectively, while for the US the future enacted rate the Company used was 34% for all three periods presented.

<u>(In thousands)</u>	<u>2012</u>	<u>2011</u>	<u>2010</u>
	<u>\$</u>	<u>\$</u>	<u>\$</u>
Income taxes at statutory rates (at a rate of 34% for all periods presented) .....	(7,152)	(4,989)	(5,298)
Expenses not deducted for tax purposes .....	(1,212)	(2,366)	425
Effect of tax rate changes on deferred tax assets and liabilities .....	—	—	—
Effect of foreign tax (Canadian) rate changes on deferred tax assets and liabilities .....	1,672	1,326	614
Reduction in benefit of operating losses .....	15	16	1,939
Reduction in the benefit of other tax attributes .....	551	468	394
Impact of withholding tax .....	—	—	(3,000)
Foreign exchange effect on valuation allowance .....	—	—	(534)
Investment tax credits .....	(485)	(588)	(252)
Research and development tax credits .....	—	—	—
Change in valuation allowance .....	6,324	6,175	2,620
Part VI.I tax deduction .....	—	—	—
Book to tax return adjustments .....	287	(42)	92
Other .....	—	—	—
Income tax expense .....	<u>—</u>	<u>—</u>	<u>(3,000)</u>

[b] At December 31, 2012, the Company has investment tax credits of \$2.0 million (2011—\$1.3 million) available to reduce future Canadian income taxes otherwise payable. The Company also has non-capital loss carryforwards of \$58.3 million (2011—\$41.1 million) available to offset future taxable income in Canada and federal net operating loss carryforwards of \$141.5 million (2011 \$133.1 million) to offset future taxable income in the United States.

Under Section 382 of the Internal Revenue Code of 1986, substantial changes in the Company's ownership may limit the amount of net operating loss carryforwards and development tax credit carryforwards that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating losses and tax credits before they expire. The Company has not completed a Section 382 study at this time to determine the impact ownership changes have had on its carryforwards. In each period since the Company's inception, it has recorded a valuation allowance for the full amount of its deferred tax asset, as the realization of the deferred tax asset is uncertain.

As a result, the Company had not recognized any federal or state income tax benefit in its statement of operations. The initial public offering of common stock by the Company in 1995 caused an ownership change pursuant to applicable regulations in effect under the Internal Revenue Code of 1986. Therefore, the Company's use of losses incurred through the date of ownership change will be limited during the carryforward period and may result in the expiration of net operating loss carryforwards in the United States before utilization.

The investment tax credits and non-capital losses and net operating losses for income tax purposes expire as follows (in thousands):

	Investment Tax Credits \$	Net Operating Losses \$	Non-capital Losses \$
2011	—	47	—
2012	—	44	—
2013	—	—	—
2014	—	—	1,707
2015	—	—	—
2016	—	—	—
2017	—	—	—
2018	—	10,795	—
2019	—	32	—
2020	—	2,745	—
2021	2	400	—
2022	2	11,766	—
2023	1	10,785	—
2024	—	16,814	—
2025	—	2,062	7,407
2026	244	27,157	4,982
2027	71	22,225	5,650
2028	148	12,648	2,410
2029	317	4,357	—
2030	346	5,034	6,124
2031	486	6,210	12,782
2032	364	8,396	17,276
	<u>1,981</u>	<u>141,517</u>	<u>58,338</u>

In addition, the Company has unclaimed tax deductions of approximately \$12.9 million related to scientific research and experimental development expenditures available to carry forward indefinitely to reduce Canadian taxable income of future years. The Company also has research and development tax credits of \$1.7 million available to reduce future taxes payable in the United States. The research and development tax credits expire between 2013 and 2028.

[c] Significant components of the Company's deferred tax assets as of December 31 are shown below (in thousands):

<u>Deferred tax assets:</u>	<u>2012</u>	<u>2011</u>
	\$	\$
Tax basis in excess of book value of assets .....	930	1,181
Non-capital loss carryforwards .....	62,489	55,499
Research and development deductions and credits .....	6,212	5,672
Share issue costs .....	—	42
Stock options .....	2,077	1,632
Capital loss carryforward .....	51	51
Restructuring liability .....	1,799	2,611
Foreign tax credit .....	—	—
Other .....	51	211
<b>Total deferred tax assets .....</b>	<b>73,609</b>	<b>66,899</b>
Valuation allowance .....	(73,609)	(66,899)

The potential income tax benefits relating to these deferred tax assets have not been recognized in the accounts as their realization did not meet the requirements of "more likely than not" under the liability method of tax allocation. Accordingly, a valuation allowance has been recorded and no deferred tax assets have been recognized as at December 31, 2012 and 2011.

[d] Under ASC 740, the benefit of an uncertain tax position that is more likely than not of being sustained upon audit by the relevant taxing authority must be recognized at the largest amount that is more likely than not to be sustained. No portion of the benefit of an uncertain tax position may be recognized if the position has less than a 50% likelihood of being sustained.

A reconciliation of the unrecognized tax benefits of uncertain tax positions for the year ended December 31, 2012 is as follows:

(in thousands)	<u>December 31,</u>
	<u>2012</u>
	\$
Balance as of December 31, 2010 .....	2,007
Additions based on tax positions related to the current year .....	87
Deductions based on tax positions related to the current year .....	(158)
Balance as of December 31, 2011 .....	1,936
Additions based on tax positions related to the current year .....	55
Deductions based on tax positions related to the current year .....	(24)
Balance as of December 31, 2012 .....	1,967

As of December 31, 2012, unrecognized benefits of approximately \$2.0 million, if recognized, would affect the Company's effective tax rate, and would reduce the Company's deferred tax assets. See note 4 for discussion of the Company's assessment of potential withholdings taxes owed to the ITA resulting from the Collaboration Agreement.

The Company's accounting policy is to treat interest and penalties relating to unrecognized tax benefits as a component of income taxes. As of December 31, 2012 and December 31, 2011 the Company had no accrued interest and penalties related to income taxes.

The Company is subject to taxes in Canada and the U.S. until the applicable statute of limitations expires. Tax audits by their very nature are often complex and can require several years to complete.

<u>Tax Jurisdiction</u>	<u>Years open to examination</u>
Canada .....	2006 to 2012
US .....	2006 to 2012

## 11. COMMON STOCK

### [a] Authorized

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

### [b] Issued and outstanding shares

#### *October 2010 Public Offering*

On October 22, 2010, the Company completed a public offering of 3,174,602 units, with each unit consisting of one share of the Company's common stock and one-half (1/2) of one warrant, at a purchase price of \$15.75 per unit for an aggregate offering amount of \$50 million.

Each whole warrant is exercisable at any time on or after the date of issuance until the fifth anniversary of the date of issuance at an exercise price of \$20, and includes a cashless exercise feature. The Company accounts for warrants issued in October 2010 under the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, the registered warrants require the issuance of registered securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. The Company classifies warrants on the accompanying consolidated balance sheet as a liability which is revalued at each balance sheet date subsequent to the initial issuance. The Company uses the Black-Scholes pricing model to value the warrants. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment. On the date of issuance, the Black-Scholes value of the warrant was based on an assumed risk-free rate of 1.17%, volatility of 75% and an expected life of 5 years. Changes in the fair market value of the warrants are reflected in the consolidated statement of loss as gain (loss) on warrants.

The net proceeds to the Company, after underwriting discounts and commissions and other offering expenses, from the sale of the units were \$46.7 million, of which \$32.3 million was allocated to common shares and included in additional paid-in capital and \$15.4 million was allocated to warrant liability. \$1 million of underwriting discounts and commissions and other offering expenses allocated to the value of warrants was expensed in warrant issuance expense on the Company's consolidated statement of loss.

At December 31, 2012, 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 years ended December 31, 2012 or 2011.

#### *March 2012 Public Offering*

On March 21, 2012, the Company completed a public offering of 4,165,000 shares of its common stock at a purchase price of \$12.00 per share. Pursuant to an overallotment option exercised on March 27, 2012 by the underwriters in the offering, an additional offering of 624,750 shares of the Company's common stock were issued at a price of \$12.00 per share. The total gross offering amount from the public offering and exercise of the overallotment option was approximately \$57.5 million. The total net proceeds to the Company from the public offering and exercise of the overallotment option, after deducting underwriting discounts and commissions and other offering expenses from the sale of the shares were approximately \$53.8 million.

### *Stock Option Exercises*

During the years ended December 31, 2012, 2011 and 2010 the Company issued 117,347, 56,228 and 194,956 common shares upon exercise of stock options, respectively. The Company issues new shares to satisfy stock option exercises.

#### [c] Stock options

As at December 31, 2012 the Company has reserved, pursuant to various plans, 1,265,857 common shares for issuance upon exercise of stock options by employees, directors, officers and consultants of the Company, of which 804,781 are reserved for options currently outstanding, and 461,076 are available for future option grants (December 31, 2011—799,624).

### *2010 Performance Incentive Plan*

At the 2010 Annual Meeting of Stockholders of the Company held on May 26, 2011, stockholders of the Company approved an amendment to the Company's 2010 Performance Incentive Plan. As a result of this amendment, the 2010 Plan was amended to provide for an increase in the total shares of common stock available for issuance under the 2010 Plan from 450,000 to 1,050,000. Under the plan, the Company may grant options to purchase common shares or restricted stock units in the Company to employees, directors, officers and consultants of the Company. The exercise price of the options is determined by the Board but generally will be at least equal to the fair value of the common shares at the grant date. The options vest in accordance with terms as determined by the Board, typically over three to four years for options issued to employees and consultants, and over one to three years for members of the Board of Directors. The expiry date for each option is set by the Board with a maximum expiry date of ten years from the date of grant.

Options remain outstanding under a number of share option plans that had been approved by shareholders prior to the approval of the 2010 Performance Incentive Plan: (a) the Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan – 1991 (1991 Plan), (b) the 1999 Nonqualified Stock Incentive Plan (1999 Plan), (c) the 2000 Stock Incentive Plan (2000 Plan), (d) the 2007 Performance Incentive Plan (2007 Plan) and (e) the OncoGenex Technologies Inc. Stock Option Plan (OncoGenex Technologies Plan).

### *ASC 718 Compensation—Stock Compensation*

The Company recognizes expense related to the fair value of its stock-based compensation awards using the provisions of ASC 718. The Company uses the Black-Scholes option pricing model as the most appropriate fair value method for its awards and recognizes compensation expense for stock options on a straight-line basis over the requisite service period. In valuing its options using the Black-Scholes option pricing model, the Company makes assumptions about risk-free interest rates, dividend yields, volatility and weighted average expected lives, including estimated forfeiture rates of the options.

The expected life was calculated based on the simplified method as permitted by the SEC's Staff Accounting Bulletin 110, *Share-Based Payment*. The Company considers the use of the simplified method appropriate because of the lack of sufficient historical exercise data following the reverse takeover of Sonus. As the Company has concluded that it now has sufficient historical share price data to estimate the volatility of the Company's stock options the expected volatility of options granted in 2012 was calculated based on the historical volatility of the shares of the Company's common stock. The computation of expected volatility of options granted prior to 2012 was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. The risk-free interest rate is based on a U.S. Treasury instrument whose term is consistent with the expected life of the stock options. In addition to the assumptions above, as required under ASC 718, management made an estimate of expected forfeitures and is recognizing compensation costs only for those equity awards expected to vest. Forfeiture rates are estimated using historical actual forfeiture rate that resulted over the estimated life of the option grant for options granted as of the

beginning of the forfeiture measurement period. These rates are adjusted on a quarterly basis and any change in compensation expense is recognized in the period of the change. The Company has never paid or declared dividends on its common stock and does not expect to pay cash dividends in the foreseeable future.

The estimated fair value of stock options granted in the respective periods was determined using the Black-Scholes option pricing model using the following weighted average assumptions:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Risk-free interest rates .....	0.96%	1.70%	2.73%
Expected dividend yield .....	0%	0%	0%
Expected life .....	5.9 years	5.9 years	6.8 years
Expected volatility .....	95%	76%	75%

The weighted average fair value of stock options granted during the year ended December 31, 2012, 2011 and 2010 was \$9.86, \$10.70 and \$11.08 per share, respectively.

Total stock-based compensation expense included in the Company's statements of loss for the years ended December 31, 2012, 2011 and 2010 was \$2.2 million, \$1.2 million and \$0.6 million respectively.

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

	<u>Years ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	<u>\$</u>	<u>\$</u>	<u>\$</u>
Research and development .....	899	509	331
General and administrative .....	1,276	679	311
Total stock-based compensation .....	2,175	1,188	642

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.

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

	Number of Optioned Common Shares #	Weighted Average Exercise Price \$
<b>Balance, December 31, 2009</b> .....	<b>802,871</b>	<b>6.95</b>
Option grants .....	170,872	15.87
Option cancellations .....	(7,311)	104.91
Option exercises .....	(194,956)	4.22
Option forfeited .....	(26,563)	7.35
<b>Balance, December 31, 2010</b> .....	<b>744,913</b>	<b>8.74</b>
Option grants .....	101,600	15.72
Option cancellations .....	(22,986)	13.95
Option exercises .....	(56,228)	3.88
Option forfeited .....	(971)	41.91
<b>Balance, December 31, 2011</b> .....	<b>766,328</b>	<b>9.82</b>
Option grants .....	172,650	12.97
Option cancellations .....	(12,309)	9.10
Option exercises .....	(117,347)	3.94
Option forfeited .....	(4,541)	15.26
<b>Balance, December 31, 2012</b> .....	<b>804,781</b>	<b>11.34</b>

The following table summarizes information about stock options outstanding at December 31, 2012 regarding the number of ordinary shares issuable upon: (1) outstanding options and (2) vested options.

**(1) Number of ordinary shares issuable upon exercise of outstanding options**

<u>Exercise Prices</u>	<u>Number of Options</u>	<u>Weighted- Average Exercise Price \$</u>	<u>Weighted- Average Remaining Contractual Life (in years)</u>
\$2.69—\$2.85 .....	34,000	2.69	2.82
\$2.86—\$3.56 .....	232,600	3.00	2.98
\$3.57—\$12.48 .....	68,840	10.12	6.85
\$12.49—\$12.81 .....	22,000	12.56	9.46
\$12.82—\$13.06 .....	118,750	13.00	9.35
\$13.07—\$15.74 .....	43,176	14.26	8.46
\$15.75—\$16.40 .....	121,700	15.97	7.95
\$16.41—\$17.67 .....	48,500	16.92	8.14
\$17.68—\$21.67 .....	39,115	18.95	5.24
\$21.68—\$22.28 .....	76,100	22.28	6.90
<b>Total</b> .....	<b>804,781</b>	<b>11.34</b>	<b>6.26</b>



(2) Number of ordinary shares issuable upon exercise of vested options

<u>Exercise Prices</u>	<u>Number of Options</u>	<u>Weighted-Average Exercise Price</u> \$	<u>Weighted-Average Remaining Contractual Life</u> (in years)
\$2.69—\$2.85 .....	34,000	2.69	2.82
\$2.86—\$3.56 .....	232,600	3.00	2.98
\$3.57—\$12.48 .....	37,839	8.56	5.10
\$12.49—\$12.81 .....	42	12.61	9.91
\$12.82—\$13.06 .....	27,214	13.00	9.35
\$13.23—\$15.74 .....	20,111	14.48	7.75
\$15.75—\$16.40 .....	60,850	15.97	7.95
\$16.41—\$17.67 .....	21,906	16.91	8.12
\$17.68—\$21.67 .....	38,327	18.90	5.26
\$21.68—\$22.28 .....	57,076	22.28	6.90
<b>Total .....</b>	<b>529,965</b>	<b>9.62</b>	<b>5.00</b>

As at December 31, 2012 the total unrecognized compensation expense related to stock options granted was \$2.7 million, which is expected to be recognized into expense over a period of approximately 2.4 years.

The estimated grant date fair value of stock options vested during the years ended December 31, 2012, 2011 and 2010 was \$1.6 million, \$1.1 million and \$0.7 million respectively.

The aggregate intrinsic value of options exercised was calculated as the difference between the exercise price of the stock options and the fair value of the underlying common stock as of the date of exercise. The aggregate intrinsic value of options exercised for the years ended December 31, 2012, 2011 and 2010 was \$1.2 million, \$0.6 million, and \$2.4 million, respectively. At December 31, 2012, the aggregate intrinsic value of the outstanding options was \$2.9 million and the aggregate intrinsic value of the exercisable options was \$2.9 million.

[d] Restricted Stock Awards

The Company grants restricted stock awards that generally vest and are expensed over a four year period. In 2012, the Company also granted restricted stock awards that vest in conjunction with certain performance conditions to certain executive officers and key employees. At each reporting date, the Company is required to evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon the Company's assessment of accomplishing each performance provision. For the year ended December 31, 2012, \$0.6 million was recognized related to these awards. No restricted stock awards were granted during 2011.

The following table summarizes the Company's restricted stock award activity during the years ended December 31, 2012 and 2011:

	2012		2011	
	Stock Awards #	Weighted-Average Grant Date Fair Value \$	Stock Awards #	Weighted-Average Grant Date Fair Value \$
<b>Outstanding January 1</b>				
Granted .....	180,085	13.01	—	—
Vested .....	—	—	—	—
Forfeited and expired .....	(8,000)	13.00	—	—
<b>Outstanding December 31</b> .....	<b>172,085</b>	<b>13.01</b>	<b>—</b>	<b>—</b>

As of December 31, 2012, the Company had approximately \$1.4 million in total unrecognized compensation expense related to the Company's restricted stock awards which is to be recognized over a weighted-average period of approximately 3.0 years

[e] Stock Warrants

At December 31, 2012, 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 years ended December 31, 2010 or December 31, 2011.

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 year end balance sheet dates:

	Years ended December 31,		
	2012	2011	2010
Risk-free interest rates .....	0.34%	0.55%	2.01%
Expected dividend yield .....	0%	0%	0%
Expected life .....	2.8 years	3.8 years	4.8 years
Expected volatility .....	45%	76%	75%

[f] Shareholder Rights Plan

The Company has a Shareholder Rights Plan which was adopted in July 1996 and subsequently amended in July 2002, October 2005, August 2006, and May 2008 (the "Rights Plan"). Under the Plan the Company's Board of Directors declared a dividend of one Preferred Stock Purchase Right (Right) for each outstanding common share of the Company. Subject to the Rights Plan, each Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock at an exercise price of \$140, subject to adjustment. These Rights provide the holders with the right to purchase, in the event a person or group acquires 15% or more of the Company's common stock, additional shares of the Company's common stock having a market value equal to two times the exercise price of the Right. Pursuant to the Rights Plan, the one-for-eighteen reverse stock split caused a proportionate adjustment of the number of Rights associated with each share of common stock. Currently, eighteen (18) Rights are associated with each share of common stock.

[g] 401(k) Plan

The Company maintains a 401(k) plan in which it provided a specified percentage match on employee contributions. Following the Arrangement, the Board of Directors of OncoGenex amended and restated the

401(k) plan whereas securities of the Company are no longer offered as an investment option. This amendment prohibits the inclusion of OncoGenex shares in the 401(k) plan, as well as any match of Company shares to employee contributions. No shares of the Company were issued subsequent to the Arrangement, and as such no related expense was incurred.

[h] Loss per common share

The following table presents the computation of basic and diluted net loss attributable to common shareholders per share:

(in thousands except shares and per share amounts)	Years ended December 31,		
	2012	2011	2010
<b>Numerator</b>			
Net loss attributable to common shareholders . . . .	\$ 21,099	\$ 14,673	\$ 12,584
<b>Denominator</b>			
Weighted average number of common shares outstanding . . . . .	13,522,723	9,729,340	7,030,903
<b>Basic and diluted net loss per common share . . .</b>	<b>\$ 1.56</b>	<b>\$ 1.51</b>	<b>\$ 1.79</b>

As of December 31, 2012, 2011 and 2010 a total of 2.6 million, 2.4 million and 2.3 million options, restricted stock units 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.

**12. RELATED PARTY TRANSACTIONS**

There were no related party transactions during the periods ended December 31, 2012, 2011 or 2010, and no amounts were included in accounts payable and accrued liabilities as at December 31, 2012 and 2011. All transactions were recorded at their exchange amounts.

**13. COMMITMENTS AND CONTINGENCIES**

*Teva Pharmaceutical Industries Ltd.*

In December 2009, OncoGenex Pharmaceuticals, Inc., through its wholly-owned subsidiary, OncoGenex Technologies, entered into a Collaboration Agreement with Teva for the development and global commercialization of custirsen (and related compounds). Under the Collaboration Agreement, Teva made upfront payments in the aggregate amount of \$50 million, and may make additional payments up to \$370 million upon the achievement of developmental and commercial milestones and royalties at percentage rates ranging from the mid-teens to mid-twenties on net sales. Teva also acquired \$10 million of the Company’s common stock at a premium under a separate Stock Purchase Agreement. The Company was required to contribute \$30 million in direct and indirect costs towards the Clinical Development Plan. As of December 31, 2012, the full amount of the of \$30.0 million in direct and indirect costs have been incurred by OncoGenex. Teva will fund all other expenses under the Clinical Development Plan.

Pursuant to the Collaboration Agreement, the Company agreed to collaborate with Teva in the development and global commercialization of custirsen. Teva received the exclusive worldwide right and license to develop and commercialize products containing custirsen and related compounds (the “Licensed Products”). The Company has an option to co-promote custirsen in the United States and Canada.

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

*Isis Pharmaceuticals Inc. and University of British Columbia*

The Company is obligated to pay milestone payments of up to CAD \$1.6 million and \$7.75 million pursuant to license agreements with the UBC and Isis, respectively, upon the achievement of specified product development milestones related to OGX-427 and OGX-225 and low to mid-single digit royalties on future product sales.

In addition, the Company is required to pay to Isis 30% of all non-royalty revenue (defined to mean revenue not based on net sales of products) it receives. Isis has disclosed in its SEC filings that it is entitled to receive 30% of the up to \$370 million in milestone payments the Company may receive from Teva as part of the Collaboration Agreement; however, the Company believes that certain of the milestone payments related to sales targets may qualify as royalty revenue (defined to mean revenue based on net sales of products), and therefore be subject to the lesser payment obligations. No assurance can be provided that the Company will be entitled to receive these milestone payments or, if it is, that the applicable amount payable to Isis will be less than 30%. The Company is 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. The Company paid Isis and UBC USD \$0.8 million and CAD \$0.1 million, respectively, in 2010 upon the initiation of a phase 2 clinical trial of OGX-427 in patients with CRPC. We did not make any royalty payments to Isis under the terms of the agreement in 2012 and do not anticipate making any royalty payments to Isis under the terms of the agreement in 2013. The UBC agreements have effective dates ranging from November 1, 2001 to April 5, 2005 and each agreement expires upon the later of 20 years from its effective date or the expiry of the last patent licensed thereunder, unless otherwise terminated.

Unless otherwise terminated, the Isis agreements for custirsen and 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.

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

The amendment to the Isis License Agreement provides, among other things, that if the Company is subject to change of control with a third party, where the surviving company immediately following such change of control has the right to develop and sell the product, then (i) a milestone payment of \$20 million will be due and payable to Isis 21 days following the first commercial sale of the product in the United States; and (ii) unless such surviving entity had previously sublicensed the product and a royalty rate payable to Isis by 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. Because 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 were to acquire the Company and become the surviving company. If the \$30 million in advanced reimbursement of development activities has not been spent by OncoGenex prior to December 20, 2012, 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. As of December 31, 2012 the Company had contributed \$30 million to the development of custirsen, therefore the Company does not owe any payment to Isis related to the \$30 million advance reimbursement from Teva.

### *Lease Arrangements*

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

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

	<u>CAD</u>
2013 .....	\$107
2014 .....	<u>\$ 81</u>
<b>Total</b> .....	<b>\$188</b>

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 (please see Note 7 to Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K). In connection with the lease, Sonus was required to provide a cash security deposit of approximately \$0.5 million, which is included in Other Long Term Assets. In addition, a standby letter of credit was issued by the Company in 2010, and \$0.3 million remains in a restricted money market account as collateral. The Company continues to evaluate opportunities to exit or sublet portions of the leased space and has recorded a liability in the excess facilities lease charge of \$4.6 million as at December 31, 2012 (please see Note 7 to Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K).

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):

2013 .....	2,180
2014 .....	2,246
2015 .....	2,313
2016 .....	2,382
Remainder .....	<u>2,455</u>
<b>Total</b> .....	<b>\$11,576</b>

Consolidated rent expense relating to both the Vancouver, Canada and Bothell, Washington offices for years ended December 31, 2012, 2011, and 2010 was \$2.7 million, \$2.6 million, and \$2.3 million respectively.

### *Guarantees and Indemnifications*

The Company indemnifies its officers, directors and certain consultants for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at its 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, the Company has obtained director and officer insurance that limits its exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2012.

The Company has certain agreements with certain organizations with which it does business that contain indemnification provisions pursuant to which it typically agrees to indemnify the party against certain types of third-party claims. The Company accrues 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.

## Material Changes in Financial Condition

(in thousands)	<u>December 31, 2012</u>	<u>December 31, 2011</u>
Total Assets .....	\$82,016	\$68,015
Total Liabilities .....	\$15,809	\$37,125
Total Equity .....	\$66,207	\$30,890

The increase in total assets from December 31, 2011 to December 31, 2012 primarily relates to increases in short term investments from funds provided by the March 2012 public offering. The decrease in total liabilities from December 31, 2011 relates predominantly to the revaluation of the warrant liability, amortization and re-measurement of restructuring-related liabilities, and the recognition of deferred collaboration revenue. The increase in total equity relates primarily to issuance of common stock from the March 2012 public offering, partially offset by the net loss for the period.

## 14. QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table summarizes the unaudited statements of operations for each quarter of 2012 and 2011 (in thousands, except per share amounts):

2012	December 31 \$	September 30 \$	June 30 \$	March 31 \$
Collaboration revenue .....	9,780	6,570	2,429	1,316
Research and development .....	15,645	12,895	6,326	5,082
General and administrative .....	2,042	1,965	2,047	1,737
Restructuring gain .....	(1,657)	—	—	—
Total expenses .....	16,030	14,860	8,373	6,819
Other income (expense) .....	2,147	2,370	1,729	(1,357)
Net loss attributable to common shareholders ...	(4,103)	(5,920)	(4,215)	(6,860)
Basic and diluted net loss per share .....	(0.28)	(0.40)	(0.29)	(0.67)
<b>2011</b>				
Collaboration revenue .....	1,236	1,174	1,887	1,199
Research and development .....	7,477	3,814	5,409	4,853
General and administrative .....	1,731	1,457	1,471	1,571
Restructuring expense .....	—	—	—	—
Total expenses .....	9,208	5,271	6,880	6,424
Other income (expense) .....	(1,596)	8,567	(1,537)	2,180
Net income (loss) attributable to common shareholders .....	(9,568)	4,470	(6,530)	(3,045)
Basic net income (loss) per share .....	(0.98)	0.46	(0.67)	(0.31)
Diluted net income (loss) per share .....	(0.98)	0.45	(0.67)	(0.31)

## 15. SUBSEQUENT EVENTS

In early January 2013, Scott Cormack, the President and Chief Executive Officer of OncoGenex Pharmaceuticals, Inc. (the "Company") and Michelle Burris, the Executive Vice President of Operations, Chief Financial Officer, Principal Accounting Officer, Treasurer and Secretary of the Company, disclosed to the Company's board of directors that they have a developing personal relationship with one another that warranted consideration of their reporting relationship and duties. After consideration and discussion by the independent members of the Company's board of directors, as well as consultations with Mr. Cormack and Ms. Burris, the

Company's board of directors determined that it would be advisable for Ms. Burris to transfer her executive duties to others and to continue portions of her work in operations as a consultant to the Company, reporting directly to the board of directors.

On February 1, 2013, Ms. Burris resigned as the Company's Principal Accounting Officer, Chief Financial Officer, Secretary and Treasurer. From February 1, 2013 to March 31, 2013, Ms. Burris will continue to serve as the Company's Executive Vice President of Operations. During such time, Ms. Burris will continue to receive her regular base salary and will be eligible to participate in benefits customarily afforded to other employees. In addition, her outstanding stock options and restricted stock units will continue to vest.

Effective March 31, 2013, Ms. Burris will resign as the Company's Executive Vice President of Operations, and the Company has agreed to pay all wages, bonuses, vacation, reimbursable expenses and similar payments due to Ms. Burris as of such date. If Ms. Burris agrees to release all claims against the Company, the Company has agreed to engage Ms. Burris as a consultant for a period of one year, beginning on the date she agrees to release all claims. The term of the consultancy may be extended by mutual agreement of the parties. As a consultant to the Company, Ms. Burris will receive a monthly retainer of approximately \$34,000 and reimbursement of health insurance coverage. Ms. Burris will also be eligible to receive an incentive payment of up to 40% of the aggregate amounts paid to Ms. Burris from the Company during the 2013 fiscal year, which will be based on a percentage according to the Company's achievement of corporate objectives, as well as continued vesting of all of her outstanding stock options and restricted stock units through the term of the consultancy.

Following the end of the consultancy, if Ms. Burris agrees to release all claims against the Company, the Company will pay Ms. Burris a lump sum payment of approximately \$410,000, which is consistent with the severance payment in her prior employment contract, or, if the consultancy ends within three months before or within 12 months after a change of control of the Company, a lump sum payment of approximately \$511,000, plus a bonus based on the average of bonus and incentive payments paid to Ms. Burris in the 24 months prior to the end of the consultancy, which is consistent with the change in control provisions in her prior employment contract. Additionally, the Company will accelerate the vesting of Ms. Burris's outstanding stock options and restricted stock units that would have vested over a 12-month period had she continued to provide services to the Company. If the consultancy ends within three months before or within 12 months after a change of control of the Company, all of Ms. Burris's outstanding stock options and restricted stock units will immediately vest. The Company will also pay Ms. Burris a lump sum payment to continue her existing health benefits for 12 months or, if the consultancy ends within three months before or within 12 months after a change of control of the Company, for 15 months. However, the Company will not pay the foregoing payments or accelerate the vesting of outstanding stock options and restricted stock units if Ms. Burris terminates the consultancy early for convenience, or the Company terminates the consultancy as a result of Ms. Burris's uncured breach of her consulting agreement.

The accounting implications of the above are in the process of being determined and will be reached beginning in fiscal 2013.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

### **ITEM 9A. 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 Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures are also designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

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 the disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on 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 Annual Report on Form 10-K.

#### *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 December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed under the supervision of our principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

As of December 31, 2012, management assessed the effectiveness of our internal control over financial reporting based on the framework established in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management has determined that our internal control over financial reporting was effective as of December 31, 2012.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included above.

### **ITEM 9B. OTHER INFORMATION**

Not applicable.



## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required hereunder is incorporated by reference from our definitive Proxy Statement to be filed within 120 days of December 31, 2012 and delivered to stockholders in connection with our 2013 Annual Meeting of Stockholders.

### ITEM 11. EXECUTIVE COMPENSATION

The information required hereunder is incorporated by reference from our definitive Proxy Statement to be filed within 120 days of December 31, 2012 and delivered to stockholders in connection with our 2013 Annual Meeting of Stockholders.

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding our equity compensation plans as of December 31, 2012:

<u>Plan category</u>	<u>(a)</u> <u>Number of securities to be issued upon exercise of outstanding options, restricted stock units, warrants and rights</u>	<u>(b)</u> <u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>(c)</u> <u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
Equity compensation plans approved by security holders . . . . .	966,148 <sup>(1)</sup>	\$9.41 <sup>(1)</sup>	461,076 <sup>(1)</sup>
Equity compensation plans not approved by security holders <sup>(2)</sup> . . . . .	10,718	2.69	—
Total . . . . .	976,866	\$9.44	461,076

(1) As of December 31, 2012, we maintained the following equity compensation plans, which were approved by security holders: (a) Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan—1991, (b) 1999 Nonqualified Stock Incentive Plan, or the 1999 Plan, (c) the 2000 Stock Incentive Plan, (d) the 2007 Performance Incentive Plan, (e) the OncoGenex Technologies Amended and Restated Stock Option Plan and (f) the 2010 Performance Incentive Plan.

(2) The 1999 Plan is a broad-based plan for which stockholder approval was not required or obtained. On February 11, 2010, the 1999 Plan terminated in accordance with its terms. All stock options, rights to purchase and restricted stock outstanding as of such time will continue in effect in accordance with their respective terms. Stock options granted under the 1999 Plan were generally granted with an exercise price equal to fair market value on the date of grant. Pursuant to the 1999 Plan, upon a change in control, the vesting period for outstanding options, rights to purchase and restricted stock granted under the 1999 Plan will accelerate and the administrator of the 1999 Plan may provide for the purchase or exchange of each option or right to purchase, adjust the terms of each option or right to purchase, cause the options and rights to purchase to be assumed, or new rights substituted therefor, or make such other provision as the administrator determines is equitable.

The remaining information required hereunder is incorporated by reference from our definitive Proxy Statement to be filed within 120 days of December 31, 2012 and delivered to stockholders in connection with our 2013 Annual Meeting of Stockholders.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required hereunder is incorporated by reference from our definitive Proxy Statement to be filed within 120 days of December 31, 2012 and delivered to stockholders in connection with our 2013 Annual Meeting of Stockholders.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required hereunder is incorporated by reference from our definitive Proxy Statement to be filed within 120 days of December 31, 2012 and delivered to stockholders in connection with our 2013 Annual Meeting of Stockholders.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(1) Financial Statements

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Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011, and 2010 .....	77
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(2) All schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

(3) Exhibits

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
2.1	Arrangement Agreement between the Company and OncoGenex Technologies Inc. dated May 27, 2008†	DEF 14A	000-21243	Annex A	July 3, 2008	
2.2	First Amendment to Arrangement Agreement between the Company and OncoGenex Technologies Inc. dated August 11, 2008	10-Q	000-21243	2.2	November 10, 2008	
2.3	Second Amendment to Arrangement Agreement between the Company and OncoGenex Technologies Inc. dated August 15, 2008	10-Q	000-21243	2.3	November 10, 2008	
3.1	Amended and Restated Certificate of Incorporation (As Amended Through October 17, 1995)	S-1	33-96112	3.2	September 25, 1995	
3.2	Certificate of Amendment to Certificate of Incorporation filed on May 6, 1999	10-Q	000-21243	3.3	May 13, 1999	
3.3	Certificate of Correction filed on March 9, 2009 to Certificate of Amendment filed on May 6, 1999	8-K	033-80623	3.1	March 11, 2009	
3.4	Certificate of Amendment to Certificate of Incorporation filed on May 7, 2004	10-K	033-80623	3.4	March 11, 2009	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.5	Certificate of Correction filed on March 9, 2009 to Certificate of Amendment filed on May 7, 2004	8-K	033-80623	3.2	March 11, 2009	
3.6	Certificate of Amendment to Certificate of Incorporation filed on August 20, 2008	10-Q	000-21243	3.2	November 10, 2008	
3.7	Certificate of Amendment to Certificate of Incorporation filed on June 8, 2010	8-K	033-80623	3.2	June 14, 2010	
3.8	Fifth Amended and Restated Bylaws of OncoGenex Pharmaceuticals, Inc.	10-Q	033-80623	3.1	August 2, 2012	
4.1	Specimen Certificate of Common Stock	10-Q	000-21243	4.1	November 10, 2008	
4.2	Amended and Restated Rights Agreement dated as of July 24, 2002 between Sonus Pharmaceuticals Inc. and U.S. Stock Transfer Corporation	8-A	000-21243	2.1	July 25, 2002	
4.3	First Amendment to Amended and Restated Rights Agreement dated as of October 17, 2005 between Sonus Pharmaceuticals Inc. and U.S. Stock Transfer Corporation	8-A	000-21243	2	October 18, 2005	
4.4	Second Amendment to Amended and Restated Rights Agreement dated as of August 10, 2006 between Sonus Pharmaceuticals Inc. and U.S. Stock Transfer Corporation	8-A	000-21243	3	August 14, 2006	
4.5	Third Amendment to Amended and Restated Rights Agreement dated May 27, 2008 between Sonus Pharmaceuticals Inc. and Computershare Trust Company, N.A.	8-K	000-21243	4.1	May 30, 2008	
4.6	Form of OncoGenex Voting Agreement	DEF 14A	000-21243	Annex D-1	July 3, 2008	
4.7	Form of Sonus Voting Agreement	DEF 14A	000-21243	Annex D-2	July 3, 2008	
10.1	Sonus Pharmaceuticals, Inc. Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan—1991 (the “1991 Plan”), as amended††	S-1	33-96112	10.1	September 25, 1995	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.2	Form of Incentive Option Agreement (pertaining to the 1991 Plan)††	S-1	33-96112	10.2	September 25, 1995	
10.3	Form of Sonus Pharmaceuticals, Inc. Nonqualified Stock Option Agreement under the 1991 Plan††	S-1	33-96112	10.3	September 25, 1995	
10.4	Sonus Pharmaceuticals, Inc. 1999 Nonqualified Stock Incentive Plan (the "1999 Plan")††	10-Q	000-21243	10.7	May 13, 1999	
10.5	Form of Sonus Pharmaceuticals, Inc. Nonqualified Stock Option Agreement under the 1999 Plan††	10-Q	000-21243	10.8	May 13, 1999	
10.6	Form of Sonus Pharmaceuticals, Inc. Restricted Stock Purchase Agreement under the 1999 Plan††	10-Q	000-21243	10.9	May 13, 1999	
10.7	Sonus Pharmaceuticals, Inc. 2000 Stock Incentive Plan (the "2000 Plan")††	10-Q	000-21243	10.41	August 14, 2000	
10.8	First Amendment to Sonus Pharmaceuticals, Inc. 2000 Plan††	10-Q	000-21243	10.23	November 8, 2006	
10.9	Form of Sonus Pharmaceuticals, Inc. Stock Option Agreement (pertaining to the 2000 Plan)††	10-Q	000-21243	10.42	August 14, 2000	
10.10	Sonus Pharmaceuticals, Inc. 2007 Performance Incentive Plan (the "2007 Plan")††	DEF 14A	000-21243	Appendix A	April 3, 2007	
10.11	Form of Sonus Pharmaceuticals, Inc. Stock Option Agreement (pertaining to the 2007 Plan)††	10-Q	000-21243	10.1	November 9, 2007	
10.12	Form of Sonus Pharmaceuticals, Inc. Restricted Stock Purchase Agreement under the 2007 Plan††	10-Q	000-21243	10.2	November 9, 2007	
10.13	OncoGenex Technologies Inc. Amended and Restated Stock Option Plan††	F-1	333-139293	10.1	December 13, 2006	
10.14	Stock Option Assumption, Amending and Confirmation Agreement dated as of August 21, 2008 between the Company and OncoGenex Technologies Inc.††	S-8	333-153206	4.2	August 26, 2008	
10.15	Form of OncoGenex Pharmaceuticals, Inc 2010 Stock Option Agreement††	8-K	033-80623	10.1	June 14, 2010	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.16	Form of OncoGenex Pharmaceuticals, Inc. 2010 Restricted Stock Purchase Agreement††	8-K	033-80623	10.2	June 14, 2010	
10.17	Form of OncoGenex Pharmaceuticals, Inc. 2010 Restricted Stock Unit Agreement††	10-Q	033-80623	10.2	November 3, 2011	
10.18	OncoGenex Pharmaceuticals, Inc. Short Term Incentive Awards Program††	8-K	033-80623	10.1	April 2, 2009	
10.19	Agreement and Consent Form (related to the Short Term Incentive Awards Program)††	8-K	033-80623	10.2	April 2, 2009	
10.20	OncoGenex Pharmaceuticals, Inc. 2010 Performance Incentive Plan, as amended and restated††	10-Q	033-80623	10.1	November 3, 2011	
10.21	Form of Indemnification Agreement for Officers and Directors of the Company††	S-1	33-96112	10.19	September 25, 1995	
10.22	Form of Indemnification Agreement between OncoGenex Technologies Inc. and each of Scott Cormack and Cindy Jacobs††	F-1	333-139293	10.7	December 13, 2006	
10.23	Form of Indemnification Agreement between OncoGenex Technologies Inc. and Neil Clendeninn††	F-1	333-139293	10.8	December 13, 2006	
10.24	Employment Agreement between OncoGenex Technologies Inc. and the Company and Scott Cormack dated as of November 4, 2009††	10-Q	033-80623	10.25	November 5, 2009	
10.25	Employment Agreement between the Company and Cindy Jacobs dated as of November 3, 2009††	10-Q	033-80623	10.27	November 5, 2009	
10.26	Employment Agreement dated October 14, 2008 between OncoGenex Technologies Inc. and Cameron Lawrence††	8-K	033-80623	10.1	March 1, 2010	
10.27	Employment Amending Agreement dated January 1, 2009 between OncoGenex Technologies Inc. and Cameron Lawrence††	8-K	033-80623	10.2	March 1, 2010	
10.28	Letter and Release Agreements with Cameron Lawrence dated May 31, 2012††	10-Q	033-80623	10.1	August 2, 2012	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.29	Employment Agreement dated November 5, 2010 between OncoGenex Technologies Inc. and Michelle Burris††	8-K	033-80623	10.1	November 8, 2010	
10.30	Transition and Separation Letter Agreement between OncoGenex Pharmaceuticals, Inc. and Michelle Burris dated February 1, 2013††	8-K	033-80623	10.1	February 4, 2013	
10.31	Employment Agreement between OncoGenex Pharmaceuticals, Inc. and Susan Wyrick dated February 1, 2013††	8-K	033-80623	10.2	February 4, 2013	
10.32	Form of Warrant to Purchase Common Stock	8-K	033-80623	4.1	October 19, 2010	
10.33	Lease by and between BMR-217th Place LLC and the Company dated as of November 21, 2006	10-K	000-21243	10.39	March 16, 2007	
10.34	First Amendment to Lease by and between BMR-217th Place LLC and the Company dated as of August 17, 2007	10-K	000-21243	10.41	March 14, 2008	
10.35	Second Amendment to Lease by and between BMR-217th Place LLC and the Company dated as of January 28, 2008	10-Q	000-21243	10.1	May 9, 2008	
10.36	Amended and Restated License Agreement effective as of July 2, 2008 by and between OncoGenex Technologies Inc. and Isis Pharmaceuticals, Inc. (OGX-011)*	10-K	033-80623	10.36	March 11, 2009	
10.37	Letter Agreement Regarding Certain Sublicense Consideration for OGX-011 between OncoGenex Technologies Inc. and Isis Pharmaceuticals, Inc. dated December 18, 2009	10-K	033-80623	10.36	March 8, 2010	
10.38	Amendment No. 1 to Amended and Restated License Agreement between OncoGenex Technologies Inc. and Isis Pharmaceuticals, Inc. dated December 19, 2009 (OGX-011)*	10-K	033-80623	10.37	March 8, 2010	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.39	License Agreement between OncoGenex Technologies Inc. and the University of British Columbia effective as of November 1, 2001, and Amending Agreement dated as of August 30, 2006 (OGX-011)*	F-1, Amendment No. 1	333-139293	10.13	January 29, 2007	
10.40	Second Amending Agreement and Consent as of August 7, 2008 between the University of British Columbia and OncoGenex Technologies Inc. (OGX-011)	10-Q	000-21243	2.3	November 10, 2008	
10.41	Third Amending Agreement to the License Agreement between OncoGenex Technologies Inc and the University of British Columbia dated as of December 20, 2009 (OGX-011)*	10-K	033-80623	10.40	March 8, 2010	
10.42	Collaboration and License Agreement between OncoGenex Technologies Inc. and Isis Pharmaceuticals, Inc. effective as of January 5, 2005 (OGX-427)*	F-1, Amendment No. 1	333-139293	10.11	January 29, 2007	
10.43	License Agreement between OncoGenex Technologies Inc. and the University of British Columbia effective as of April 5, 2005, and Amending Agreement dated as of August 30, 2006 (OGX-427)*	F-1, Amendment No. 1	333-139293	10.14	January 29, 2007	
10.44	Second Amending Agreement as of August 7, 2008 between the University of British Columbia and OncoGenex Technologies Inc. (OGX-427)	10-Q	000-21243	10.40	November 10, 2008	
10.45	Collaboration and License Agreement between OncoGenex Technologies Inc. and Teva Pharmaceutical Industries Ltd. dated as of December 20, 2009 (OGX-011)*	10-K	033-80623	10.44	March 8, 2010	
10.46	Amendment to the Collaboration and License Agreement between OncoGenex Technologies Inc. and Teva Pharmaceutical Industries Ltd. dated March 6, 2012	10-K	033-80623	10.49	March 8, 2012	
21.1	Subsidiaries of the Registrant					X



Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
23.1	Consent of Ernst & Young LLP					X
24.1	Power of Attorney (included on Page 114)					X
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					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
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**					X
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101.INS	XBRL Instance Document <sup>#</sup>					X
101.SCH	XBRL Taxonomy Extension Schema Document <sup>#</sup>					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document <sup>#</sup>					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document <sup>#</sup>					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document <sup>#</sup>					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document <sup>#</sup>					X

† Schedules and similar attachments to the Arrangement Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish supplementally a copy of any omitted schedule or similar attachment to the SEC upon request.

†† Indicates management contract or compensatory plan or arrangement.

- \* Confidential portions of this exhibit have been omitted and filed separately with the Commission pursuant to an application for Confidential Treatment under Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.
- \*\* The certifications attached as Exhibits 32.1 and 32.2 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.
- # These exhibits are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.  
(Registrant)

Date: March 7, 2013

By: /s/ SCOTT CORMACK  
Scott Cormack  
Chief Executive Officer and President  
(principal executive officer)

## Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Scott Cormack and [Michelle Burris], jointly and severally, as such person's attorneys-in-fact, each with the power of substitution, for such person in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By: <u>/s/ SCOTT CORMACK</u> Scott Cormack	Chief Executive Officer, President and Director (principal executive officer)	Date: March 7, 2013
By: <u>/s/ SUSAN WYRICK</u> Susan Wyrick	Senior Director, Finance and Principal Accounting Officer (principal accounting officer)	Date: March 7, 2013
By: <u>/s/ JACK GOLDSTEIN</u> Jack Goldstein	Chairman of the Board and Director	Date: March 7, 2013
By: <u>/s/ NEIL CLENDENINN</u> Neil Clendeninn	Director	Date: March 7, 2013
By: <u>/s/ MARTIN MATTINGLY</u> Martin Mattingly	Director	Date: March 7, 2013
By: <u>/s/ H. STEWART PARKER</u> H. Stewart Parker	Director	Date: March 7, 2013
By: <u>/s/ DAVID SMITH</u> David Smith	Director	Date: March 7, 2013

**SUBSIDIARIES OF THE REGISTRANT**

**OncoGenex Technologies Inc., incorporated under the federal laws of Canada**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-56933) pertaining to the OncoGenex Pharmaceuticals, Inc. Incentive Stock Option, Non-qualified Stock Option and Restricted Stock Purchase Plan-1991;
- (2) Registration Statement (Form S-8 No. 333-87897) pertaining to the OncoGenex Pharmaceuticals, Inc. Incentive Stock Option, Non-qualified Stock Option and Restricted Stock Purchase Plan-1991, 1995 Stock Option Plan for Directors, Employee Stock Purchase Plan, and 1999 Non-qualified Stock Incentive Plan;
- (3) Registration Statement (Form S-8 No. 333-49892) pertaining to the OncoGenex Pharmaceuticals, Inc. 1999 Non-qualified Stock Incentive Plan and 2000 Stock Incentive Plan;
- (4) Registration Statement (Form S-8 No. 333-56704) pertaining to the OncoGenex Pharmaceuticals, Inc. 2000 Stock Incentive Plan and 401(k) Profit Sharing Plan and Trust;
- (5) Registration Statement (Form S-8 No. 333-135697) pertaining to the OncoGenex Pharmaceuticals, Inc. 2000 Stock Incentive Plan;
- (6) Registration Statement (Form S-8 No. 333-144552) pertaining to the OncoGenex Pharmaceuticals, Inc. 2007 Performance Incentive Plan and 401(k) Profit Sharing Plan and Trust;
- (7) Registration Statement (Form S-8 No. 333-153206) pertaining to the OncoGenex Technologies Inc. Amended and Restated Stock Option Plan;
- (8) Registration Statement (Form S-8 No. 333-168820) pertaining to the OncoGenex Pharmaceuticals, Inc. 2010 Performance Incentive Plan;
- (9) Registration Statement (Form S-3 No. 333-177719) pertaining to the registration of securities of OncoGenex Pharmaceuticals, Inc. and in the related prospectus; and
- (10) Registration Statement (Form S-3 No. 333-184829) pertaining to the registration of securities of OncoGenex Pharmaceuticals, Inc. and in the related prospectus

of our reports dated March 7, 2013, with respect to the consolidated financial statements of OncoGenex Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of OncoGenex Pharmaceuticals, Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2012.

Vancouver, Canada,  
March 7, 2013.

/s/ Ernst & Young LLP  
Chartered Accountants

**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 annual report on Form 10-K 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 officers 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 officers 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: March 7, 2013

/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, Scott Cormack, certify that:

1. I have reviewed this annual report on Form 10-K 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 officers 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 officers 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: March 7, 2013

/s/ Scott Cormack

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Scott Cormack  
Chief Executive Officer and President  
(principal 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 Annual Report on Form 10-K of the Company for the annual period ended December 31, 2012 (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: March 7, 2013

/s/ SCOTT CORMACK

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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, 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 Annual Report on Form 10-K of the Company for the annual period ended December 31, 2012 (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: March 7, 2013

/s/ Scott Cormack

Scott Cormack  
President and Chief Executive Officer  
(principal financial officer)

