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ANNUAL REPORT

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Dear Fellow Stockholders,

At Oncothyreon, we are dedicated to the development of novel therapeutics to improve the lives and outcomes of cancer patients. This mission guides our approach to both our vaccine and small molecule product candidates, which are designed to target cancer in new and specific ways. While the risks associated with the development of novel therapies are significant, so are the potential rewards. Oncothyreon is focused on overcoming risk and achieving these rewards for the benefit of both patients and our stockholders.

In 2012 our focus was primarily on the development of our internal product pipeline. We made substantial progress in the enrollment of patients in multiple clinical trials, setting the stage for upcoming data events in 2013. We believe these data events, combined with our ongoing business development activities and decisions about the future of L-BLP25 (formerly Stimuvax), will define our future growth and opportunities.

#### **L-BLP25 START Trial**

As all of you are aware, at the end of 2012 we received news from Merck Serono that the pivotal Phase 3 clinical trial of L-BLP25 known as START did not meet its primary endpoint of an improvement in overall survival in patients with unresectable, locally advanced stage IIIA or stage IIIB non-small cell lung cancer who achieved a response or stable disease after chemoradiotherapy. START was a randomized, multicenter, double-blind, placebo-controlled trial that began in February 2007 and enrolled over 1,500 patients from 33 countries. The trial was conducted by Merck Serono, a division of Merck KGaA of Darmstadt, Germany, under a license agreement with Oncothyreon.

While these results were disappointing, Merck Serono did indicate that notable treatment effects were seen in certain patient subgroups. Merck Serono has further indicated that discussions with key opinion leaders and regulatory authorities are taking place, and that the data have been submitted for presentation at the American Society of Clinical Oncology meeting in June 2013. Moreover, additional studies of L-BLP25 in non-small cell lung cancer are ongoing, including the Phase 3 INSPIRE trial in multiple Asian countries and a Phase 2 trial in Japan. Merck Serono has indicated that these trials will continue pending discussions with the relevant regulatory authorities.

As of the date of this letter, we do not believe Merck Serono has reached a decision regarding the future of L-BLP25. We expect that decision will come during 2013 as Merck Serono further analyzes results from the START trial and evaluates input from the regulatory authorities and key opinion leaders.

## **ONT-10 and PET-Lipid A**

In the meantime, we are continuing with the development of ONT-10, our follow-on vaccine directed against the same target as L-BLP25, MUC-1. ONT-10 is a liposomal vaccine, similar to L-BLP25, but which incorporates a larger and glycosylated antigen and a novel, proprietary adjuvant. In preclinical models, ONT-10 produces a robust humoral immune response, as well as a cellular response comparable to that seen with L-BLP25. We initiated a Phase 1 trial of ONT-10 in March 2012. This trial has progressed well, with the dose-escalation portion of the study nearly complete as of the date of this letter.

ONT-10 contains a novel adjuvant that we believe may prove of interest to other vaccine developers. The fully synthetic lipid A analog, called PET-Lipid A, is a TLR4 agonist that has demonstrated enhanced potency compared to the adjuvant monophosphoryl lipid A (MPL), which is the only currently approved TLR4 agonist adjuvant. We believe the fully synthetic composition of this adjuvant may provide manufacturing and cost advantages.

## **PX-866 PI-3 Kinase Inhibitor**

During 2012, substantial progress was made in advancing our broad development program for PX-866, a small molecule inhibitor of PI-3 kinase. This program includes four open-label Phase 2 trials and an additional Phase 1/2 trial started in 2012.

Together these trials are evaluating PX-866 as a combination or single agent treatment in six different cancer indications. Our current trials of PX-866, as listed by cancer indication, include:

- A randomized trial in combination with docetaxel in patients with locally advanced, recurrent or metastatic non-small cell lung cancer who are receiving second or third line treatment. Enrollment of more than 90 patients was completed during 2012. The primary endpoint of this trial is progression-free survival, with data on this endpoint expected in 2013.
- A randomized Phase 2 trial of PX-866 in combination with cetuximab in patients with metastatic colorectal carcinoma who have a history of progression or recurrence following prior treatment regimens containing irinotecan and oxaliplatin. This trial is fully enrolled and the primary endpoint data of objective response rate is expected in 2013.
- Two randomized trials of PX-866 in patients with squamous cell carcinoma of the head and neck. These trials are evaluating PX-866 in combination with docetaxel and cetuximab, respectively. Enrollment in both of these trials is targeted for completion by the middle of 2013, with top line data currently expected to be reported around the end of 2013.
- Two single-agent Phase 2 trials of PX-866, one in patients with glioblastoma multiforme and the other in patients with castration resistant prostate cancer, being conducted by the National Cancer Institute of Canada Clinical Trials Group. Data from these trials will be presented in 2013.
- A Phase 1/2 trial of PX-866 in combination with vemurafenib in patients with advanced BRAF-mutant melanoma. This trial, which is being conducted in collaboration with the Melanoma

Research Foundation Breakthrough Consortium, was initiated in 2012 and is currently enrolling the Phase 1 dose escalation portion.

Our goal for 2012 was to enroll these trials as expeditiously as possible. As noted above, we have completed enrollment in four of the indications and are expecting data from these trials during 2013.

The primary reason for conducting such a broad development program for PX-866 was to provide as much information and as many options as possible to guide future development of this product candidate. If the data are supportive, it is our intention to move PX-866 into a Phase 2b or 3 trial as soon as possible. We will also be sharing the Phase 2 data with potential partners for PX-866. The competition in the field of drugs targeting PI-3 kinase is intense, and we believe a partnership for later stage development of PX-866 would be beneficial.

### **Future Pipeline Development & Financial Resources**

During the course of 2013, we will continue to evaluate additional opportunities to further strengthen our pipeline. Our business development efforts have been enhanced during 2012 with the appointment of Guy Cipriani, Vice President, Business Development, to the Oncothyreon executive management team. He joins Gary Christianson, Chief Operating Officer; Julie Eastland, Chief Financial Officer and Vice President Corporate Development; Diana Hausman, Chief Medical Officer; and Scott Peterson, Chief Scientific Officer. I am grateful for the efforts of this team, and of all our Oncothyreon employees, in their dedicated efforts to advance our programs efficiently and expeditiously.

Underlying all of our activities, both current and future, is a steadfast commitment to maintaining a solid financial position to ensure continuous progress and to allow us to operate from a position of strength. Indeed, we ended 2012 in a strong financial position with approximately \$84 million in cash, cash equivalents and investments. This provides the company with sufficient resources to support our ongoing trials and to advance to the next phases of development for both ONT-10 and PX-866.

The field of cancer drug development is challenging but is one that offers great potential. We remain focused on the future and the opportunities ahead. On behalf of the entire Oncothyreon team, we would like to extend our thanks to the patients who are involved in our clinical programs, to their families and to our stockholders for their continued support.

Sincerely,



Robert L. Kirkman, M.D.

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

**Form 10-K**

(Mark One)

**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  
FOR THE TRANSITION PERIOD FROM TO**

Commission file number: 001-33882

**ONCOTHYREON INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**26-0868560**

(I.R.S. Employer  
Identification Number)

**2601 Fourth Ave, Suite 500  
Seattle, Washington**

(Address of principal executive offices)

**98121**

(Zip Code)

**Registrant's telephone number, including area code:  
(206) 801-2100**

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

**Title of Each Class**

**Name of Exchange on Which Registered**

Common Stock, \$0.0001 par value

The NASDAQ Stock Market LLC  
(The NASDAQ Global 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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark 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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of the 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. (Check one):  
Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the Registrant, based on the closing sale price of the Registrant's common stock on the last day of its most recently completed second fiscal quarter, as reported on the NASDAQ Global Market, was approximately \$216 million. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock, based on filings with the Securities and Exchange Commission, have been excluded from this computation since such persons may be deemed affiliates of the Registrant. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

There were 57,216,237 shares of the Registrant's common stock, \$0.0001 par value, outstanding on March 13, 2013.

**DOCUMENTS INCORPORATED BY REFERENCE**

**None.**

**ONCOTHYREON INC.  
ANNUAL REPORT ON FORM 10 K  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012**

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## PART I

### ITEM 1. **Business**

*This annual report on Form 10-K, including Part I, Item 1, "Business," Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operation" and other materials accompanying this annual report on Form 10-K, contain forward-looking statements or incorporate by reference forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward-looking statements. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our, or in some cases our partners' future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements.*

*All forward-looking statements are based on information available to us on the date of this annual report and we will not update any of the forward-looking statements after the date of this annual report, except as required by law. Our actual results could differ materially from those discussed in this annual report. The forward-looking statements contained in this annual report, and other written and oral forward-looking statements made by us from time to time, are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in the following discussion and within Part I, Item 1A, "Risk Factors" of this annual report.*

#### **Overview**

We are a clinical-stage biopharmaceutical company focused primarily on the development of therapeutic products for the treatment of cancer. Our goal is to develop and commercialize novel synthetic vaccines and targeted small molecules that have the potential to improve the lives and outcomes of cancer patients. Our cancer vaccines are designed to stimulate the immune system to attack cancer cells, while our small molecule compounds are designed to inhibit the activity of specific cancer-related proteins. We are advancing our product candidates through in-house development efforts and strategic collaborations.

Our lead cancer vaccine product candidate, L-BLP25 (formerly known as Stimuvax), is being evaluated for the treatment of non-small cell lung cancer, or NSCLC. We have granted an exclusive, worldwide license to Merck KGaA of Darmstadt, Germany, or Merck KGaA, for the development, manufacture and commercialization of L-BLP25. In December 2012, Merck KGaA announced that the Phase 3 START trial of L-BLP25 did not meet its primary endpoint of an improvement in overall survival in patients with unresectable, locally advanced stage IIIA or stage IIIB NSCLC. Merck KGaA also announced, however, that notable treatment effects were seen for L-BLP25 in certain subgroups. Merck KGaA has stated that they are consulting with external experts and regulatory authorities to determine potential next steps, if any, for L-BLP25. The ongoing clinical program of L-BLP25 that includes studies in the Asia Pacific region is continuing pending discussion with relevant regulatory agencies. We have also initiated a Phase 1 trial for ONT-10, a cancer vaccine directed against a target similar to L-BLP25, which is proprietary to us. In addition to our vaccine product candidates, we have developed novel vaccine technology we may further develop ourselves and/or license to others, including the novel vaccine adjuvant PET-Lipid A.

We are also developing novel targeted small molecules for treatment of cancer. Our most advanced targeted small molecule is PX-866, for which we are currently conducting four Phase 2 trials in a variety of cancer indications with results expected in 2013. PX-866 is an irreversible, pan-isoform phosphatidylinositol-3-kinase, or PI-3-kinase inhibitor we obtained when we acquired ProIX Pharmaceuticals Corporation in 2006. We are also developing ONT-701, a preclinical pan-inhibitor of the B-cell lymphoma-2, or Bcl-2, family of anti-apoptotic proteins. Overexpression of one or more of the Bcl-2 family of proteins is common in most human cancers. We obtained rights to ONT-701 as part of an exclusive,



worldwide license agreement with Sanford Burnham Medical Research Institute or SBMRI. As of the date of this report, we have not licensed any rights to our small molecules to any third party and retain all development, commercialization and manufacturing rights.

We believe the quality and breadth of our product candidate pipeline, strategic collaborations and scientific team will potentially enable us to become an integrated biopharmaceutical company with a diversified portfolio of novel, commercialized therapeutics for major diseases.

We were incorporated in 1985 in Canada under the name Biomira Inc., or Biomira. On December 10, 2007, Oncothyreon became the successor corporation to Biomira by way of a plan of arrangement effected pursuant to Canadian law. The plan of arrangement represents a transaction among entities under common control. The assets and liabilities of the predecessor Biomira have been reflected at their historical cost in the accounts of Oncothyreon.

Our executive office is located at 2601 Fourth Avenue, Suite 500, Seattle, Washington 98121 and our telephone number is (206) 801-2100. Our common stock trades on the NASDAQ Global Market under the symbol "ONTY".

### **Available Information**

We make available free of charge through our investor relations website, [www.oncothyreon.com](http://www.oncothyreon.com), our annual reports, quarterly reports, current reports, proxy statements and all amendments to those reports as soon as reasonably practicable after such material is electronically filed or furnished with the SEC. These reports may also be obtained without charge by contacting Investor Relations, Oncothyreon Inc., 2601 Fourth Avenue, Suite 500, Seattle, Washington 98121, e-mail: [IR@oncothyreon.com](mailto:IR@oncothyreon.com). Our Internet website and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. In addition, the public may read and copy any materials we file or furnish with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 or may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Moreover, the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with them at [www.sec.gov](http://www.sec.gov).

### **Our Strategy**

Our pipeline of product candidates is comprised of cancer vaccines and small molecules. Our cancer vaccines attack cancer cells by stimulating the immune system, while our small molecule product candidates inhibit critical cancer-related pathways. The resulting product pipeline provides us with opportunities to diversify risk, develop new therapies and establish strategic partnerships. This pipeline is the foundation on which we intend to build a valuable oncology franchise and become a leading developer of vaccine and small molecule therapies for cancer. Key elements of our strategy are to:

*Advance Our Product Pipeline.* Our primary focus is advancing our pipeline of product candidates: L-BLP25, PX-866 and ONT-10, which are in clinical trials, and ONT-701, which is in pre-clinical development, on our own or with partners. To that end, we maintain and are building internal expertise in our development, regulatory and clinical groups. We also have relationships with key scientific advisors, research organizations and contract manufacturers to supplement our internal efforts.

*Establish and Maintain Strategic Collaborations to Advance our Product Pipeline.* Our strategy is to enter into collaborations or license arrangements at appropriate stages in our research and development process to accelerate the commercialization of our product candidates. Collaborations can supplement our own internal expertise in areas such as clinical trials and manufacturing, as well as provide us with access to our collaborators'

and/or licensees' marketing, sales and distribution capabilities. For example, in 2001 we initiated a collaboration with Merck KGaA to pursue joint global product research, clinical development and commercialization of L-BLP25. That collaboration evolved over time and in December 2008, the collaboration arrangement with Merck KGaA was replaced with a license agreement, pursuant to which Merck KGaA has sole responsibility for the clinical development, manufacture and commercialization of L-BLP25. All development costs for L-BLP25 have been borne exclusively by Merck KGaA since March 1, 2006, with the exception of manufacturing process development costs, which Merck KGaA also assumed beginning on December 18, 2008. We have no further performance obligations under our arrangement with Merck KGaA and will potentially receive cash payments upon the occurrence of certain events and royalties based on net sales. The opportunity to realize such payments is dependent upon Merck KGaA's decisions regarding potential next steps with L-BLP25.

*Selectively License our Technologies.* As a result of our experience in cancer vaccine development, we have acquired and developed unique technologies that are available for license. For example, we have developed a fully synthetic toll-like receptor 4 agonist called PET-lipid A, which we believe to be useful as a vaccine adjuvant.

*Acquire or In-license Attractive Product Candidates and Technologies.* In addition to our internal research and development initiatives, we have ongoing efforts to identify products and technologies to acquire or in-license from biotechnology and pharmaceutical companies and academic institutions. For example, we acquired ProIX in 2006 and we in-licensed ONT-701 from the SBMRI in 2011. We plan to continue supplementing our internal development programs through strategic acquisition or in-licensing transactions.

#### **Product Candidates Overview**

<u>Product Candidate</u>	<u>Technology</u>	<u>Most Advanced Indication</u>	<u>Development Stage</u>
L-BLP25	Vaccine	Non-small cell lung cancer	Phase 3
PX-866	Small Molecule	To be determined	Phase 2
ONT-10	Vaccine	To be determined	Phase 1
ONT-701	Small Molecule	To be determined	Preclinical

In the table above, under the heading "Development Stage," "Phase 3" indicates evaluation of clinical efficacy and safety within an expanded patient population, at geographically dispersed clinical trial sites; "Phase 2" indicates clinical safety testing, dosage testing and initial efficacy testing in a limited patient population; "Phase 1" indicates initial clinical testing of safety, dosage tolerance, pharmacokinetics and pharmacodynamics and "Preclinical" indicates the program has not yet entered human clinical trials.

#### **Vaccine Products**

##### ***General***

The immunotherapeutic or cancer "vaccine" approach is based on the concept that tumors possess distinct antigens, like the Mucin 1, or MUC1, antigen incorporated in our L-BLP25 and ONT-10 vaccines, which should be recognized by the body's immune system. Immunotherapy is designed to stimulate an individual's immune system to recognize cancer cells and control the growth and spread of cancers in order to increase the survival of cancer patients.

##### ***L-BLP25 (formerly known as Stimuvax)***

Our lead product candidate currently under clinical development is a vaccine we call L-BLP25. L-BLP25 incorporates a 25 amino acid sequence of the cancer antigen MUC1, in a liposomal formulation. L-BLP25 is designed to induce an immune response to destroy cancer cells that express MUC1, a protein antigen widely expressed on many common

cancers, such as lung cancer, breast cancer and colorectal cancer. L-BLP25 is thought to work by stimulating the body's immune system to identify and destroy cancer cells expressing MUC1. L-BLP25 is being evaluated for the treatment of NSCLC.

*Lung Cancer.* Lung cancer is the leading cause of cancer death for both men and women. More people die of lung cancer than of colon, breast and prostate cancers combined. According to a report of the World Health Organization, lung cancer (both non-small cell and small cell type) affects more than 1.2 million patients a year, with around 1.1 million deaths annually and around 500,000 in the United States, Europe and Japan. About 85% of all lung cancers are of the non-small cell type. Further, only about 15% of people diagnosed with NSCLC survive this disease after five years. For most patients with NSCLC, current treatments provide limited success.

According to a 2010 Global Data report, the NSCLC market was estimated to exceed \$4.0 billion. There are currently no therapeutic vaccines approved for the treatment of NSCLC. We believe therapeutic vaccines have the potential to substantially enlarge the NSCLC market, both because of their novel mechanism of action and their expected safety profile. L-BLP25 is currently being developed as maintenance therapy following treatment of inoperable locoregional Stage III NSCLC with induction chemotherapy.

Stage I-IIIa NSCLC patients are generally treated with surgery and radiation, while Stage IIIB-IV patients are inoperable and generally treated with chemotherapy, radiation and palliative care. The market is currently driven by the use of several drug classes, namely chemotherapeutic agents (taxanes and cytotoxics) and targeted therapies (Iressa, Nexavar, Sutent, Tarceva and Avastin). There are currently two products approved as maintenance therapy following treatment of inoperable locoregional Stage III NSCLC with induction chemotherapy, Tarceva (erlotinib), a targeted small molecule from Genentech, Inc., a member of the Roche Group, and Alimta (pemetrexed), a chemotherapeutic from Eli Lilly and Company. L-BLP25 has not been tested in combination with or in comparison to these products. It is possible that other existing or new agents will be approved for this indication.

*Clinical Results and Status.* In December 2012, Merck KGaA announced that the Phase 3 START trial of L-BLP25 did not meet its primary endpoint of an improvement in overall survival in patients with unresectable, locally advanced stage IIIA or stage IIIB NSCLC. START was a randomized, multicenter, double-blind, placebo-controlled trial initiated in January 2007 that assessed the efficacy, safety and tolerability of L-BLP25 in patients with unresectable stage III NSCLC who achieved a response or stable disease after chemoradiotherapy. Patients were randomized to receive either a single low dose of cyclophosphamide followed by L-BLP25 (weekly injections for eight weeks followed by injections every six-weeks until progression) plus best supportive care, or BSC or placebo plus BSC. More than 1,500 patients from 33 countries were recruited into the START trial.

Despite not meeting the primary endpoint, Merck KGaA has indicated that notable treatment effects were seen for L-BLP25 in certain subgroups. We believe that Merck KGaA is conducting further analyses of the data from the START trial to explore the potential benefit-risk profile of L-BLP25 in certain populations. In addition, we believe that Merck KGaA is consulting with external scientific advisors and regulatory authorities about potential next steps for the development of L-BLP25.

Patient safety in the START trial was monitored frequently by an independent data monitoring committee and no new or unexpected safety concerns were noted for the study. In prior clinical studies, the most frequently reported adverse events included injection site reactions, flu-like symptoms, nausea, cough, fatigue and dyspnea.

Merck KGaA has indicated that other ongoing studies of L-BLP25 will continue pending discussions with the relevant regulatory authorities. These studies include an additional Phase 3 trial of L-BLP25 in NSCLC being conducted in Asia, referred to as the INSPIRE

study. The INSPIRE study is a Phase III, multi-center, randomized, double-blind, placebo-controlled clinical trial initiated in December 2009 designed to evaluate the efficacy, safety and tolerability of L-BLP25 in patients of Asian heritage suffering from unresectable, stage IIIA or IIIB NSCLC who have had a response or stable disease after at least two cycles of platinum-based chemoradiotherapy. The design of the INSPIRE study is almost identical to the START study. INSPIRE will enroll approximately 420 unresectable, stage III NSCLC patients across China, Hong Kong, Korea, Singapore and Taiwan. Merck KGaA is also conducting a Phase 2 trial of L-BLP25 in patients with NSCLC in Japan.

On March 23, 2010, we announced that Merck suspended the clinical development program for L-BLP25 as the result of a suspected unexpected serious adverse event reaction in a patient with multiple myeloma participating in an exploratory clinical trial. The exploratory trial was designed to investigate the mechanism of action of L-BLP25 and the effect of cyclophosphamide on regulatory T cells which may affect the response to the therapeutic vaccine. The adverse event occurred in a patient receiving a more intensive cyclophosphamide regimen than is utilized in the Phase 3 clinical program for L-BLP25. The patient developed an encephalitis, or inflammation of the brain, of unknown cause, and subsequently died of such condition. This suspension was a precautionary measure while investigation of the cause of this adverse event was conducted. In June 2010, the FDA lifted the clinical hold on the NSCLC trials. The suspension affected the Phase 3 clinical program for L-BLP25 in NSCLC. For example, patients enrolled in the START trial were unable to receive L-BLP25 during the duration of the suspension.

#### ***ONT-10 Liposome Vaccine Product Candidate***

We have developed a completely synthetic MUC1-based liposomal glycolipopeptide cancer vaccine, ONT-10, for potential use in several cancer indications, including breast, thyroid, colon, stomach, pancreas, ovarian and prostate, as well as certain types of lung cancer. The ONT-10 glycolipopeptide combines carbohydrate and peptide determinates in a multi-epitopic vaccine that evokes both cellular and humoral immune responses against major cancer-associated epitopes expressed on adenocarcinomas. ONT-10 is our first completely synthetic vaccine candidate. ONT-10 includes our proprietary liposomal delivery technology.

We initiated a Phase 1 clinical trial of ONT-10 in March 2012. The Phase 1 trial of ONT-10 consists of two parts. Part 1 will study a dose escalation schedule in up to 48 patients to determine the maximally tolerated and/or recommended dose of ONT-10 administered either once every other week or once every week over an 8 week period. Part 2 will further investigate the safety of ONT-10 at the maximally tolerated or recommended dose in up to 15 additional patients at the weekly and/or biweekly schedule. The ability of ONT-10 to induce both a humoral and a cellular immune response will be investigated in both parts of the study.

We currently expect to complete Part 1 of the Phase 1 trial of ONT-10 in 2013. Because both ONT-10 and L-BLP25 are targeted at the MUC1 antigen, we currently expect that the further development of ONT-10 will depend, in part, on the results of further analysis of results from the START trial. We currently own all rights to ONT-10. As discussed in the section captioned, “— Our Strategic Collaboration with Merck KGaA,” if we intend to license the development or marketing rights to ONT-10, Merck KGaA will have a right of first negotiation with respect to such license rights.

#### ***PET Lipid-A Vaccine Adjuvant Product Candidate***

We have developed a proprietary synthetic lipid-A analog, PET lipid-A, a toll like receptor 4 (TLR4) agonist. PET lipid-A has been produced under current Good Manufacturing Practices, or cGMP, conditions as an adjuvant for vaccine formulations for clinical trials and is a component of our vaccine candidate, ONT-10. We also have other effective lipid-A

analogs available for our own use and for evaluation by our licensing partners. Our synthetic lipid analogs provide strong innate immune stimulation. These synthetic structures are easy to formulate and manufacture. We are seeking new collaborations to discover novel applications of these molecules as stand-alone therapeutics and as synergistic adjuvants for antibiotic and antiviral vaccines.

## **Small Molecule Drugs**

### ***General***

On October 30, 2006, we acquired ProIX Pharmaceuticals Corporation, or ProIX, of Tucson, Arizona, a privately held biopharmaceutical company focused on the development of novel targeted small molecules for the treatment of cancer. We are currently developing PX-866, which we obtained as a part of the ProIX acquisition. We continue to evaluate new opportunities to acquire or in-license additional small molecule compounds designed to inhibit the activity of specific cancer-related proteins. We believe this approach gives us multiple opportunities for successful clinical development while diversifying risk.

### ***PX-866***

PX-866 is an inhibitor of the PI-3-kinase PTEN/Akt pathway, an important survival signaling pathway that is activated in many types of human cancer. PI-3-kinase is over expressed in a number of human cancers, especially ovarian, colon, head and neck, urinary tract and cervical cancers, where it leads to increased proliferation and inhibition of apoptosis, or programmed cell death. The PI-3-kinase inhibitor PX-866 induces prolonged inhibition of tumor PI-3-kinase signaling following both oral and intravenous administration and has been shown to have good in vivo anti-tumor activity in human ovarian and lung cancer, as well as intracranial glioblastoma, tumor models. PX-866 may potentiate the anti-tumor activity of other cancer therapeutics and radiation.

We have completed a Phase 1 trial of PX-866 in patients with advanced metastatic cancer which evaluated both an intermittent and a continuous dosing schedule of PX-866. Based on the results in this open label trial, we initiated two Phase 1/2 trials of PX-866 in combination with other agents in 2010. We have completed the Phase 1 portions of both trials, and we initiated the randomized Phase 2 portions in 2011. The first trial is examining PX-866 in combination with docetaxel (Taxotere) versus docetaxel alone in patients with either NSCLC or locally advanced, recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). The NSCLC arm of this trial has completed enrollment, with data currently expected in the first half of 2013. The SCCHN arm is currently expected to complete enrollment in the first half of 2013, with data currently expected late in 2013. The second trial is randomizing patients to cetuximab (Erbix) with or without PX-866 and will include patients with either SCCHN or colorectal cancer. The SCCHN arm of this trial is currently expected to complete enrollment in the first half of 2013, with data currently expected late in 2013. The colorectal arm of this trial has completed enrollment, with data currently expected in mid-2013. We also initiated two Phase 2 trials of PX-866 as a single agent in 2011, one in patients with glioblastoma and the other in patients with castration-resistant metastatic prostate cancer. These single agent trials are being conducted by the National Cancer Institute of Canada Clinical Trials Group. Data from both Phase 2 single arm trials is currently expected in mid-2013. We also initiated a Phase 1/2 trial of PX-866 in combination with vemurafenib (Zelboraf®) in 2012. Vemurafenib is a kinase inhibitor indicated for the treatment of unresectable or metastatic melanoma with the BRAF<sup>V600E</sup> mutation.

## **Market Opportunity for Targeted Small Molecules**

The market for targeted cancer drugs, both small molecules and biologic agents, is expanding rapidly, with the approval of such agents as Gleevec, Herceptin, Tarceva, Nexavar, Sutent and Avastin. For example, Roche Group reported aggregate world-wide sales for Herceptin, Tarceva and Avastin of \$14.1 billion in 2012. Our small molecule compounds are highly targeted agents directed at proteins found in many types of cancer cells. Therefore, we believe that these product candidates could potentially be useful for many different oncology indications that address large markets.

## **Our Strategic Collaboration with Merck KGaA**

In May 2001, we and Merck KGaA entered into a collaborative arrangement to pursue joint global product research, clinical development and commercialization for our then two most advanced product candidates, L-BLP25 vaccine and Theratope vaccine. The collaboration covered the entire field of oncology for these two product candidates and was documented in collaboration and supply agreements, which we refer to as the 2001 agreements. In addition to granting the license with respect to certain rights to develop and commercialize the product candidates, the parties agreed to collaborate in substantially all aspects of clinical development and commercialization and we agreed to manufacture the clinical and commercial supply of the product candidates. In 2004, following the failure of Theratope in a Phase 3 clinical trial, Merck KGaA returned all rights to Theratope to us. Development of Theratope was subsequently discontinued and we do not currently plan further clinical development. Following the discontinuation of Theratope development efforts, we continued to collaborate with Merck KGaA with respect to the development of L-BLP25, pursuant to the terms of the 2001 agreements.

In January 2006, we and Merck KGaA entered into a binding letter of intent, pursuant to which the 2001 agreements were amended and we and Merck KGaA agreed to negotiate in good faith to amend and restate the 2001 agreements. Pursuant to the letter of intent, in addition to the rights granted to Merck KGaA under the 2001 agreements, we granted to Merck KGaA additional rights with respect to the clinical development and commercialization of L-BLP25 in the United States and, subject to certain conditions, the right to act as a secondary manufacturer of L-BLP25.

In August 2007, we amended and restated the collaboration and supply agreements with Merck KGaA, which restructured the 2001 agreements and formalized the terms of the 2006 letter of intent. Pursuant to the 2007 agreements, Merck KGaA assumed world-wide responsibility for the clinical development and commercialization of L-BLP25, while we retained responsibility for manufacturing process development and manufacturing the clinical and commercial supply of L-BLP25.

In December 2008, we entered into a license agreement which replaced the 2007 agreements. Under the 2008 license agreement, (1) we licensed to Merck KGaA the exclusive right to manufacture L-BLP25 (in addition to the previously licensed rights) and the right to sublicense to other persons all rights licensed to Merck KGaA by us, (2) we transferred certain manufacturing know-how, (3) we agreed not to develop any product, other than ONT-10, that is competitive with L-BLP25 and (4) if we intend to license the development or commercialization rights to ONT-10, Merck KGaA will have a right of first negotiation with respect to such rights.

Upon the execution of the 2008 license agreement and asset purchase agreement described below, all of our future performance obligations related to the collaboration for the clinical development and development of the manufacturing process for L-BLP25 were

removed and continuing involvement by us in the development and manufacturing of L-BLP25 ceased (although we continue to be entitled to certain information rights with respect to clinical testing, development and manufacture of L-BLP25).

In return for the license of manufacturing rights and transfer of manufacturing know-how under the 2008 license agreement, we received an up-front cash payment of approximately \$10.5 million. In addition, under the 2008 license agreement we may receive additional future cash payments of up to \$90 million (which figure excludes the final \$2.0 million manufacturing process transfer payment received on December 31, 2009, pursuant to the terms of the 2008 license agreement and \$19.8 million received prior to the execution of the 2008 license agreement pursuant to the terms of the predecessor agreements), for biologics license application, or BLA, submission for first and second cancer indications, for regulatory approval for first and second cancer indications, and for sales milestones. We understand Merck KGaA plans to investigate the use of L-BLP25 in multiple types of cancer. We will receive a royalty based on certain net sales thresholds, ranging from a percentage in the mid-teens to the high single digits, depending on the territory in which the net sales occur. The royalty rate is higher in North America than in the rest of the world in return for our relinquishing our prior co-promotion interest in U.S. and Canadian sales.

In connection with the entry into the 2008 license agreement, we also entered into an asset purchase agreement, pursuant to which we sold to Merck KGaA certain assets related to the manufacture of, and inventory of, L-BLP25, placebo and raw materials, and Merck KGaA agreed to assume certain liabilities related to the manufacture of L-BLP25 and our obligations related to the lease of our Edmonton, Alberta, Canada facility. The aggregate purchase price paid by Merck KGaA pursuant to the terms of the asset purchase agreement consisted of approximately \$2.5 million, for aggregate consideration payable to us in connection with the 2008 license agreement and the asset purchase agreement of approximately \$13.0 million.

### **License Agreements**

We have in-licensed targets and intellectual property from academic institutions for use in our pipeline programs, including the following:

*Cancer Research Technology Limited.* In 1991, we acquired from Cancer Research Technology Limited, or CRTL, of London, England an exclusive world-wide license of CRTL's rights to the Mucin 1 peptide antigen, or MUC1, found on human breast, ovarian, colon and pancreatic cancer and other types of solid tumor cells for uses in the treatment and diagnosis of cancer. MUC1 is incorporated in our L-BLP25 and ONT-10 vaccines. This license agreement was amended and restated in November 2000. Under the terms of the amended and restated agreement, we are required to pay royalties on net sales of products covered by issued patents licensed from CRTL. Based on these issued patents, we would be required to pay a royalty on U.S. sales of L-BLP25 in the mid single digits until expiry of these patents in the United States, which is currently anticipated to be 2018. We are also required to pay certain royalties on sublicense revenue received by us ranging from a percentage in the mid to high single digits. These sublicense royalties will be credited against minimum sublicense royalty payments of \$0.75 million made by us in 2001. To date, we have utilized approximately \$0.68 million of these credits.

*University of Alberta.* In 2001, we entered into an exclusive license with the University of Alberta for certain patents relating to uses of liposomal cancer vaccines of MUC1, and an adjuvant, lipid A, for vaccine formulations which we use in L-BLP25. Under the terms of this agreement, we have made payments of CDN \$0.2 million, and are required to make progress-dependent milestone payments of up to CDN \$0.3 million and to pay royalties at a fraction of a percent on net sales of products covered by issued patents licensed from the University of Alberta. Based on these issued patents, this royalty would be due on sales of L-BLP25 in the U.S. until as late as January 1, 2018.

*University of Arizona.* We have an exclusive worldwide license to certain intellectual property related to PX-866 from the University of Arizona. If PX-866 is commercialized, we will owe the University of Arizona certain progress-dependent milestone payments up to a maximum of \$375,000. We will also owe the University of Arizona low single-digit royalties on net sales of products sold by us or sublicensees that are covered by the license agreements. In addition, if we grant a third party a sublicense to patents we have licensed from the University of Arizona, after we recoup any research costs relating to the applicable product that we incurred prior to granting the sublicense, we will owe to the University of Arizona a sub-teen double-digit percentage of any sublicensing income we receive from a third party sublicensee with regard to such product.

*Sanford-Burnham Medical Research Institute.* In September 2011, we entered into an exclusive, worldwide license agreement with SBMRI for certain intellectual property related to SBMRI's small molecule program based on ONT-701 and related compounds. ONT-701 is a pan-inhibitor of the Bcl-2 family of anti-apoptotic proteins and is currently in pre-clinical development. Under the terms of this agreement, we made a payment of \$1.5 million to SBMRI, which was recorded as part of research and development expense. In addition, we may be required to make milestone payments of up to approximately \$26 million upon the occurrence of certain clinical development and regulatory milestones and up to \$25 million based on certain net sales targets. We would be required to pay a royalty in the low to mid single digits on net sales of licensed products. In addition, if we generate income other than royalties on sales of licensed products from a sublicense of any of the licensed rights, we must pay SBMRI a portion of certain income received from the sublicensee at a rate between mid single digits and 30%, depending on stage of the clinical development of the rights when the sublicense is granted. Unless earlier terminated in accordance with the license agreement, the agreement shall terminate on a country-by-country basis upon the later of (1) 10 years after the first commercial sale of the first licensed product and (2) the expiration of the last-to-expire patent within the licensed patents.

**Patents and Proprietary Information**

We seek appropriate patent protection for our proprietary technologies by filing patent applications in the United States and other countries. As of December 31, 2012, we owned approximately 29 U.S. patents and patent applications, as well as the corresponding foreign patents and patent applications and held exclusive or partially exclusive licenses to 21 U.S. patents and patent applications, as well as the corresponding foreign patents and patent applications.

Our patents and patent applications are directed to our product candidates as well as to our liposomal formulation technology. Although we believe our patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our corporate collaborators may not be able to develop patentable products or processes or obtain patents from pending patent applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us or our corporate collaborators.

Our clinical product candidates are protected by composition and use patents and patent applications. Patent protection afforded by the patents and patent applications covering our product candidates will expire over the following time frames:

<u>Product Candidate</u>	<u>Expiration of U.S. Patent Protection</u>
L-BLP25 .....	2018 (patent) - 2029 (patent application)
PX - 866 .....	2022 (patent) - 2033 (patent application)
ONT - 10 .....	2023 (patent) - 2032 (patent, application)
ONT - 701 .....	2028 (patent) - 2030 (patent, application)



In addition, our composition of matter patents for L-BLP25 and PX-866 will expire in 2018 and 2022, respectively, and our composition of matter patents, for ONT-10 and ONT-701 will expire in 2032 and 2028, respectively. We also rely on trade secrets and proprietary know-how, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also provide that we shall own all inventions conceived by the individual in the course of rendering services to us.

### **Manufacturing**

We currently outsource the manufacturing of drug substances and drug products for all of our products in clinical development. This arrangement allows us to use contract manufacturers that already have extensive cGMP manufacturing experience. We have a staff with experience in the management of contract manufacturing and the development of efficient commercial manufacturing processes for our products. We currently intend to outsource the supply of all our commercial products.

As discussed above under the caption, “ — Our Strategic Collaboration with Merck KGaA,” in December 2008, we entered into a license agreement with Merck KGaA pursuant to which we licensed to Merck KGaA the exclusive right to manufacture L-BLP25. Prior to the entry into the 2008 license agreement, we were responsible for the manufacture of L-BLP25 and Merck KGaA purchased L-BLP25 and placebo from us for use in clinical trials in accordance with our arrangement with them. Concurrently with the entry into the 2008 license agreement, we also entered into an asset purchase agreement pursuant to which we sold to Merck KGaA our remaining inventory of both L-BLP25 and placebo. The manufacture of L-BLP25 is outsourced pursuant to agreements with Baxter International Inc., or Baxter (for the manufacture of L-BLP25) and Corixa Corporation, or Corixa, a subsidiary of GlaxoSmithKline plc, or GlaxoSmithKline, (for the manufacture of the adjuvant used in L-BLP25). These agreements were assigned to Merck KGaA in accordance with the terms of the asset purchase agreement. The Corixa agreement includes royalty payments payable to Corixa, which Merck KGaA is responsible for paying. If L-BLP25 is not approved by 2015, Corixa may terminate its obligation to supply the adjuvant. Although in such a case we would retain the necessary licenses from Corixa required to have the adjuvant manufactured, the transfer of the process to a third party would delay the development and commercialization of L-BLP25. In addition, prior to the entry into the 2008 license agreement and asset purchase agreement, we performed process development, assay development, quality control and scale-up activities for L-BLP25 at our Edmonton facility; this facility and those activities were also transferred to Merck KGaA.

For our small molecule programs, we rely on third parties to manufacture both the active pharmaceutical ingredients, or API, and drug product. We believe there are several contract manufacturers capable of manufacturing both the API and drug product for these compounds; however, establishing a relationship with an alternative supplier would likely delay our ability to produce material.

We believe that our existing supplies of drug product and our contract manufacturing relationships with our existing and other potential contract manufacturers with whom we are in discussions, will be sufficient to accommodate our planned clinical trials. However, we may need to obtain additional manufacturing arrangements, if available on commercially reasonable terms, or increase our own manufacturing capability to meet our future needs, both of which would require significant capital investment. We may also enter

into collaborations with pharmaceutical or larger biotechnology companies to enhance the manufacturing capabilities for our product candidates.

### **Competition**

The pharmaceutical and biotechnology industries are intensely competitive, and any product candidate developed by us would compete with existing drugs and therapies. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations that compete with us in developing various approaches to cancer therapy. Many of these organizations have substantially greater financial, technical, manufacturing and marketing resources than we have. Several of them have developed or are developing therapies that could be used for treatment of the same diseases that we are targeting. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on our ability to:

- design and develop products that are superior to other products in the market and under development;
- attract and retain qualified scientific, product development and commercial personnel;
- obtain patent and/or other proprietary protection for our product candidates and technologies;
- obtain required regulatory approvals;
- successfully collaborate with pharmaceutical companies in the design, development and commercialization of new products;
- compete on, among other things, product efficacy and safety, time to market, price, extent of adverse side effects and the basis of and convenience of treatment procedures; and
- identify, secure the rights to and develop products and exploit these products commercially before others are able to develop competitive products.

In addition, our ability to compete may be affected if insurers and other third party payors seek to encourage the use of generic products, making branded products less attractive to buyers from a cost perspective.

*L-BLP25.* There are currently two products approved as maintenance therapy following treatment of inoperable locoregional Stage III NSCLC with induction chemotherapy, Tarceva (erlotinib), a targeted small molecule from Genentech, Inc., a member of the Roche Group, and Alimta (pemetrexed), a chemotherapeutic from Eli Lilly and Company. L-BLP25 has not been tested in combination with or in comparison to these products. It is possible that other existing or new agents will be approved for this indication. In addition, there are at least three vaccines in development for the treatment of NSCLC, including GSK's MAGE A3 vaccine in Phase 3, NovaRx Corporation's Lucanix in Phase 3 and Transgene's TG-4010 in Phase 2. TG-4010 also targets MUC1, although using technology different from L-BLP25. To our knowledge, these vaccines are not currently being developed in the same indications as L-BLP25. However, subsequent development of these vaccines, including L-BLP25, may result in direct competition.

*Small Molecule Products.* We have two small molecule programs in development; PX-866 and ONT-701. PX-866 is an inhibitor of PI-3-kinase. We are aware of numerous companies that have entered clinical trials with competing compounds targeting the same protein, many of which have significantly greater financial, manufacturing, marketing and drug development resources than we do. Among these competitors are Novartis (Phase 3), Roche/Genentech (Phase 2), Bayer (Phase 1), Sanofi-Aventis (Phase 2), Chugai (Phase 1) and GlaxoSmithKline (Phase 1/2). There are also several approved targeted therapies for cancer and in development against which PX-866 might compete. ONT-701 is a small

molecule inhibitor of the Bcl-2 anti-apoptotic protein family. We are aware of at least one company that is developing a competing drug that targets the same family, Ascenta (Phase 2). There are also several approved targeted therapies for cancer and in development against which our small molecule product candidates might compete.

### **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and export and import of biopharmaceutical products such as those we are developing.

#### ***U.S. Government Regulation***

In the United States, the information that must be submitted to the FDA in order to obtain approval to market a new drug varies depending on whether the drug is a new product whose safety and effectiveness has not previously been demonstrated in humans or a drug whose active ingredient(s) and certain other properties are the same as those of a previously approved drug. A new drug will follow the New Drug Application, or NDA, route for approval, a new biologic will follow the Biologics License Application, or BLA, route for approval, and a drug that claims to be the same as an already approved drug may be able to follow the Abbreviated New Drug Application, or ANDA, route for approval.

#### ***NDA and BLA Approval Process***

In the United States, the FDA regulates drugs and biologics under the Federal Food, Drug and Cosmetic Act, and, in the case of biologics, also under the Public Health Service Act, and implementing regulations. If we fail to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The steps required before a drug or biologic may be marketed in the United States include:

- completion of pre-clinical laboratory tests, animal studies and formulation studies under the FDA's good laboratory practices regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each indication;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP; and
- FDA review and approval of the NDA or BLA.

Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any

outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each clinical protocol must be submitted to the FDA as part of the IND.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent institutional review board at each site where the trial will be conducted before it can begin at that site. Phase 1 clinical trials usually involve the initial introduction of the investigational drug into humans to evaluate the product's safety, dosage tolerance, pharmacokinetics and pharmacodynamics and, if possible, to gain an early indication of its effectiveness. Phase 2 clinical trials usually involve controlled trials in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks, and evaluate preliminarily the efficacy of the drug for specific indications. Phase 3 clinical trials usually further evaluate clinical efficacy and further test for safety in an expanded patient population. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical studies, together with other detailed information, including information on the chemistry, manufacture and control criteria of the product, are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and whether the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. In connection with the submission of an NDA or BLA, an applicant may seek a special protocol assessment, or SPA, which is an agreement between an applicant and the FDA on the design and size of clinical trials that is intended to form the basis of an NDA or BLA.

Before approving an application, the FDA will inspect the facility or the facilities at which the product is manufactured. The FDA will not approve the product unless cGMP compliance is satisfactory. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our product candidates. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of our product candidates. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

### ***Fast Track Designation / Priority Review***

A Fast Track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Under the Fast Track program, the sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a Fast Track product at any time during the development of the product, prior to marketing.

The FDA can base approval of a marketing application for a Fast Track product on an effect on a surrogate endpoint, or on another endpoint that is reasonably likely to predict clinical benefit. The FDA may condition approval of an application for a Fast Track product on a commitment to do post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint and require prior review of all promotional materials. In addition, the FDA may withdraw approval of a Fast Track product in an expedited manner on a number of grounds, including the sponsor's failure to conduct any required post-approval study in a timely manner.

The FDA also has established priority and standard review classifications for original NDAs and efficacy supplements. Priority review applies to the time frame for FDA review of completed marketing applications and is separate from and independent of the Fast Track and accelerated approval mechanisms. The classification system, which does not preclude the FDA from doing work on other projects, provides a way of prioritizing NDAs upon receipt and throughout the application review process.

Priority designation applies to new drugs that have the potential for providing significant improvement compared to marketed products in the treatment or prevention of a disease. Hence, even if an NDA is initially classified as a priority application, this status can change during the FDA review process, such as in the situation where another product is approved for the same disease for which previously there was no available therapy. In addition, priority review does not guarantee that a product candidate will receive regulatory approval. To date, none of our product candidates have obtained priority designation from the FDA.

### ***Post-Approval Requirements***

After regulatory approval of a product is obtained, we are required to comply with a number of post-approval requirements. Holders of an approved NDA or BLA are required to report certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes certain procedural, substantive and recordkeeping requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We use, and in at least the near-term will continue to use, third party manufacturers to produce our product candidates in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Also, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

In addition, as a condition of approval of an NDA or BLA, the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy.

### ***Canadian and Foreign Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product candidate, we must obtain approval of a product candidate by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product candidate in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under the Canadian regulatory system, Health Canada is the regulatory body that governs the sale of drugs for the purposes of use in clinical trials. Accordingly, any company that wishes to conduct a clinical trial in Canada must submit a clinical trial application to Health Canada. Health Canada reviews the application and notifies the company within 30 days if the application is found to be deficient. If the application is deemed acceptable, Health Canada will issue a letter to the company within the 30-day review period which means the company may proceed with its clinical trial(s).

Under European Union regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization from one member state may submit an application to the remaining member states. Within 90 days of receiving the application and assessment report, each member state must decide whether to recognize approval.

### ***Reimbursement***

Sales of biopharmaceutical products depend in significant part on the availability of third party reimbursement, including Medicare. Each third party payor may have its own policy regarding what products it will cover, the conditions under which it will cover such products, and how much it will pay for such products. It is time consuming and expensive for us to seek reimbursement from third party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business, including the Affordable Care Act of 2010. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to

consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures include:

- controls on government funded reimbursement for drugs;
- controls on healthcare providers;
- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;
- reform of drug importation laws; and
- expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person.

We are unable to predict what legislation, regulations or policies, if any, relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future or what the magnitude of the effect such legislation, regulations or policies would have on our business. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted could have a material adverse effect on our business, financial condition and profitability.

### **Research and Development**

We devote a substantial portion of our resources to developing new product candidates. During the years ended December 31, 2012, 2011 and 2010, we expended approximately \$22.0 million, \$17.9 million and \$11.6 million, respectively, on research and development activities.

### **Employees**

As of December 31, 2012, we (including our consolidated subsidiaries) had 42 employees, 31 of whom are engaged in development activities, 11 in finance and administration, and 8 of whom hold Ph.D. and/or M.D. degrees. A number of our management and professional employees have had prior experience with other pharmaceutical or medical products companies.

Our ability to develop marketable products and to establish and maintain our competitive position in light of technological developments will depend, in part, on our ability to attract and retain qualified personnel. Competition for such personnel is intense. We have also chosen to outsource activities where skills are in short supply or where it is economically prudent to do so.

None of our employees are covered by collective bargaining agreements and we believe that our relations with our employees are good.

### **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, 2010, 2011 and 2012 and our total assets as of December 31, 2011 and 2012, is included in our audited financial statements located elsewhere in this Annual Report on Form 10-K.

## ITEM 1A. Risk Factors

*Set forth below and elsewhere in this report, and in other documents we file with the SEC are descriptions of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. Because of the following factors, as well as other variables affecting our operating results, past financial performance should not be considered a reliable indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods. The risks and uncertainties described below are not the only ones facing us. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition.*

### **Risks Relating to our Business**

***We cannot be certain that our lead product candidate L-BLP25 (formerly known as Stimuvax) will be successfully developed or receive regulatory approval or be successfully commercialized.***

Our lead cancer vaccine product candidate, L-BLP25, is being evaluated for the treatment of non-small cell lung cancer, or NSCLC. Under our license agreement with Merck KGaA for L-BLP25, Merck KGaA is entirely responsible for the development, manufacture and worldwide commercialization of L-BLP25. In December 2012, Merck KGaA announced that the Phase 3 START trial of L-BLP25 did not meet its primary endpoint of an improvement in overall survival in patients with unresectable, locally advanced stage IIIA or stage IIIB NSCLC. Merck KGaA announced, however, that notable treatment effects were seen for L-BLP25 in certain subgroups and has stated that they are consulting with external experts and regulatory authorities to determine potential next steps, if any, for L-BLP25. Before submitting a biologic license application or its foreign equivalent for approval, we expect that Merck KGaA must successfully complete one or more clinical trials in NSCLC potentially in a subgroup or additional subgroups identified in the START trial. This process can take many years and require the expenditure of substantial resources, and may ultimately be unsuccessful.

Pursuant to our agreement with Merck KGaA, Merck KGaA is responsible for the development and the regulatory approval process and any subsequent commercialization of L-BLP25. We cannot assure you that Merck KGaA will identify subgroups in which to conduct additional clinical trials of L-BLP25 or continue to advance the development and commercialization of L-BLP25. In the event ongoing clinical trials proceed or additional clinical trials are pursued and these clinical trials fail to demonstrate that L-BLP25 is safe and effective, it will not receive regulatory approval. Even if L-BLP25 receives regulatory approval, it may never be successfully commercialized. If L-BLP25 does not receive regulatory approval or is not successfully commercialized, or if Merck KGaA decides not to continue to advance the development and commercialization of L-BLP25, we may not be able to generate revenue, become profitable or continue our operations which would have a material adverse effect on our business, operating results, and financial condition and could result in a substantial decline in the price of our common stock.

***The results of further analysis of results from the START trial for L-BLP25 will influence our decisions regarding further development of our product candidate ONT-10.***

We have initiated a Phase 1 trial for ONT-10, a cancer vaccine directed against a target similar to L-BLP25, which is proprietary to us. The Phase 1 trial of ONT-10 consists of two parts. Part 1 will study a dose escalation schedule in up to 48 patients to determine the maximally tolerated or recommended dose of ONT-10 administered either once every other week or once every week over an 8 week period. Part 2 will further investigate the safety of ONT-10 at the maximally tolerated or recommended dose in up to 15 additional patients at the weekly or biweekly schedule. We currently expect to complete Part 1 of the Phase 1 trial on ONT-10 in 2013.



Because both ONT-10 and L-BLP25 are targeted at the MUC1 antigen, we currently expect that the further development of ONT-10 will depend, in part, on the results of further analysis of results from the START trial. In the event that the results of this analysis indicate that further development of ONT-10 is unlikely to result in a safe and effective vaccine in its targeted indications or that further development is unwarranted for other reasons, then we may choose to discontinue further development of ONT-10 or otherwise modify our development efforts related to ONT-10. Any announcement regarding the abandonment of or changes in our current plans for the development of ONT-10 would reduce the number of our clinical product candidates and could adversely impact the trading price of our common stock or our ability to obtain further funding for our remaining pre-clinical and clinical pipeline of drug candidates.

***The suspension or termination of Merck's clinical development program for L-BLP25 could severely harm our business.***

Pursuant to our agreement, Merck KGaA has the exclusive right to develop, manufacture and commercialize L-BLP25 in return for our right to receive cash payments upon the occurrence of certain events and royalties based on net sales. Merck KGaA has the right to terminate the license agreement upon 30 days' prior written notice if, in its reasonable judgment, it determines there are issues concerning the safety or efficacy of L-BLP25 that would materially and adversely affect L-BLP25's medical, economic or competitive viability. We believe that Merck KGaA is consulting with external scientific advisors and regulatory authorities about potential next steps for the development of L-BLP25, if any, and Merck KGaA may ultimately decide not to continue development of L-BLP25 and may terminate the 2008 license agreement. Additionally, in March 2010, Merck KGaA temporarily suspended the clinical development program for L-BLP25 as the result of a suspected unexpected serious adverse event reaction in a patient participating in an exploratory clinical trial. If other safety concerns arise in current or future clinical trials involving L-BLP25, Merck KGaA may decide to suspend the clinical trials or terminate the 2008 license agreement. Any future payments under the license agreement, including royalties to us, will depend on the extent to which Merck KGaA advances L-BLP25 through development and commercialization. The opportunity for us to realize these payments is dependent upon Merck KGaA's decisions regarding potential next steps with L-BLP25.

If Merck KGaA terminates the agreement for safety or efficacy reasons, or breaches the agreement, the further development and commercialization of L-BLP25 would be severely impaired. If we determined that we desired to continue the development, manufacturing and/or commercialization of L-BLP25 subsequent to any such termination, we would be unable to use any data generated during Merck KGaA's development of the product unless we were able to negotiate terms with Merck KGaA for the use of such data. We cannot provide any assurance that we would be able to reach an agreement with Merck KGaA on commercially reasonable terms, or at all. If we were unable to use those data, the development, manufacturing and commercialization of L-BLP25 would be more costly and could be delayed or terminated. Even if we were able to acquire the rights to use the Merck KGaA data related to L-BLP25, we would need to obtain the capital necessary to fund the further development and commercialization of L-BLP25 or enter into alternative arrangements with a third party related to such development and commercialization. We could also become involved in disputes with Merck KGaA, which could lead to delays in or termination of our development and commercialization of L-BLP25 and time-consuming and expensive litigation or arbitration. If Merck KGaA terminates or breaches its agreement with us, or otherwise fails to complete its obligations in a timely manner, the likelihood of successfully developing or commercializing L-BLP25 would be materially and adversely affected.

***Products that appear promising in research and development may be delayed or may fail to reach later stages of clinical development.***

The successful development of pharmaceutical products is highly uncertain. Products that appear promising in research and development may be delayed or fail to reach later stages of development. For example, our product candidate L-BLP25 did not meet its primary endpoint in a Phase 3 clinical trial. Additionally, the Phase 2 clinical trials currently being run for PX-866 and for which we expect results in 2013, may fail to demonstrate that PX-866 is sufficiently safe and effective to warrant further development. Furthermore, decisions regarding the further development of product candidates, such as Phase 2 product candidates with product profiles similar to PX-866, must be made with limited and incomplete data, which makes it difficult to ensure or even accurately predict whether the allocation of limited resources and the expenditure of additional capital on specific product candidates will result in desired outcomes. Preclinical and clinical data can be interpreted in different ways, and negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent the development of a product candidate, which could harm our business, financial condition and results or the trading price of our securities. There can be no assurance as to whether or when we will receive regulatory approvals for any of our product candidates, including L-BLP25 or PX-866.

***L-BLP25 and ONT-10 are based on novel technologies, which may raise new regulatory issues that could delay or make FDA or foreign regulatory approval more difficult.***

The process of obtaining required FDA and other regulatory approvals, including foreign approvals, is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. L-BLP25 and ONT-10 are novel; therefore, regulatory agencies may lack experience with them, which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of L-BLP25 and our other active vaccine products under development.

To date, the FDA has approved for commercial sale in the United States only one active vaccine designed to stimulate an immune response against cancer. Consequently, there is limited precedent for the successful development or commercialization of products based on our technologies in this area. This may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our products under development.

***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.***

The success of our product pipeline strategy depends, in part, on our ability to identify, select and acquire 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 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 to which we acquire rights 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 have a history of net losses, we anticipate additional losses and we may never become profitable.***

Other than the year ended December 31, 2008, we have incurred net losses in each fiscal year since we commenced our research activities in 1985. The net income we realized in 2008 was due entirely to our December 2008 transactions with Merck KGaA, and we do not anticipate realizing net income again for the foreseeable future. As of December 31, 2012, our accumulated deficit was approximately \$393.3 million. Our losses have resulted primarily from expenses incurred in research and development of our product candidates. We may make significant capital commitments to fund the development of our product candidates. If these development efforts are unsuccessful, the development costs would be incurred without any future revenue, which could have a material adverse effect on our financial condition. We do not know when or if we will complete our product development efforts, receive regulatory approval for any of our product candidates, or successfully commercialize any approved products. As a result, it is difficult to predict the extent of any future losses or the time required to achieve profitability, if at all. Any failure of our products to complete successful clinical trials and obtain regulatory approval and any failure to become and remain profitable would adversely affect the price of our common stock and our ability to raise capital and continue operations.

***There is no assurance that we will be granted regulatory approval for any of our product candidates.***

Merck KGaA has been testing our lead product candidate, L-BLP25, in clinical trials for the treatment of NSCLC. We are conducting four Phase 2 trials and one Phase 1/2 trial for PX-866 and a Phase 1 trial for ONT-10. Our other product candidates remain in the pre-clinical testing stages. There can be no assurance that we will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals. A number of companies in the biotechnology and pharmaceutical industries, including our company, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. For example, in December 2012, we and Merck KGaA announced that L-BLP25 did not meet its primary endpoint of improvement in overall survival in a Phase 3 trial in patients with NSCLC.

Further, we, any of our collaborators or Merck KGaA may be unable to submit applications to regulatory agencies within the time frame we currently expect. Once submitted, applications must be approved by various regulatory agencies before we, any of our collaborators or Merck KGaA can commercialize the product described in the application. Additionally, even if applications are submitted, regulatory approval may not be obtained for any of our product candidates, and regulatory agencies could require additional studies to verify safety or efficacy, which could make further development of our product candidates impracticable. If our product candidates are not shown to be safe and effective in clinical trials, we may not receive regulatory approval, which would have a material adverse effect on our business, financial condition and results of operations.

***We and Merck KGaA currently rely on third-party manufacturers to supply our product candidates. Any disruption in production, inability of these third-party manufacturers to produce adequate quantities to meet our needs or Merck's needs or other impediments with respect to development or manufacturing could adversely affect the clinical development and commercialization of L-BLP25, our ability to continue our research and development activities or successfully complete pre-clinical studies and clinical trials, delay submissions of our regulatory applications or adversely affect our ability to commercialize our other product candidates in a timely manner, or at all.***

Merck KGaA currently depends on a single manufacturer, Baxter International Inc., or Baxter, for the supply of our lead product candidate, L-BLP25, and on Corixa Corp. (now a part of GlaxoSmithKline plc, or GSK) for the manufacture of the adjuvant in L-BLP25. If L-BLP25 is not approved by 2015, Corixa/GSK may terminate its obligation to supply the adjuvant. In this case, we would retain the necessary licenses from Corixa/GSK required to have the adjuvant manufactured, but the transfer of the process to a third party would delay the development and commercialization of L-BLP25, which could materially harm our business.

Our product candidates have not yet been manufactured on a commercial scale. In order to commercialize a product candidate, the third-party manufacturer may need to increase its manufacturing capacity, which may require the manufacturer to fund capital improvements to support the scale up of manufacturing and related activities. With respect to PX-866, we may be required to provide all or a portion of these funds. The third-party manufacturer may not be able to successfully increase its manufacturing capacity for our product candidate for which we obtain marketing approval in a timely or economic manner, or at all. If any manufacturer is unable to provide commercial quantities of a product candidate, we (or Merck KGaA, in the case of L-BLP25) will need to successfully transfer manufacturing technology to a new manufacturer. Engaging a new manufacturer for a particular product candidate could require us (or Merck KGaA, in the case of L-BLP25) to conduct comparative studies or use other means to determine equivalence between product candidates manufactured by a new manufacturer and those previously manufactured by the existing manufacturer, which could delay or prevent commercialization of our product candidates. If any of these manufacturers is unable or unwilling to increase its manufacturing capacity or if alternative arrangements are not established on a timely basis or on acceptable terms, the development and commercialization of our product candidates may be delayed or there may be a shortage in supply.

Any manufacturer of our products must comply with current Good Manufacturing Practices, or cGMP, requirements enforced by the FDA through its facilities inspection program or by foreign regulatory agencies. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products.

***Pre-clinical and clinical trials are expensive and time consuming, and any failure or delay in commencing or completing clinical trials for our product candidates could severely harm our business.***

We are currently conducting clinical trials for PX-866 and ONT-10 and pre-clinical studies for ONT-701. Each of our product candidates must undergo extensive pre-clinical studies and clinical trials as a condition to regulatory approval. Pre-clinical studies and clinical trials are expensive and take many years to complete. The commencement and completion of clinical trials for our product candidates may be delayed by many factors, including:

- safety issues or side effects;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- poor effectiveness of product candidates during clinical trials;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- our or our collaborators' ability to obtain regulatory approval to commence a clinical trial;
- our or our collaborators' ability to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials; and
- varying interpretation of data by the FDA and similar foreign regulatory agencies.

It is possible that none of our product candidates will complete clinical trials in any of the markets in which we or our collaborators intend to sell those product candidates.

Accordingly, we or our collaborators may not receive the regulatory approvals necessary to market our product candidates. Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for product candidates would prevent or delay their commercialization and severely harm our business and financial condition.

***The failure to enroll patients for clinical trials may cause delays in developing our product candidates.***

We may encounter delays if we, any collaboration partners or Merck KGaA are unable to enroll enough patients to complete clinical trials. Patient enrollment depends on many factors, including, the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial. Moreover, when one product candidate is evaluated in multiple clinical trials simultaneously, patient enrollment in ongoing trials can be adversely affected by negative results from completed trials. Our product candidates are focused in oncology, which can be a difficult patient population to recruit. If we fail to enroll patients for clinical trials, our clinical trials may be delayed or suspended, which could delay our ability to generate revenues.

***We rely on third parties to conduct our clinical trials. If these third parties do not perform as contractually required or otherwise expected, we may not be able to obtain regulatory approval for or be able to commercialize our product candidates.***

We rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to assist in conducting our clinical trials. We have, in the ordinary course of business, entered into agreements with these third parties. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties

do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

***Our product candidates may never achieve market acceptance even if we obtain regulatory approvals.***

Even if we receive regulatory approvals for the commercial sale of our product candidates, the commercial success of these product candidates will depend on, among other things, their acceptance by physicians, patients, third-party payers such as health insurance companies and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. New patterns of care, alternative new treatments or different reimbursement and payor paradigms, possibly due to economic conditions or governmental policies, could negatively impact the commercial viability of our product candidates. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of adverse side effects;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the effectiveness of our marketing and distribution strategy;
- publicity concerning our products or competing products and treatments; and
- our ability to obtain sufficient third-party insurance coverage or reimbursement.

If our product candidates do not become widely accepted by physicians, patients, third-party payers and other members of the medical community, our business, financial condition and results of operations would be materially and adversely affected.

***Even if regulatory approval is received for our product candidates, the later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions, including withdrawal of the product from the market.***

Approval of a product candidate may be conditioned upon certain limitations and restrictions as to the drug's use, or upon the conduct of further studies, and may be subject to continuous review. After approval of a product, if any, there will be significant ongoing regulatory compliance obligations, and if we or our collaborators fail to comply with these requirements, we, any of our collaborators or Merck KGaA could be subject to penalties, including:

- warning letters;
- fines;
- product recalls;
- withdrawal of regulatory approval;
- operating restrictions;
- disgorgement of profits;
- injunctions; and
- criminal prosecution.

Regulatory agencies may require us, any of our collaborators or Merck KGaA to delay, restrict or discontinue clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. In addition, all statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Any unanticipated delays in clinical studies could delay our ability to generate revenues and harm our financial condition and results of operations.

***Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.***

We intend to have our product candidates marketed outside the United States. In order to market our products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. To date, we have not filed for marketing approval for any of our product candidates and may not receive the approvals necessary to commercialize our product candidates in any market.

The approval procedure varies among countries and may include all of the risks associated with obtaining FDA approval. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval, and additional testing and data review may be required. We may not obtain foreign regulatory approvals on a timely basis, if at all. Additionally, approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could limit commercialization of our products, reduce our ability to generate profits and harm our business.

***Our ability to continue with our planned operations is dependent on our success at raising additional capital sufficient to meet our obligations on a timely basis. If we fail to obtain additional financing when needed, we may be unable to complete the development, regulatory approval and commercialization of our product candidates.***

We have expended and continue to expend substantial funds in connection with our product development activities and clinical trials and regulatory approvals. The very limited funds generated currently from our operations will be insufficient to enable us to bring all of our products currently under development to commercialization. Accordingly, we need to raise additional funds from the sale of our securities, partnering arrangements or other financing transactions in order to finance the commercialization of our product candidates. We cannot be certain that additional financing will be available when and as needed or, if available, that it will be available on acceptable terms. If financing is available, it may be on terms that adversely affect the interests of our existing stockholders or restrict our ability to conduct our operations. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If adequate financing is not available, we may need to continue to reduce or eliminate our expenditures for research and development, testing, production and marketing for some of our product candidates. Our actual capital requirements will depend on numerous factors, including:

- activities and arrangements related to the commercialization of our product candidates;
- the progress of our research and development programs;
- the progress of pre-clinical and clinical testing of our product candidates;
- the time and cost involved in obtaining regulatory approvals for our product candidates;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights with respect to our intellectual property;
- the effect of competing technological and market developments;
- the effect of changes and developments in our existing licensing and other relationships; and
- the terms of any new collaborative, licensing and other arrangements that we may establish.

If we require additional financing and cannot secure sufficient financing on acceptable terms, we may need to delay, reduce or eliminate some or all of our research and development programs, any of which would be expected to have a material adverse effect on our business, operating results, and financial condition.

***We may expand our business through the acquisition of companies or businesses or in-licensing product candidates that could disrupt our business and harm our financial condition.***

We may in the future seek to expand our products and capabilities by acquiring one or more companies or businesses or in-licensing one or more product candidates. For example, in September 2011 we entered into an exclusive, worldwide license agreement with Sanford-Burnham Medical Research Institute, or SBMRI, for certain intellectual property related to SBMRI's small molecule program based on ONT-701 and related compounds. Acquisitions and in-licenses involve numerous risks, including:

- substantial cash expenditures;
- potentially dilutive issuance of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- potential disputes regarding contingent consideration;
- diverting our management's attention away from other business concerns;
- entering markets in which we have limited or no direct experience; and
- potential loss of our key employees or key employees of the acquired companies or businesses.

Other than our license from SBMRI, under our current management team we have not expanded our business through in-licensing and we have completed only one acquisition; therefore, our experience in making acquisitions and in-licensing is limited. We cannot assure you that any acquisition or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed product candidate. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions and in-licenses. We cannot assure you that we would be able to make the combination of our business with that of acquired businesses or companies or in-licensed product candidates work or be successful. Furthermore, the development or expansion of our business or any acquired business or company or in-licensed product candidate may require a substantial capital investment by us. We may also seek to raise funds by selling shares of our capital stock, which could dilute our current stockholders' ownership interest, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest upon conversion.



***If we are unable to maintain and enforce our proprietary rights, we may not be able to compete effectively or operate profitably.***

Our success is dependent in part on maintaining and enforcing our patents and other proprietary rights and will depend in large part on our ability to:

- defend patents once issued;
- preserve trade secrets; and
- operate without infringing the patents and proprietary rights of third parties.

As of December 31, 2012, we owned approximately 13 U.S. patents and 16 U.S. patent applications, as well as the corresponding foreign patents and patent applications, and held exclusive or partially exclusive licenses to approximately 13 U.S. patents and 8 U.S. patent applications, as well as the corresponding foreign patents and patent applications. The degree of future protection for our proprietary rights is uncertain. For example:

- we might not have been the first to make the inventions covered by any of our patents, if issued, or our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or products and/or duplicate any of our technologies and/or products;
- it is possible that none of our pending patent applications will result in issued patents or, if issued, these patents may not be sufficient to protect our technology or provide us with a basis for commercially-viable products and may not provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as infringed, invalid or unenforceable under U.S. or foreign laws;
- if issued, the patents under which we hold rights may not be valid or enforceable; or
- we may develop additional proprietary technologies that are not patentable and which may not be adequately protected through trade secrets, if for example a competitor were to independently develop duplicative, similar or alternative technologies.

The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves many complex legal and technical issues. There is no clear policy involving the breadth of claims allowed in patents or the degree of protection afforded under patents. Although we believe our potential rights under patent applications provide a competitive advantage, it is possible that patent applications owned by or licensed to us will not result in patents being issued, or that, if issued, the patents will not give us an advantage over competitors with similar products or technology, nor can we assure you that we can obtain, maintain and enforce all ownership and other proprietary rights necessary to develop and commercialize our product candidates.

In addition to the intellectual property and other rights described above, we also rely on unpatented technology, trade secrets, trademarks and confidential information, particularly when we do not believe that patent protection is appropriate or available. However, trade secrets are difficult to protect and it is possible that others will independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our unpatented technology, trade secrets and confidential information. We require each of our employees, consultants and advisors to execute a confidentiality and invention assignment agreement at the commencement of an employment or consulting relationship with us. However, it is possible that these agreements will not provide effective protection of our confidential information or, in the event of unauthorized use of our intellectual property or the intellectual property of third parties, provide adequate or effective remedies or protection.

***If we are unable to obtain intellectual property rights to develop or market our products or we infringe on a third-party patent or other intellectual property rights, we may need to alter or terminate a product development program.***

If our vaccine technology or our product candidates infringe or conflict with the rights of others, we may not be able to manufacture or market our product candidates, which could have a material and adverse effect on us and on our collaboration with Merck KGaA.

Issued patents held by others may limit our ability to develop commercial products. All issued patents are entitled to a presumption of validity under the laws of the United States. If we need licenses to such patents to permit us to develop or market our product candidates, we may be required to pay significant fees or royalties, and we cannot be certain that we would be able to obtain such licenses on commercially reasonable terms, if at all. Competitors or third parties may obtain patents that may cover subject matter we use in developing the technology required to bring our products to market, that we use in producing our products, or that we use in treating patients with our products.

We know that others have filed patent applications in various jurisdictions that relate to several areas in which we are developing products. Some of these patent applications have already resulted in the issuance of patents and some are still pending. We may be required to alter our processes or product candidates, pay licensing fees or cease activities. Certain parts of our vaccine technology, including the MUC1 antigen, originated from third-party sources.

These third-party sources include academic, government and other research laboratories, as well as the public domain. If use of technology incorporated into or used to produce our product candidates is challenged, or if our processes or product candidates conflict with patent rights of others, third parties could bring legal actions against us, in Europe, the United States and elsewhere, claiming damages and seeking to enjoin manufacturing and marketing of the affected products. Additionally, it is not possible to predict with certainty what patent claims may issue from pending applications. In the United States, for example, patent prosecution can proceed in secret prior to issuance of a patent. As a result, third parties may be able to obtain patents with claims relating to our product candidates, which they could attempt to assert against us. Further, as we develop our products, third parties may assert that we infringe the patents currently held or licensed by them and it is difficult to provide the outcome of any such action. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations, as a result of claims of patent infringement or violation of other intellectual property rights, which could have a material and adverse effect on our business, financial condition and results of operations.

***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 in, or to use, our technology.***

There has been significant litigation in the biotechnology industry over patents and other proprietary rights and if we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. Others may challenge the validity, inventorship, ownership, enforceability or scope of our patents or other technology used in or otherwise necessary for the development and commercialization of our product candidates. We may not be successful in defending against any such challenges. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license, grant cross-licenses and pay substantial royalties in order to continue to manufacture or market the affected products.

Moreover, the cost of litigation to uphold the validity of patents to prevent infringement or to otherwise protect our proprietary rights can be substantial. If the outcome of litigation is

adverse to us, third parties may be able to use the challenged technologies without payment to us. There is also the risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the inventions, including on the ground that its activities do not infringe that patent. There is no assurance that we would prevail in any legal action or that any license required under a third-party patent would be made available on acceptable terms or at all. If any of these events were to occur, our business, financial condition and results of operations would be materially and adversely effected.

***If any products we develop become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, our ability to successfully commercialize our products will be impaired.***

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payers to contain or reduce the costs of health care through various means. We expect a number of federal, state and foreign proposals to control the cost of drugs through government regulation. We are unsure of the impact recent health care reform legislation may have on our business or what actions federal, state, foreign and private payers may take in response to the recent reforms. Therefore, it is difficult to provide the effect of any implemented reform on our business. Our ability to commercialize our products successfully will depend, in part, on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, particularly for indications for which there is no current effective treatment or for which medical care typically is not sought. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development. If adequate coverage and reimbursement levels are not provided by government and third-party payers for use of our products, our products may fail to achieve market acceptance and our results of operations will be harmed.

***Governments often impose strict price controls, which may adversely affect our future profitability.***

We intend to seek approval to market our future products in both the United States and foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product. In some foreign countries, particularly in the European Union, prescription drug pricing is subject to government control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our future product to other available therapies.

In addition, it is unclear what impact, if any, recent health care reform legislation will have on the price of drugs in the United States. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry.

We anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and downward pressure on the price for any approved product, and could seriously harm our prospects. Any reduction in reimbursement from Medicare or other government programs may result

in a similar reduction in payments from private payers. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

***We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.***

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

Although we currently have product liability insurance coverage for our clinical trials for expenses or losses up to a \$10 million aggregate annual limit, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any or all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

***We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.***

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. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product candidates. We expect any product candidate that we commercialize with our collaborative partners or on our own will compete with existing, market-leading products and products in development.

*L-BLP25.* There are currently two products approved as maintenance therapy following treatment of inoperable locoregional Stage III NSCLC with induction chemotherapy, Tarceva (erlotinib), a targeted small molecule from Genentech, Inc., a member of the Roche Group, and Alimta (pemetrexed), a chemotherapeutic from Eli Lilly and Company. L-BLP25 has not been tested in combination with or in comparison to these products. It is possible

that other existing or new agents will be approved for this indication. In addition, there are at least three vaccines in development for the treatment of NSCLC, including GSK's MAGE A3 vaccine in Phase 3, NovaRx Corporation's Lucanix in Phase 3 and Transgene's TG-4010 in Phase 2. TG-4010 also targets MUC1, although using technology different from L-BLP25. Of these vaccines, only Lucanix is being developed as a maintenance therapy in Stage III NSCLC, the same indication as L-BLP25. However, subsequent development of these vaccines, including L-BLP25, may result in additional direct competition.

*Small Molecule Products.* We have two small molecule programs in development; PX-866 and ONT-701. PX-866 is an inhibitor of PI-3-kinase. We are aware of numerous companies that have entered clinical trials with competing compounds targeting the same protein, many of which have significantly greater financial, manufacturing, marketing and drug development resources than we do. Among these competitors are Novartis (Phase 3), Roche/Genentech (Phase 2), Bayer (Phase 1), Sanofi-Aventis (Phase 2), Chugai (Phase 1) and GlaxoSmithKline (Phase 1/2). There are also several approved targeted therapies for cancer and in development against which PX-866 might compete. ONT-701 is a small molecule inhibitor of the Bcl-2 anti-apoptotic protein family. We are aware of at least one company that is developing a competing drug that targets the same family, Ascenta (Phase 2). There are also several approved targeted therapies for cancer and in development against which our small molecule product candidates might compete.

Many of our potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on our ability to:

- design and develop products that are superior to other products in the market;
- attract qualified scientific, medical, sales and marketing and commercial personnel;
- obtain patent and/or other proprietary protection for our processes and product candidates;
- obtain required regulatory approvals; and
- successfully collaborate with others in the design, development and commercialization of new products.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidates obsolete. In addition, any new product that competes with a generic market-leading product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome severe price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

***If we are unable to enter into agreements with partners to perform sales and marketing functions, or build these functions ourselves, we will not be able to commercialize our product candidates.***

We currently do not have any internal sales, marketing or distribution capabilities. In order to commercialize any of our product candidates, we must either acquire or internally develop a sales, marketing and distribution infrastructure or enter into agreements with partners to perform these services for us. Under our agreements with Merck KGaA, Merck KGaA is responsible for developing and commercializing L-BLP25, and any problems with that relationship could delay the development and commercialization of L-BLP25. Additionally, we may not be able to enter into arrangements with respect to our product candidates not covered by the Merck KGaA agreements on commercially acceptable terms,

if at all. Factors that may inhibit our efforts to commercialize our product candidates without entering into arrangements with third parties include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating a sales and marketing organization.

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing and distribution infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

***If we lose key personnel, or we are unable to attract and retain highly-qualified personnel on a cost-effective basis, it would be more difficult for us to manage our existing business operations and to identify and pursue new growth opportunities.***

Our success depends in large part upon our ability to attract and retain highly qualified scientific, clinical, manufacturing, and management personnel. In addition, future growth will require us to continue to implement and improve our managerial, operational and financial systems, and continue to retain, recruit and train additional qualified personnel, which may impose a strain on our administrative and operational infrastructure. Any difficulties in hiring or retaining key personnel or managing this growth could disrupt our operations. The competition for qualified personnel in the biopharmaceutical field is intense. We are highly dependent on our continued ability to attract, retain and motivate highly-qualified management, clinical and scientific personnel. Due to our limited resources, we may not be able to effectively recruit, train and retain additional qualified personnel. If we are unable to retain key personnel or manage our growth effectively, we may not be able to implement our business plan.

Furthermore, we have not entered into non-competition agreements with all of our key employees. In addition, we do not maintain “key person” life insurance on any of our officers, employees or consultants. The loss of the services of existing personnel, the failure to recruit additional key scientific, technical and managerial personnel in a timely manner, and the loss of our employees to our competitors would harm our research and development programs and our business.

***Our business is subject to increasingly complex environmental legislation that has increased both our costs and the risk of noncompliance.***

Our business may involve the use of hazardous material, which will require us to comply with environmental regulations. We face increasing complexity in our product development as we adjust to new and upcoming requirements relating to the materials composition of many of our product candidates. If we use biological and hazardous materials in a manner that causes contamination or injury or violates laws, we may be liable for damages. Environmental regulations could have a material adverse effect on the results of our operations and our financial position. We maintain insurance under our general liability policy for any liability associated with our hazardous materials activities, and it is possible in the future that our coverage would be insufficient if we incurred a material environmental liability.

***If we fail to establish and maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which would adversely affect our consolidated operating results, our ability to operate our business, and our stock price and could result in litigation or similar actions.***

Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause the trading price of our common stock to fall dramatically. Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the company will have been detected.

For the year ended December 31, 2011, we and our independent registered public accounting firm identified a material weakness in our internal controls that is described in "Item 9A— Controls and Procedures – Management's Report on Internal Control over Financial Reporting," of our Annual Report on Form 10-K/A for the year ended December 31, 2011. Remediation of the material weakness was fully completed as of December 31, 2012. We cannot be certain that the actions we are taking to improve our internal controls over financial reporting will be sufficient or that we will be able to implement our planned processes and procedures in a timely manner. In future periods, if the process required by Section 404 of the Sarbanes-Oxley Act reveals any other material weaknesses or significant deficiencies, the correction of any such material weaknesses or significant deficiencies could require additional remedial measures which could be costly and time-consuming. In addition, in such a case, we may be unable to produce accurate financial statements on a timely basis. Any associated accounting restatement could create a significant strain on our internal resources and cause delays in our release of quarterly or annual financial results and the filing of related reports, increase our cost and cause management distraction. Any of the foregoing could cause investors to lose confidence in the reliability of our consolidated financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

#### **Risks Related to the Ownership of Our Common Stock**

##### ***The trading price of our common stock may be volatile.***

The market prices for and trading volumes of securities of biotechnology companies, including our securities, have been historically volatile. In particular, we experienced significant volatility after we and Merck KGaA announced in December 2012 that L-BLP25 failed to meet its primary endpoint in a Phase 3 trial. The market has from time to time experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. The market price of our common shares may fluctuate significantly due to a variety of factors, including:

- the results of pre-clinical testing and clinical trials by us, our collaborators, our competitors and/or companies that are developing products that are similar to ours (regardless of whether such products are potentially competitive with ours);

- public concern as to the safety of products developed by us or others
- technological innovations or new therapeutic products;
- governmental regulations;
- developments in patent or other proprietary rights;
- litigation;
- comments by securities analysts;
- the issuance of additional shares of common stock, or securities convertible into, or exercisable or exchangeable for, shares of our common stock in connection with financings, acquisitions or otherwise;
- the incurrence of debt;
- general market conditions in our industry or in the economy as a whole; and
- political instability, natural disasters, war and/or events of terrorism.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

***We may seek to raise additional capital in the future; however, such capital may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing stockholders would experience further dilution.***

We expect that we will seek to raise additional capital from time to time in the future. For example, in connection with our April 2012 underwritten public offering, we sold an aggregate of 13,512,500 shares of our common stock. Future financings may involve the issuance of debt, equity and/or securities convertible into or exercisable or exchangeable for our equity securities. These financings may not be available to us on reasonable terms or at all when and as we require funding. If we are able to consummate such financings, the trading price of our common stock could be adversely affected and/or the terms of such financings may adversely affect the interests of our existing stockholders. Any failure to obtain additional working capital when required would have a material adverse effect on our business and financial condition and would be expected to result in a decline in our stock price. Any issuances of our common stock, preferred stock, or securities such as warrants or notes that are convertible into, exercisable or exchangeable for, our capital stock, would have a dilutive effect on the voting and economic interest of our existing stockholders.

In February 2012 we entered into an agreement with Cowen and Company, LLC to sell shares of our common stock having aggregate sales proceeds of \$50,000,000, from time to time, through an "at the market" equity offering program under which Cowen will act as sales agent. If we access the "at the market" equity offering program, we will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of our agreement with Cowen, they may sell the shares by methods deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act, including sales made directly on The NASDAQ Global Market or other trading market or through a market maker. The sale of additional shares of our common stock pursuant to our agreement with Cowen will have a dilutive impact on our existing stockholders. Sales by us through Cowen could cause the market price of our common stock to decline significantly. Sales of our common stock under such agreement,



or the perception that such sales will occur, could encourage short sales by third parties, which could contribute to the further decline of our stock price.

***Because we do not expect to pay dividends on our common stock, stockholders will benefit from an investment in our common stock only if it appreciates in value.***

We have never paid cash dividends on our common shares and have no present intention to pay any dividends in the future. We are not profitable and do not expect to earn any material revenues for at least several years, if at all. As a result, we intend to use all available cash and liquid assets in the development of our business. Any future determination about the payment of dividends will be made at the discretion of our board of directors and will depend upon our earnings, if any, capital requirements, operating and financial conditions and on such other factors as our board of directors deems relevant. As a result, the success of an investment in our common stock will depend upon any future appreciation in its value. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

***We can issue shares of preferred stock that may adversely affect the rights of a stockholder of our common stock.***

Our certificate of incorporation authorizes us to issue up to 10,000,000 shares of preferred stock with designations, rights, and preferences determined from time-to-time by our board of directors. Accordingly, our board of directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights superior to those of holders of our common stock. For example, an issuance of shares of preferred stock could:

- adversely affect the voting power of the holders of our common stock;
- make it more difficult for a third party to gain control of us;
- discourage bids for our common stock at a premium;
- limit or eliminate any payments that the holders of our common stock could expect to receive upon our liquidation; or
- otherwise adversely affect the market price or our common stock.

We have in the past, and we may at any time in the future, issue additional shares of authorized preferred stock.

***We expect our quarterly operating results to fluctuate in future periods, which may cause our stock price to fluctuate or decline.***

Our quarterly operating results have fluctuated in the past, and we believe they will continue to do so in the future. Some of these fluctuations may be more pronounced than they were in the past as a result of the issuance by us in May 2009 and September 2010 of warrants to purchase shares of our common stock in connection with equity financings. As of December 31, 2012, there were outstanding warrants from the May 2009 and September 2010 financings exercisable for up to 2,691,241 shares of our common stock and 3,182,147 shares of our common stock, respectively. These warrants are classified as a liability. Accordingly, the fair value of the warrants is recorded on our consolidated balance sheet as a liability, and such fair value is adjusted at each financial reporting date with the adjustment to fair value reflected in our consolidated statement of operations. The fair value of the warrants is determined using the Black-Scholes option-pricing model. Fluctuations in the assumptions and factors used in the Black-Scholes model can result in adjustments to the fair value of the warrants reflected on our balance sheet and, therefore, our statement of operations. Due to the classification of such warrants and other factors, quarterly results of operations are difficult to forecast, and period-to-period comparisons of our operating results may not be predictive of future performance. In one or more future quarters, our results of operations

may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could decline. In addition, the market price of our common stock may fluctuate or decline regardless of our operating performance.

***Our management will have broad discretion over the use of proceeds from the sale of shares of our common stock and may not use such proceeds in ways that increase the value of our stock price.***

In April 2012, we generated approximately \$50.3 million of net proceeds from the sale of shares of our common stock in an underwritten public offering. We will have broad discretion over the use of proceeds from the sale of those shares and the sale, if any, of additional shares of common stock to Cowen pursuant to the “at the market” equity offering program that replaced our committed equity line financing facility and we could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

**ITEM 1B. *Unresolved Staff Comments***

None.

**ITEM 2. *Properties***

**Description of Property**

In May 2008, we entered into a lease for a facility in Seattle, Washington totaling approximately 17,000 square feet, which includes laboratory space, to house our research and development and administrative activities. The lease expires in December 2018. We believe that our Seattle facility is in good condition, adequately maintained and suitable for the conduct of our business.

**ITEM 3. *Legal Proceedings***

We are not a party to any material legal proceedings with respect to us, our subsidiaries, or any of our material properties.

**ITEM 4. *Mine Safety Disclosures***

**Not applicable.**

## PART II

### ITEM 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

#### Market Information for Common Stock

Our common stock is quoted on the NASDAQ Global Market under the symbol "ONTY". The following table sets forth for the indicated periods the high and low sales prices of our common stock as reported by the NASDAQ Global Market.

	<u>High</u>	<u>Low</u>
Fiscal year ended December 31, 2012:		
First Quarter .....	\$9.23	\$ 4.11
Second Quarter .....	4.92	3.35
Third Quarter .....	6.24	4.03
Fourth Quarter .....	5.58	1.71
Fiscal year ended December 31, 2011:		
First Quarter .....	\$ 4.11	\$2.99
Second Quarter .....	9.61	3.63
Third Quarter .....	11.59	5.67
Fourth Quarter .....	8.61	5.63

#### Dividends

We have never declared nor paid cash dividends on our common stock. We currently expect to retain future earnings, if any, to finance the operation and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

#### Stockholders

As of February 28, 2013, there were 57,216,237 shares of our common stock outstanding held by approximately 675 stockholders of record and approximately 26,500 stockholders in nominee name.

#### Securities Authorized for Issuance under Equity Compensation Plans

For information concerning our equity compensation plans see the section of this Annual Report on Form 10-K captioned "Part III — Item 12 — Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

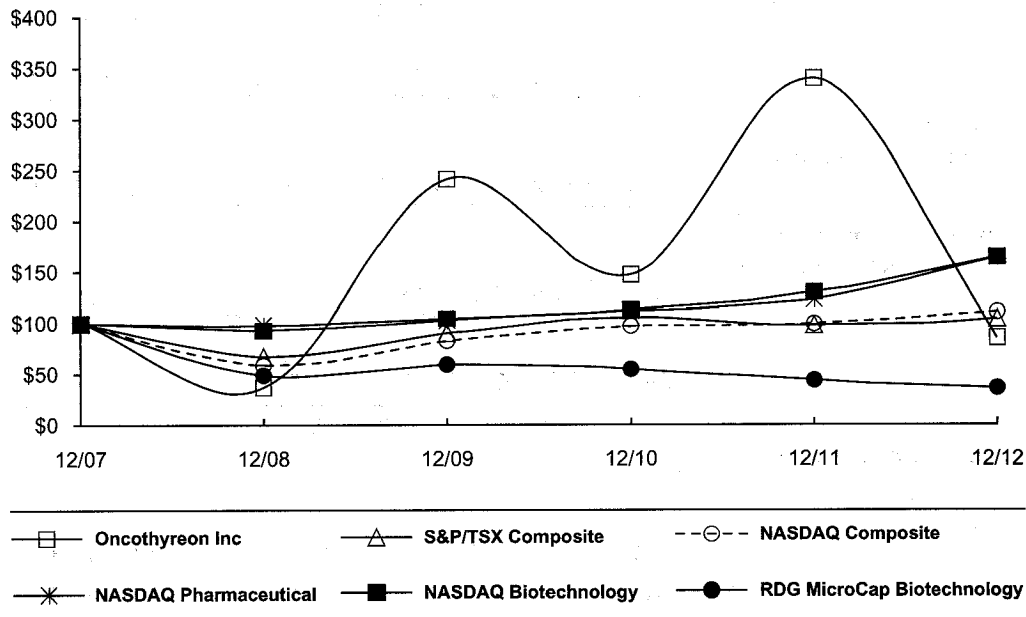
**Stock Performance Graph**

The following information relating to the price performance of our common stock shall not be deemed to be "filed" with the SEC or to be "soliciting material" under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and it shall not be deemed to be incorporated by reference into any of our filings under the Exchange Act or the Securities Act of 1933, as amended, except to the extent we specifically incorporate it by reference into such filing.

The graph below compares the cumulative total stockholder return of our common stock with that of the NASDAQ Pharmaceutical Index, NASDAQ Biotechnology Index, RDG MicroCap Biotechnology Index and a composite S&P/TSX index from December 31, 2007 through December 31, 2012. The comparisons in this graph below are based on historical data and are not intended to forecast or be indicative of future performance of our common stock. The graph assumes that \$100 was invested and that all dividends were reinvested.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***

Among Oncothreon Inc, the S&P/TSX Composite Index, the NASDAQ Composite Index, the NASDAQ Pharmaceutical Index, the NASDAQ Biotechnology Index, and the RDG MicroCap Biotechnology Index



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

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**Unregistered Sale of Equity Securities**

During the three months ended December 31, 2012, we did not issue or sell any shares of our common stock or other equity securities pursuant to unregistered transactions in reliance upon exemption from the registration requirements of the Securities Act of 1933, as amended.

**Issuer Purchases of Equity Securities**

We did not make any purchases of our outstanding common stock during the three months ended December 31, 2012.

## ITEM 6. Selected Financial Data

The data set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this annual report on Form 10-K and also with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Year Ended December 31,				
	2012	2011	2010	2009	2008(1)
	(Amounts in thousands, except share and per share data.)				
<b>Consolidated Statements of Operations Data:</b>					
Total revenues .....	\$ —	\$ 145	\$ 18	\$ 2,078	\$ 40,295
Total operating expenses(1) .....	28,499	24,844	19,502	12,939	33,164
Income (loss) from operations .....	(28,499)	(24,699)	(19,484)	(10,861)	7,131
Net income (loss)(2) .....	\$ (3,415)	\$ (42,656)	\$ (15,618)	\$ (17,219)	\$ 7,422
Income (loss) per share — basic .....	\$ (0.06)	\$ (1.12)	\$ (0.58)	\$ (0.76)	\$ 0.38
Income (loss) per share — diluted .....	\$ (0.53)	\$ (1.12)	\$ (0.72)	\$ (0.76)	\$ 0.38
Weighted average number of common shares outstanding — basic .....	53,728,672	38,197,666	26,888,588	22,739,138	19,490,621
Weighted average number of common shares outstanding — diluted .....	54,899,955	38,197,666	26,972,969	22,739,138	19,570,170

	As of December 31,				
	2012	2011	2010	2009	2008(1)
	(Amounts in thousands, except share data.)				
<b>Consolidated Balance Sheets Data:</b>					
Cash, cash equivalents and short-term investments .....	\$ 81,254	\$ 63,876	\$ 28,877	\$ 33,218	\$ 19,166
Total assets .....	\$ 89,435	\$ 71,539	\$ 34,445	\$ 38,225	\$ 24,971
Total long-term liabilities .....	\$ 4,041	\$ 33,236	\$ 13,727	\$ 10,732	\$ 578
Stockholders' equity .....	\$ 82,323	\$ 33,433	\$ 18,857	\$ 25,418	\$ 20,717
Common shares outstanding .....	57,216,237	43,613,107	30,088,628	25,753,405	19,492,432

(1) The effect of the asset purchase agreement and 2008 license agreement with Merck KGaA is reflected for the year ended December 31, 2008. See "Note 8 — Collaborative and License Agreements" of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

(2) Net income(loss) includes income(expense) from the change in fair market value of warrant liability of \$25.5, (\$17.6), \$3.0, (\$6.2) and \$0 million for the years ended December 31, 2012, 2011, 2010, 2009 and 2008 respectively. Please refer to the audited financial statements included elsewhere in this Annual Report on Form 10-K for details on net income (loss) for the years ended December 31, 2012, 2011 and 2010. For additional information on net income (loss) for the years ended December 31, 2009 and 2008, please refer to our Annual Reports on Form 10-K or Form 10-K/A.

## **ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this report. All dollar amounts included in this discussion and analysis of our financial condition and results of operations represent U.S. dollars unless otherwise specified. Throughout this discussion, unless the context specifies or implies otherwise, the terms "Company," "Oncothyreon," "Biomira," "we," "us," and "our" refer to Oncothyreon Inc., its predecessor, Biomira Inc., and its subsidiaries.*

### **Overview**

We are a clinical-stage biopharmaceutical company focused primarily on the development of therapeutic products for the treatment of cancer. Our goal is to develop and commercialize novel synthetic vaccines and targeted small molecules that have the potential to improve the lives and outcomes of cancer patients. Our cancer vaccines are designed to stimulate the immune system to attack cancer cells, while our small molecule compounds are designed to inhibit the activity of specific cancer-related proteins. We are advancing our product candidates through in-house development efforts and strategic collaborations.

Our lead cancer vaccine product candidate, L-BLP25 (formerly known as Stimuvax), is being evaluated for the treatment of non-small cell lung cancer, or NSCLC. We have granted an exclusive, worldwide license to Merck KGaA of Darmstadt, Germany, or Merck KGaA, for the development, manufacture and commercialization of L-BLP25. In December 2012 Merck KGaA announced that the Phase 3 START trial of L-BLP25 did not meet its primary endpoint of an improvement in overall survival in patients with unresectable, locally advanced stage IIIA or stage IIIB NSCLC. Merck KGaA also announced, however, that notable treatment effects were seen for L-BLP25 in certain subgroups. Merck KGaA has stated that they are consulting with external experts and regulatory authorities to determine potential next steps, if any, for L-BLP25. The ongoing clinical program of L-BLP25 that includes studies in the Asia Pacific region is continuing pending discussion with relevant regulatory agencies. We have also initiated a Phase 1 trial for ONT-10, a cancer vaccine directed against a target similar to L-BLP25, which is proprietary to us. In addition to our vaccine product candidates, we have developed novel vaccine technology we may further develop ourselves and/or license to others, including the novel vaccine adjuvant PET-Lipid A.

We are also developing novel targeted small molecules for the treatment of cancer. Our most advanced targeted small molecule is PX-866, for which we are currently conducting four Phase 2 trials in a variety of cancer indications with results expected in 2013. PX-866 is an irreversible, pan-isoform phosphatidylinositol-3-kinase, or PI-3-kinase inhibitor we obtained when we acquired ProIX Pharmaceuticals Corporation in 2006. We are also developing ONT-701, a preclinical pan-inhibitor of the B-cell lymphoma-2, or Bcl-2, family of anti-apoptotic proteins. Overexpression of one or more of the Bcl-2 family of proteins is common in most human cancers. We obtained rights to ONT-701 as part of an exclusive, worldwide license agreement with SBMRI. As of the date of this report, we have not licensed any rights to our small molecules to any third party and retain all development, commercialization and manufacturing rights.

We believe the quality and breadth of our product candidate pipeline, strategic collaborations and scientific team will potentially enable us to become an integrated biopharmaceutical company with a diversified portfolio of novel, commercialized therapeutics for major diseases.

In May 2001, we entered into a collaborative arrangement with Merck KGaA to pursue joint global product research, clinical development and commercialization of L-BLP25. The collaboration covered the entire field of oncology for this product candidate and was documented in collaboration and supply agreements, which we refer to as the 2001 agreements. In connection with the execution of the 2001 collaboration and supply agreements, we received up-front cash payments of \$2.8 million and \$4.0 million, respectively. In January 2006, we and Merck KGaA entered into a binding letter of intent, pursuant to which the 2001 agreements were amended and we granted additional rights to Merck KGaA. In August 2007, we amended and restated our collaboration and supply agreements with Merck KGaA, which we refer to as the 2007 agreements, which restructured the 2001 agreements and formalized the terms set forth in the 2006 letter of intent. As a result of the 2007 agreements, Merck KGaA obtained an exclusive world-wide license with respect to the development and commercialization of L-BLP25. We had responsibility for the development of the manufacturing process and plans for the scale-up for commercial manufacturing and Merck KGaA had the right to act as a secondary manufacturer of L-BLP25. We also continued to be responsible for manufacture of the clinical and commercial supply of L-BLP25 for which Merck KGaA agreed to pay us our cost of goods and provisions for certain contingent payments to us related to manufacturing scale-up and process transfer were added.

The entry into the 2007 agreements triggered a \$2.5 million payment to us contemplated by the 2006 letter of intent, which we received in September 2007. In addition, under the 2007 agreements, we were entitled to receive (1) a \$5.0 million payment tied to the transfer of certain assays and methodology related to the manufacture of L-BLP25, which we received in December 2007, a \$3.0 million payment tied to the transfer of certain L-BLP25 manufacturing technology, which we received in May 2008, and a \$2.0 million payment tied to the earlier of receipt of the first manufacturing run at commercial scale of L-BLP25 and December 31, 2009, which we received in December 2009, (2) various additional contingent payments up to a maximum of \$90.0 million in the aggregate tied to a biologics license application, or BLA, submission for first and second cancer indications, for regulatory approval of first and second cancer indications, and for various sales milestones, (3) royalties in the low twenties based on net sales outside of North America and (4) royalties based on net sales inside of North America with percentages in the mid-twenties, depending on the territory in which the net sales occur. If the manufacturing process payments due by December 31, 2009 were paid in full, the royalty rates would be reduced in all territories by 1.25%, relative to the 2001 agreements and the letter of intent.

In December 2008, we entered into a license agreement with Merck KGaA which replaced the 2007 agreements. Pursuant to the 2008 license agreement, in addition to the rights granted pursuant to the 2007 agreements, (1) we licensed to Merck KGaA the exclusive right to manufacture L-BLP25 and the right to sublicense to other persons all such rights licensed, (2) we transferred certain manufacturing know-how to Merck KGaA, (3) we agreed not to develop any product, other than ONT-10, that is competitive with L-BLP25 and (4) we granted to Merck a right of first negotiation in connection with any contemplated collaboration or license agreement with respect to the development or commercialization of ONT-10. Upon the execution of the 2008 license agreement, all of our future performance obligations related to the collaboration for the clinical development and development of the manufacture process of L-BLP25 were removed and our continuing involvement in the development and manufacturing of L-BLP25 ceased. In return for the license of manufacturing rights and transfer of manufacturing know-how, we received an up-front cash payment of approximately \$10.5 million. The provisions with respect to contingent payments under the 2007 agreements remained unchanged, and we may receive cash payments of up to \$90 million, which figure excludes the \$2.0 million received in December 2009 and \$19.8 million received prior to the execution of the 2008

license agreement. We are also entitled to receive royalties based on net sales of L-BLP25 ranging from a percentage in the mid-teens to high single digits, depending on the territory in which the net sales occur. Royalty rates were reduced relative to prior agreements by a specified amount that we believe is consistent with our estimated costs of goods, manufacturing scale-up costs and certain other expenses assumed by Merck KGaA.

In connection with the entry into the 2008 license agreement, we also entered into an asset purchase agreement, which, together with the 2008 license agreement we refer to as the 2008 agreements, pursuant to which we sold to Merck KGaA certain assets related to the manufacture and inventory of L-BLP25, placebo and raw materials, and Merck KGaA agreed to assume certain liabilities related to the manufacture of L-BLP25 and our obligations related to the lease of our Edmonton, Alberta, Canada facility. The plant and equipment in the Edmonton facility and inventory of raw materials, work-in-process and finished goods were sold for a purchase price of \$0.6 million (including the assumption of lease obligation of \$56,000) and \$11.2 million, respectively. The purchase price of the inventory was first offset against advances made in prior periods resulting in net cash to us of \$2.0 million. In addition, 43 employees at our former Edmonton facility were transferred to an affiliate of Merck KGaA, significantly reducing our operating expenses related to this program.

For additional information regarding our relationship with Merck KGaA, see “Note 8 – Collaborative and License Agreements” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

We have not developed a therapeutic product to the commercial stage. As a result, with the exception of the unusual effects of the transaction with Merck KGaA in December 2008, our revenue has been limited to date, and we do not expect to recognize any material revenue for the foreseeable future. In particular, our ability to generate revenue in future periods will depend substantially on the progress of ongoing clinical trials for L-BLP25 and our small molecule compounds, our ability to obtain development and commercialization partners for our small molecule compounds, Merck KGaA’s success in obtaining regulatory approval for L-BLP25, our success in obtaining regulatory approval for our small molecule compounds, and Merck KGaA’s and our respective abilities to establish commercial markets for these drugs.

Any adverse clinical results relating to L-BLP25 or any decision by Merck KGaA to discontinue its efforts to develop and commercialize the product would have a material and adverse effect on our future revenues and results of operations and would be expected to have a material adverse effect on the trading price of our common stock. Our small molecule compounds are much earlier in the development stage than L-BLP25, and we do not expect to realize any revenues associated with the commercialization of our products candidates for the foreseeable future.

The continued research and development of our product candidates will require significant additional expenditures, including preclinical studies, clinical trials, manufacturing costs and the expenses of seeking regulatory approval. We rely on third parties to conduct a portion of our preclinical studies, all of our clinical trials and all of the manufacturing of cGMP material. We expect expenditures associated with these activities to increase in future years as we continue the development of our small molecule product candidates and ONT-10.

We have incurred substantial losses since our inception. As of December 31, 2012, our accumulated deficit totaled \$393.3 million. We incurred a net loss of \$3.4 million for 2012 compared to a net loss of \$42.7 million for 2011 primarily due to the noncash income from the change in the fair value of the warrant liability. The change in the fair value of the warrant liability is primarily due to changes in our stock price. In future periods, we expect to continue to incur substantial net losses as we expand our research and development activities with respect to our small molecules product candidates. To date we have funded



our operations principally through the sale of our equity securities, cash received through our strategic alliance with Merck KGaA, government grants, debt financings, and equipment financings. In September 2010, we completed a financing in which we raised approximately \$13.6 million in net proceeds. In addition, in February 2011, we entered into a loan and security agreement, which we refer to as the loan agreement, pursuant to which we incurred \$5.0 million in term loan indebtedness. In June 2012, we paid approximately \$4.1 million to extinguish our term loan prior to its maturity date. In May 2011, we completed a financing, in which we issued an aggregate of 11.5 million shares and generated net proceeds of approximately \$43.1 million. In October 2011, we sold an aggregate of 639,071 shares of our common stock at a per share price of approximately \$6.43 resulting in net proceeds of \$4.1 million. In November 2011, we sold an aggregate of 805,508 shares of our common stock at a per share purchase price of approximately \$6.21 resulting in net proceeds of \$4.9 million. During 2011, warrants with respect to 402,101 underlying shares of our common stock were exercised, resulting in gross proceeds of approximately \$1.9 million. In April 2012, we completed a financing in which we issued an aggregate of 13.5 million shares and generated net proceeds of approximately \$50.3 million. See “-Liquidity and Capital Resources” below and “Note 5 – Notes Payable” of the audited financial statements included elsewhere in this Annual Report on Form 10-K for additional information. Because we have limited revenues and substantial research and development and operating expenses, we expect that we will in the future seek additional working capital funding from the sale of equity, debt securities, or loans or the licensing of rights to our product candidates.

## **Key Financial Metrics**

### ***Revenue***

We had no revenue in 2012. Our revenue in 2011 and 2010 was immaterial; however, the type of revenue described in this section, which relates to revenue from collaborative arrangements, is relevant for 2011 and 2010. Historically, our revenue has been derived from payments under our collaborative and license agreements.

*Licensing Revenue from Collaborative and License Agreements.* Revenue from collaborative and license agreements consists of (1) up-front cash payments for initial technology access or licensing fees and (2) contingent payments triggered by the occurrence of specified events or other contingencies derived from our collaborative and license agreements. Royalties from the commercial sale of products derived from our collaborative and license agreements are reported as licensing, royalties, and other revenue. For more information on revenue recognition for licensing revenue from collaborative and license agreements, see “Critical Accounting Policies and Significant Judgments and Estimates Revenue Recognition Licensing Revenue from Collaborative and License Agreements” below.

### ***Expenses***

*Research and Development.* Research and development consists of costs associated with research activities as well as costs associated with our product development efforts, conducting preclinical studies, and clinical trial and manufacturing costs. These expenses include external research and development expenses incurred pursuant to agreements with third party manufacturing organizations; technology access and licensing fees related to the use of proprietary third party technologies; employee and consultant-related expenses, including salaries, share-based compensation expense, benefits, and related costs; allocated facility overhead, which includes depreciation and amortization; and third party supplier expenses.

We recognize research and development expenses, including those paid to third parties, as they have been incurred.

Our research and development programs are at an early stage and may not result in any approved products. Product candidates that appear promising at early stages of development may not reach the market for a variety of reasons. Similarly, any of our continuing product candidates may be found to be ineffective or cause harmful side effects during clinical trials, may take longer to complete clinical trials than we have anticipated, may fail to receive necessary regulatory approvals, and may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality. As part of our business strategy, we may enter into collaboration or license agreements with larger third party pharmaceutical companies to complete the development and commercialization of our small molecule or other product candidates, and it is unknown whether or on what terms we will be able to secure collaboration or license agreements for any candidate. In addition, it is difficult to provide the impact of collaboration or license agreements, if any, on the development of product candidates. Establishing product development relationships with large pharmaceutical companies may or may not accelerate the time to completion or reduce our costs with respect to the development and commercialization of any product candidate.

*General and Administrative.* General and administrative expense consists principally of salaries, benefits, share-based compensation expense, and related costs for personnel in our executive, finance, accounting, information technology, and human resource functions. Other general and administrative expenses include professional fees for legal, consulting, accounting services and allocation of our facility costs, which includes depreciation and amortization.

*Investment and Other Income (Expense), Net.* Net investment and other income (expense) consists of interest and other income on our cash, short-term investments, long-term investments and foreign exchange gains and losses. Our investments consist of debt securities of U.S. government agencies, corporate bonds and certificates of deposit insured by the Federal Deposit Insurance Corporation. In 2010, we were awarded a federal grant for \$0.5 million under the U.S. Government's Qualifying Therapeutic Discovery Project program, which was recorded as other income since the amounts pertained to expenses incurred in 2009 and 2010. In 2012 we incurred a loss on extinguishment of debt which consists of a prepayment penalty of 3% on the outstanding principal, the write-off of unamortized deferred financing costs and unamortized debt discount and legal expenses. For more information, see "Note 5 — Notes Payable" of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

*Interest Expense.* Interest expense consists of interest paid and accrued and includes non-cash amortization of the debt discount and capitalized loan fees. For more information, see "Note 5 — Notes Payable" of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

*Change in Fair Value of Warrants.* Warrants issued in connection with our securities offering in September 2010 and May 2009 are classified as a liability due to their settlement features and, as such, were recorded at their estimated fair value on the date of the closing of the transaction. The warrants are marked to market for each financial reporting period, with changes in fair value recorded as a gain or loss in our statement of operations. The fair value of the warrants is determined using the Black-Scholes option-pricing model, which requires the use of significant judgment and estimates for the inputs used in the model. For more information, see "Note 3 — Fair Value Measurements" and "Note 6 — Share Capital" of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

*Income Tax Benefit (Provision) for Income Tax.* Due to our history of significant losses, we do not recognize the benefit of net operating losses and have established a full valuation allowance, since it is more likely than not that these benefits will not be realized. In 2010 we

recorded a tax benefit for recovery of taxes paid in the previous year. In 2012 and 2011, no provision or benefit for income taxes was recorded.

### **Critical Accounting Policies and Significant Judgments and Estimates**

We have prepared this management's discussion and analysis of financial condition and results of operations based on our audited consolidated financial statements, which have been included in this report beginning on page F-1 and which have been prepared in accordance with generally accepted accounting principles in the United States. These accounting principles require us to make significant estimates and judgments that can affect the reported amounts of assets and liabilities as of the dates of our consolidated financial statements as well as the reported amounts of revenue and expense during the periods presented. We believe that the estimates and judgments upon which we rely are reasonable based upon historical experience and information available to us at the time that we make these estimates and judgments. To the extent there are material differences between these estimates and actual results, our consolidated financial statements will be affected.

The Securities and Exchange Commission considers an accounting policy to be critical if it is important to a company's financial condition and results of operations and if it requires the exercise of significant judgment and the use of estimates on the part of management in its application. We have discussed the selection and development of our critical accounting policies with the audit committee of our board of directors, and our audit committee has reviewed our related disclosures in this report. Although we believe that our judgments and estimates are appropriate, actual results may differ from these estimates.

We believe the following to be our critical accounting policies because they are important to the portrayal of our financial condition and results of operations and because they require critical management judgment and estimates about matters that are uncertain:

- revenue recognition;
- goodwill impairment;
- share-based compensation; and
- warrant liability.

### **Revenue Recognition**

We had no revenue in 2012. Our revenue in 2011 and 2010 was immaterial; however, the type of revenue described in this section, which relates to revenue from collaborative arrangements, is relevant for 2011 and 2010. We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. We evaluate revenue from arrangements with multiple deliverables to determine whether the deliverables represent one or more units of accounting. Revenue arrangements entered into, or materially modified, through December 31, 2010 have been accounted for in accordance with accounting standards that state that a delivered item is considered a separate unit of accounting if the following separation criteria are met: (1) the delivered item has stand-alone value to the customer; (2) there is objective and reliable evidence of the fair value of any undelivered items; and (3) if the arrangement includes a general right of return relative to the delivered item, the delivery of undelivered items is probable and substantially in our control. The relevant revenue recognition accounting policy is then applied to each unit of accounting.

Effective January 1, 2011, we adopted new accounting guidance on a prospective basis and will no longer rely on objective and reliable evidence of the fair value of the elements in a revenue arrangement in order to separate a deliverable into a separate unit of accounting.

We will instead use a selling price hierarchy for determining the selling price of a deliverable, which will be used to determine the allocation of consideration to each unit of accounting under an arrangement. The selling price used for each deliverable will be based on vendor-specific objective evidence if available, third-party evidence if vendor-specific objective evidence is not available or estimated selling price if neither vendor-specific objective evidence nor third-party evidence is available. This new guidance will be applied by us to revenue arrangements entered into, or materially modified, beginning January 1, 2011. As of December 31, 2012, we have not entered into any new revenue arrangements, or materially modified any of our existing, revenue arrangements and as such, these provisions do not apply.

We have historically generated revenue from the following activities:

*Licensing Revenue from Collaborative and License Agreements.* Revenue from collaborative and license agreements consists of (1) up-front cash payments for initial technology access or licensing fees and (2) contingent payments triggered by the occurrence of specified events or other contingencies derived from our collaborative and license agreements. Royalties from the commercial sale of products derived from our collaborative and license agreements are reported as licensing, royalties and other revenue.

If we have continuing obligations under a collaborative agreement and the deliverables within the collaboration cannot be separated into their own respective units of accounting, we utilize a multiple attribution model for revenue recognition as the revenue related to each deliverable within the arrangement should be recognized upon the culmination of the separate earnings processes and in such a manner that the accounting matches the economic substance of the deliverables included in the unit of accounting. As such, up-front cash payments are recorded as deferred revenue and recognized as revenue ratably over the period of performance under the applicable agreement.

If we have no continuing obligations under a license agreement, or a license deliverable qualifies as a separate unit of accounting included in a collaborative arrangement, consideration that is allocated to the license deliverable is recognized as revenue upon commencement of the license term and contingent payments are recognized as revenue upon the occurrence of the events or contingencies provided for in such agreement, assuming collectability is reasonably assured.

Effective January 1, 2011, we adopted new accounting guidance for recognizing milestone revenue, which will be applied on a prospective basis. Consideration that is contingent upon achievement of a milestone for research or development deliverables will be recognized in its entirety as revenue in the period in which the milestone is achieved if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the arrangement, such that it: (1) is commensurate with either our performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone; (2) relates solely to past performance; and (3) is reasonable relative to all deliverables and payment terms in the arrangement.

The provisions of the new milestone revenue guidance apply only to those milestones payable for research or development activities and do not apply to contingent payments for which payment is either contingent solely upon the passage of time or the result of a collaborative partner's performance. Our existing collaboration agreements entail no performance obligations on our part, and milestone payments would be earned based on the collaborative partner's performance; therefore, milestone payments under existing agreements are considered contingent payments to be accounted for outside of the new milestone revenue guidance. We will recognize contingent payments as revenue upon the occurrence of the specified events, assuming the payments are deemed collectible at that time.

With respect to our arrangement with Merck KGaA, we determined that the estimated useful life of the products and estimated period of our ongoing obligations corresponded to the estimated life of the issued patents for such product. Under the 2001 agreements, payments that we received were recorded as deferred revenue and recognized ratably over the period from the date of execution of the 2001 agreements to 2011. We chose that amortization period because, at the time, we believed it reflected an anticipated period of "market exclusivity" based upon our expectation of the life of the patent protection, after which the market entry of competitive products would likely occur. Payments received pursuant to the letter of intent and the 2007 agreements were recorded as deferred revenue and recognized ratably over the remaining estimated product life of L-BLP25, which was until 2018. Upon entering into the 2008 agreements, all of our future performance obligations related to our collaboration with Merck KGaA regarding L-BLP25 were removed and our continuing involvement in the development and manufacturing of L-BLP25 ceased; therefore, we recognized the balance of all previously recorded deferred revenue relating to our arrangement with Merck KGaA. Similarly, our receipt of the final manufacturing process transfer milestone payment in December 2009 was recognized since we had no continuing obligations pursuant to such arrangement. Any future contingent payments we receive pursuant to the 2008 license agreement will be immediately recognized in revenue.

### ***Goodwill Impairment***

Goodwill is not amortized, but is reviewed annually for impairment on October 1 of each year, or more frequently when events or changes in circumstances indicate that the asset may be impaired. As of December 31, 2012, we had one reporting unit and there was an excess of fair value compared to the carrying value. There were no impairment charges recorded for any of the periods presented.

### ***Share-based Compensation***

We maintain a share option plan under which an aggregate of 2,934,453 shares of common stock underlie outstanding options as of December 31, 2012 and an aggregate of 1,852,606 shares of common stock were available for future issuance. We maintain an Employee Stock Purchase Plan, or ESPP, under which a total of 900,000 shares of common stock were reserved for sale to employees of the Company. As of December 31, 2012, there were 752,173 shares reserved for future purchases. We maintain a restricted share unit plan under which an aggregate of 140,968 shares of common stock underlie restricted stock units, or RSUs, as of December 31, 2012 and an aggregate of 170,898 shares of common stock were available for future issuance as of December 31, 2012. We have generally granted options to our employees and directors under the share option plan, and we have granted RSUs to non-employee directors under the RSU plan. Pursuant to an October 2011 amendment to the RSU plan, we are required to settle 25% of the shares of our common stock otherwise deliverable in connection with the vesting of any RSU and deliver to each non-employee director an amount in cash equal to the fair market value of the shares on the vesting date. The amendment is designed to facilitate satisfaction of the non-employee directors' income tax obligation with respect to the vested RSUs. This modification resulted in the RSUs being classified as a liability. The outstanding RSU awards are required to be remeasured at each reporting date until settlement of the award, and any changes in valuation are recorded as compensation expense for the period. To the extent that the liability recorded in the balance sheet is less than the original award value, the difference is recognized in equity.

We use the closing share price of our shares in The NASDAQ Global Market at the reporting or settlement date to determine the fair value of RSUs. We use the Black-Scholes option pricing model for determining the estimated fair value for our share option plan and employee stock purchase plan awards, which requires the use of highly subjective and

complex assumptions to determine the fair value of stock-based awards, including the option's expected term and the price volatility of the underlying stock. We recognize the value of the portion of the awards that is ultimately expected to vest as non-cash expense over the requisite vesting periods on a straight-line basis for the entire award in our consolidated statements of operations. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We base our risk free interest rate for the expected term of the option on the yield available on a U.S. Treasury security with an equivalent expected term. The expected life of options in years represents the period of time stock-based awards are expected to be outstanding and was determined based on the simplified method. The expected volatility is based on the historical volatility of our common stock for a period equal to the stock option's expected life. For more information, see "Note 7 — Share-based Compensation" of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

### **Warrant liability**

In May 2009 and September 2010, we issued warrants to purchase 2,909,244 and 3,182,147 shares of our common stock respectively in connection with a registered direct offering of our common stock and warrants. These warrants are classified as liabilities due to potential cash settlement upon the occurrence of certain transactions specified in the warrant agreement. Accordingly, the estimated fair value of the outstanding warrants is recorded on our consolidated balance sheet as a liability, and such fair value is adjusted at each financial reporting period with the adjustment to fair value reflected in our consolidated statement of operations. The fair value of the warrants is determined using the Black-Scholes option pricing model. Fluctuations in the assumptions and factors used in the Black-Scholes model can result in adjustments to the fair value of the warrants reflected on our balance sheet and, therefore, our statement of operations.

### **Results of Operations for the years ended December 31, 2012, 2011 and 2010**

The following table sets forth selected consolidated statements of operations data for each of the periods indicated.

#### **Overview**

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	<u>(In millions, except per share amounts)</u>		
Revenue .....	\$ —	\$ 0.1	\$ —
Operating expenses .....	(28.5)	(24.9)	(19.5)
Other income (expense), net .....	(0.4)	(0.3)	0.7
Change in fair value of warrant liability .....	25.5	(17.6)	3.0
Benefit for income tax .....	—	—	0.2
Net loss .....	<u>\$ (3.4)</u>	<u>\$ (42.7)</u>	<u>\$ (15.6)</u>
Loss per share — basic .....	<u>\$(0.06)</u>	<u>\$(1.12)</u>	<u>\$(0.58)</u>
Loss per share — diluted .....	<u>\$(0.53)</u>	<u>\$(1.12)</u>	<u>\$(0.72)</u>

We incurred a net loss of \$3.4 million in 2012 compared to a net loss of \$42.7 million in 2011. The decrease in our net loss was primarily due to \$25.5 million non-cash income from the change in the fair value of our warrant liability during the year ended December 31, 2012 compared to a \$17.6 million non-cash loss during the year ended December 31, 2011, partially offset by increases in research and development expenses primarily related to the development of PX-866.

The increase in our net loss of \$42.7 million in 2011 compared to a net loss of \$15.6 million in 2010 was primarily driven by a \$17.6 million non-cash loss from the change in the fair value of our warrant liability during the year ended December 31, 2011 compared to a \$3.0 million non-cash income charge during the year ended December 31, 2010. In addition, the increase in our net loss was also due to increases in research and development expenses related to the development of PX-866 and ONT-10. This increase was partly offset by lower general and administrative professional expenses incurred in 2011.

Income or loss associated with the change in fair value of the warrant liability are the result of the remeasurement of the fair value of the warrant liability at each reporting date. Changes in the fair value of the warrant liability are primarily attributable to increases or decreases in our stock price. For more information, see “Note 3 — Fair Value Measurements” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

Based on our development plans for our small molecule and vaccine candidates, we will continue to incur operating losses for the foreseeable future.

**Revenue**

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In millions)		
Licensing revenues from collaborative and license agreements .....	\$—	\$0.1	\$—

We did not recognize any revenue for the years ended December 31, 2012 and 2010. During 2011, we recognized \$0.1 million of previously deferred revenue relating to an agreement with Prima Biomed Limited as we have no continuing performance obligations related to such agreement. We do not expect revenue in 2013.

**Research and Development**

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In millions)		
Research and development .....	\$22.0	\$17.9	\$11.6

The \$4.1 million, or 22.9%, increase in research and development expenses for 2012 compared to 2011 was primarily driven by higher clinical trial expenses of \$6.0 million related to the development of PX-866 and increased salaries and benefits expense of \$1.4 million attributable to increased headcount. Such increase was partly offset by lower preclinical and manufacturing development expenses of \$1.8 million, including a reduction in license payments due to a \$1.5 million payment to SBMRI in 2011. For more information see “Note 8 — Collaborative and License Agreements” of the audited financial statements included elsewhere in this Annual Report on Form 10-K. As we continue with our development on PX-866 and ONT-10, we expect that our research and development costs will be similar in 2013 compared to 2012.

The \$6.3 million, or 54.3%, increase in research and development expenses for 2011 compared to 2010 was primarily driven by higher clinical trial expense of \$2.7 million due to greater activity related to the development of PX-866 compared to 2010. Research and development expenses in 2011 included a license payment of \$1.5 million to SBMRI and higher salaries and benefits expense of \$1.2 million attributable to increased headcount. Preclinical and manufacturing development expenses were higher by \$0.8 million due to greater preclinical and manufacturing activity.

**General and Administrative**

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In millions)		
General and administrative .....	\$6.5	\$6.9	\$7.9

The \$0.4 million, or 5.8%, decrease in general and administrative expense for 2012 relative to 2011 was principally due to a \$1.8 million decrease in director fees primarily related to the decrease in fair value of the outstanding RSUs, which was attributable principally to the decrease in the price of our common stock. The decrease was partially offset by a \$0.6 million increase in salaries and benefits expense attributable to increased headcount, a \$0.6 million increase in professional fees related to patents and regulatory compliance and a \$0.1 million increase in expenses related to insurance and property and business taxes.

The October 2011 amendment to our RSU plan resulted in the RSUs being classified as a liability. The outstanding RSU awards are required to be remeasured at each reporting date until settlement of the award. For more information, see “Note 7 – Share-based Compensation” of the audited financial statements included elsewhere in this Annual Report on Form 10-K. During the year ended December 31, 2012, we recorded a reduction of \$0.7 million in expense for the outstanding RSUs revalued at December 31, 2012.

We expect general and administrative expenses to be higher in 2013 compared to 2012; however, these expenses will be subject to fluctuations related to the changes in the fair value of the RSU liability.

The \$1.0 million decrease in 2011 relative to 2010 was principally due to \$2.0 million lower professional fees incurred in 2011. The decrease was partially offset by higher director fees of \$1.0 million. During the year ended December 31, 2011, we recorded additional expense of \$0.3 million for RSUs that were revalued upon settlement and \$0.7 million for outstanding RSUs revalued at December 31, 2011.

**Investment and Other Income (Expense), Net**

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In millions)		
Investment and other income (expense), net .....	\$(0.1)	\$0.3	\$0.6

Net investment and other income (expense) decreased by \$0.4 million for 2012 compared to 2011 primarily due to a loss of \$0.3 million on early extinguishment of debt during 2012 and derecognition of notes payable in the amount of \$0.2 million during 2011. For additional information on the early extinguishment of debt, see “Note 5 – Notes Payable” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

The \$0.3 million decrease in net investment and other income in 2011 compared to 2010 was primarily attributable to receipt of a government grant of \$0.5 million in 2010. The decrease was partly offset by derecognition of notes payable in the amount of \$0.2 million.

**Interest Expense**

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In millions)		
Interest expense .....	\$0.3	\$0.6	\$—

Interest expense for 2012 decreased by \$0.3 million compared to 2011 primarily due to paying off the outstanding balance of our term loan with GECC in June 2012, prior to its scheduled maturity. Interest expense in 2012 included cash interest payments and non-cash amortization of debt issuance costs and debt discount associated with our term loan with



GECC. For additional information, see “Note 5 — Notes Payable” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

**Change in Fair Value of Warrant Liability**

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In millions)		
Change in fair value of warrant liability .....	\$25.5	\$(17.6)	\$3.0

The \$25.5 million income recorded for the year ended December 31, 2012 was due to the decrease in fair value of warrant liability. Such decrease was attributable principally to the decrease in the price of our common stock and pertains to warrants issued in connection with the September 2010 and May 2009 financings.

The \$17.6 million expense recorded for the year ended 2011 was due to the increase in fair value of warrant liability. Such increase was attributable principally to the increase in the price of our common stock.

**Income tax benefit**

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In millions)		
Income tax benefit .....	\$ —	\$ —	\$0.2

There is no income tax benefit for the years ended December 31, 2012 and 2011. In 2010, we recorded a tax benefit for the recovery of taxes paid in 2009. Given we have incurred substantial losses in historical periods, there are no assurances that we will realize any tax benefits and we have recorded a full valuation allowance against our net deferred tax assets.

**Liquidity and Capital Resources**

**Cash, Cash Equivalents, Short-Term Investments, Long-Term Investments and Working Capital**

As of December 31, 2012, our principal sources of liquidity consisted of cash and cash equivalents of \$22.3 million, short-term investments of \$59.0 million and long-term investments of \$2.5 million. Our cash and cash equivalents consist of cash, money market funds and securities with an initial maturity of less than 90 days. Our short-term investments are invested in debt securities of U.S government agencies and corporate bonds with maturities not exceeding 12 months from the reporting date. Our long-term investments are invested in debt securities of U.S government agencies with maturities exceeding 12 months from the reporting date. Our primary source of cash has historically been proceeds from the issuance of equity securities, exercise of warrants, debt and equipment financings, and payments to us under grants, licensing and collaboration agreements. These proceeds have been used to fund our operations.

Our cash and cash equivalents were \$22.3 million as of December 31, 2012 compared to \$11.6 million as of December 31, 2011, an increase of \$10.7 million, or 92.2%. The increase was primarily attributable to net proceeds of \$50.3 million from our April 2012 underwritten public offering of common stock. Such increase was partially offset by cash used to fund our operations of \$27.3 million, net purchase of investments of \$6.7 million, principal payments of \$0.9 million on notes payable, repayment of \$4.1 million to GECC to extinguish the term loan and purchase of equipment in the amount of \$0.8 million.

As of December 31, 2012, our working capital was \$79.3 million compared to \$59.9 million as of December 31, 2011, an increase of \$19.4 million, or 32.4%. The increase in working capital was primarily attributable to an increase in cash and cash equivalents of

\$10.7 million and an increase in short-term investments of \$6.7 million (as a result of the application of the net proceeds of our April 2012 underwritten public offering of common stock). In addition, such increase was also attributable to a decrease in current portion of notes payable of \$1.7 million.

On February 8, 2011, we entered into a loan agreement with GE Capital, pursuant to which the lenders extended to us a term loan with an aggregate principal amount of \$5.0 million. The proceeds of the term loan, after payment of lender fees and expenses, were approximately \$4.8 million. In June 2012, we paid approximately \$4.1 million to extinguish the loan prior to its scheduled maturity. For more information see "Note 5 – Notes Payable" of the audited financial statements included elsewhere in this Annual Report on Form 10-K. On April 3, 2012, we closed an underwritten public offering of 13,512,500 shares of our common stock at a price to the public of \$4.00 per share. The net proceeds from the sale of the shares, after deducting the underwriters' discounts and other estimated offering expenses payable by us, were approximately \$50.3 million.

We believe that our currently available cash and cash equivalents and investments will be sufficient to finance our operations for at least the next 12 months. Nevertheless, we expect that we will require additional capital from time to time in the future in order to continue the development of products in our pipeline and to expand our product portfolio. We would expect to seek additional financing from the sale and issuance of equity or debt securities, but we cannot provide assurance that financing will be available when and as needed or that, if available, the financing terms will be commercially reasonable. If we are unable to raise additional capital when and if we require, it would have a material adverse effect on our business and results of operations. To the extent we issue additional equity securities, our existing stockholders could experience substantial dilution.

#### ***Cash Flows from Operating Activities***

Cash used in operating activities is primarily driven by our net loss. However, operating cash flows differ from net loss as a result of non-cash charges or differences in the timing of cash flows, changes in warrant liabilities and earnings recognition.

Net cash used in operating activities totaled \$27.3 million in 2012, compared to \$21.2 million in 2011. The increase in net cash used in operating activities for 2012 as compared to 2011 was primarily due to an increase in research and development expenses related to increased activity in the development of PX-866 and ONT-10.

Net cash used in operating activities totaled \$21.2 million in 2011, compared to \$17.7 million in 2010. The increase in net cash used in operating activities for 2011 as compared to 2010 was primarily due to an increase in research and development expenses related to increased activity in the development of PX-866 and ONT-10, which was partially offset by a decrease in general and administrative expenses.

#### ***Cash Flows from Investing Activities***

We had cash outflows of \$7.4 million from investing activities during the year ended December 31, 2012, a decrease of \$24.2 million from the \$31.6 million outflow during the year ended December 31, 2011. This change was attributable principally to a decrease in net purchases of investments of \$24.7 million, partly offset by increased expenditures on capital assets of \$0.6 million.

We had cash outflows of \$31.6 million from investing activities during 2011, an increase of \$22.2 million from the \$9.4 million outflow in 2010. This change was attributable principally to increased net purchases of investments of \$31.4 million in 2011 compared to \$9.1 million in 2010 and lower expenditures on capital assets of \$0.2 million.

### **Cash Flows from Financing Activities**

Cash provided by financing activities during 2012 was \$45.4 million, which consisted primarily \$50.3 million of proceeds from our April 2012 common stock offering. The proceeds from this offering were partially offset by principal payments made on the GECC term loan of \$0.9 million for the first half year of 2012 and the repayment of the GECC term loan of \$4.1 million in June 2012.

Cash provided by financing activities during 2011 was \$58.8 million, which consisted of net proceeds of \$43.1 million from the sale of our common stock pursuant to an underwritten public offering, net proceeds of \$9.0 million received from sale of our common stock pursuant to our equity line financing facility, \$4.8 million received from a term loan with GECC, and approximately \$1.9 million received from warrant exercises. This was partially offset by a principal payment of approximately \$0.1 million on our term loan with GECC.

We generated \$13.7 million in net cash during 2010 from the September 2010 equity financing, which involved the issuance of common stock and warrants.

### **Contractual Obligations and Contingencies**

In our continuing operations, we have entered into long-term contractual arrangements from time to time for our facilities, the provision of goods and services, and the acquisition of technology access rights, among others. The following table presents contractual obligations arising from these arrangements as of December 31, 2012:

	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1 – 3 Years</b>	<b>3 – 5 Years</b>	<b>After 5 Years</b>
Operating leases .....	<u>\$3,641</u>	<u>\$590</u>	<u>\$1,208</u>	<u>\$1,239</u>	<u>\$604</u>

In May 2008, we entered into a lease for an office and laboratory facility in Seattle, Washington totaling approximately 17,000 square feet. The lease provides for a base monthly rent of \$47,715, increasing to \$52,259 in 2018. We also have entered into operating lease obligations through June 2017 for certain office equipment.

In connection with the acquisition of ProIX, we may become obligated to issue additional shares of our common stock to the former stockholders of ProIX upon satisfaction of certain milestones. We may become obligated to issue shares of our common stock with a fair market value of \$5.0 million (determined based on a weighted average trading price at the time of issuance) upon the initiation of the first Phase 3 clinical trial for a ProIX product that qualifies as a “subject product” as such term is defined in the ProIX acquisition agreement, which we refer to as a ProIX product. We may also become obligated to issue shares of our common stock with a fair market value of \$10.0 million (determined based on a weighted average trading price at the time of issuance) upon regulatory approval of a ProIX product in a major market.

Under certain licensing arrangements for technologies incorporated into our product candidates, we are contractually committed to payment of ongoing licensing fees and royalties, as well as contingent payments when certain milestones (as defined in the agreements) have been achieved.

### **Guarantees and Indemnification**

In the ordinary course of our business, we have entered into agreements with our collaboration partners, vendors, and other persons and entities that include guarantees or indemnity provisions. For example, our agreements with Merck KGaA contain certain tax indemnification provisions, and we have entered into indemnification agreements with our officers and directors. Based on information known to us as of December 31, 2012, we believe that our exposure related to these guarantees and indemnification obligations is not material.

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

During the period presented, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for another contractually narrow or limited purpose.

### **Recent Accounting Pronouncements**

In September 2011, Financial Accounting Standards Board, or FASB issued guidance on testing goodwill for impairment. The guidance simplifies how an entity tests goodwill for impairment. It allows an entity the option to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. An entity is no longer required to calculate the fair value of a reporting unit unless the entity determines, based on a qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The guidance was effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this accounting pronouncement on January 1, 2012 has no impact on our financial position or results of operations.

In June 2011, FASB and the International Accounting Standards Board, or IASB issued guidance on presentation of items within other comprehensive income. The guidance requires an entity to present components of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive statements. The option to report other comprehensive income and its components in the statement of stockholders' equity has been eliminated. Although the new guidance changes the presentation of comprehensive income, there are no changes to the components that are recognized in net income or other comprehensive income under existing guidance. We adopted these standards using the two separate but consecutive statements approach on January 1, 2012 for all periods presented, which impacted presentation only and had no effect on our financial position or results of operations.

In May 2011, FASB and the IASB published converged standards on fair value measurement and disclosure. The standards do not require additional fair value measurements and are not intended to establish valuation standards or affect valuation practices outside of financial reporting. The standards clarified some existing rules and provided guidance for additional disclosures: (1) the concepts of "highest and best use" and "valuation premise" in a fair value measurement are relevant only when measuring the fair value of nonfinancial assets and are not relevant when measuring the fair value of financial assets or of liabilities; (2) when measuring the fair value of instruments classified in equity (for example, equity issued in a business combination), the entity should measure it from the perspective of a market participant that holds that instrument as an asset; and (3) quantitative information about the unobservable inputs used in Level 3 measurements should be included. The amendments in this update are applied prospectively. For public entities, the amendments are effective during interim and annual periods beginning after December 15, 2011. The adoption of this new accounting pronouncement on January 1, 2012 only impacted the disclosures within our financial statements, and not our financial position or results of operations.

### **ITEM 7A. Quantitative and Qualitative Disclosure About Market Risk**

#### **Foreign Currency Exchange Risk**

We are not exposed to any significant foreign exchange risk.

## **Interest Rate Sensitivity**

We had cash, cash equivalents, short-term investments and long-term investment totaling \$83.8 million and \$66.4 million as of December 31, 2012 and 2011, respectively. We do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates since a majority of these assets are of a short term nature. Declines in interest rates, however, would reduce future investment income. A 10 basis points decline in interest rates, occurring January 1, 2012 and sustained throughout the period ended December 31, 2012, would have resulted in a decline in investment income of approximately \$75,080 for that same period.

## **ITEM 8. *Financial Statements and Supplementary Data***

See Financial Statements beginning on page F-1.

## **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**

Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness, as of the end of the period covered by this report, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. The purpose of this evaluation was to determine whether as of the evaluation date our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (1) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, our chief executive officer and chief financial officer have concluded that, as of December 31, 2012, our disclosure controls and procedures were effective.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. We have designed our internal controls to provide reasonable assurance that our financial statements are prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, and include those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of our assets;
- 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 are being made only in accordance with authorization of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our management conducted an evaluation of the effectiveness of our internal controls based on the COSO criteria as of December 31, 2012.

Based on our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2012. 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 thereto, appearing below.

#### **Inherent Limitation on the Effectiveness of Internal Controls**

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

#### **Changes in Internal Control over Financial Reporting**

During the year ended December 31, 2012, we implemented changes to our internal controls over financial reporting to fully remediate the material weakness identified in our evaluation of the effectiveness of our internal controls based on the criteria set forth in the *Internal Control – Integrated Framework* developed by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO over our December 31, 2011 financial reporting. (See Amendment No. 1 to our 2011 Annual Report on Form 10-K filed on August 13, 2012)

The plan to remediate the material weaknesses was presented to our audit committee on September 6, 2012, and we executed our plan during the remainder of 2012. The remediation plan consisted of the following modifications and improvements in our internal controls: the addition of a new process control for the calculation of diluted earnings per share, the development of an audit test plan for the remaining quarters and year end 2012 and a review of the plans and new control language with our independent registered public accounting firm, Ernst & Young LLP.

Our efforts to remediate the material weaknesses identified in our 2011 Annual Report on Form 10-K/A and to enhance our overall control environment have been regularly reviewed with, and monitored by, our Audit Committee. We believe the remediation measures described above have been successful in correcting and remediating the material weaknesses previously identified and have strengthened and enhanced our internal control over financial reporting.

## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Oncothyreon Inc.

We have audited Oncothyreon 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 (the COSO criteria). Oncothyreon Inc.'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, Oncothyreon 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 2012 consolidated financial statements of Oncothyreon Inc. and our report dated March 14, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington  
March 14, 2013

### **ITEM 9B. Other Information**

None.

### PART III

#### ITEM 10. *Directors, Executive Officers and Corporate Governance*

##### Executive Officers

The names, ages as of March 14, 2013 and positions of each of our executive officers in 2012 are set forth below.

<u>Name</u>	<u>Age</u>	<u>Office</u>
<b>Executive Officers</b>		
ROBERT KIRKMAN, M.D. ....	64	President, Chief Executive Officer and Director
JULIA M. EASTLAND .....	48	Chief Financial Officer, Secretary and Vice President, Corporate Development
GARY CHRISTIANSON .....	58	Chief Operating Officer
DIANA HAUSMAN, M.D. ....	49	Chief Medical Officer and Vice President, Clinical Development
SCOTT PETERSON, Ph.D. ....	51	Chief Scientific Officer and Vice President, Research and Development

*Robert Kirkman*, M.D. See “Directors, Executive Officers and Corporate Governance — Our Directors” included elsewhere in this Annual Report on Form 10-K for Dr. Kirkman’s biographical information.

*Julia M. Eastland* was appointed as our chief financial officer and vice president, corporate development in August 2010 and was appointed as our secretary in October 2010. From February 2006 to 2010, Ms. Eastland served as chief financial officer and vice president Finance and Operations of VLST Corporation, a privately held biotechnology company. From 2000 to 2005, Ms. Eastland held various finance positions at Dendreon Corporation, a publicly-traded biotechnology company, most recently as the vice president of strategic planning. Prior to Dendreon, Ms. Eastland worked for Amgen, Inc. as area finance manager and assistant controller for its Colorado operations. Ms. Eastland has also worked as director of finance and planning for Encore Media Group, international finance and business manager and senior financial analyst for SCIENCE Magazine and financial manager for the Discovery Channel. Ms. Eastland received an M.B.A. from Edinburgh University Management School and a B.S. in finance from Colorado State University.

*Gary Christianson* was appointed as our chief operating officer in July 2007. From 2005 to 2007, Mr. Christianson was site director for the Biologics Unit of GlaxoSmithKline plc, a global healthcare company. From 1999 to 2003, Mr. Christianson was vice president, technical operations at Corixa Corp., a biopharmaceutical and biotechnology company, and from 2003 to 2005, he was promoted to general manager of the Hamilton, Montana site in addition to his duties as vice president. From 1987 to 1999, Mr. Christianson held various positions at RIBI ImmunoChem Research, Inc., a biopharmaceuticals company. Mr. Christianson received a B.S. in mechanical engineering technology from Montana State University and is a licensed and board certified professional engineer.

*Diana Hausman*, M.D. was appointed vice president, clinical development in August 2009 and Chief Medical Officer in January 2012. From 2005 to 2009, Dr. Hausman served in a variety of positions at Zymogenetics, Inc., a biopharmaceutical company, most recently as senior director, clinical research. From 2002 until 2009, Dr. Hausman served as senior associated medical director at Berlex Inc., a biopharmaceutical company. Dr. Hausman received her A.B. in Biology from Princeton University, and her M.D. from the University of Pennsylvania School of Medicine. She was trained in internal medicine and hematology/oncology at the University of Washington and is board certified in medical oncology.



*Scott Peterson*, Ph.D. was appointed vice president, research and development in June 2009 and Chief Scientific Officer in June 2012. From 2007 until 2009 Dr. Peterson served as director and department head, Oncology Research at Zymogenetics, Inc., a biopharmaceutical company. From 1999 to 2007, Dr. Peterson held a variety of positions at ICOS Corporation, a biopharmaceutical company. Dr. Peterson received his Ph.D. in chemistry (biochemistry) from the University of Colorado, Boulder and holds a B.S. in biology from Washington State University.

### **Our Directors**

The name, age, position(s), term, board committee membership and biographical information for each member of our Board of Directors is set forth below as of March 14, 2013:

#### ***Directors Continuing in Office Until the 2013 Annual Meeting of Stockholders***

*Richard Jackson*, Ph.D., age 73, has been a member of our board of directors since May 2003. Dr. Jackson is the chairman of our compensation committee and a member of our corporate governance and nominating committee. Dr. Jackson is president of Jackson Associates, LLC, a biotechnology and pharmaceutical consulting company. Since September 2006, Dr. Jackson has also been president and chief executive officer of Ausio Pharmaceuticals, LLC, a drug development company. From May 2002 to May 2003, Dr. Jackson was president, chief executive officer and chairman of the board of directors of EmerGen, Inc., a biotechnology company. From November 1998 to January 2002, Dr. Jackson served as senior vice president, research and development for Atrix Laboratories, Inc., a biotechnology company. From January 1993 to July 1998, Dr. Jackson served as senior vice president, discovery research, at Wyeth Ayerst Laboratories, the pharmaceuticals division of American Home Products Corporation. Our corporate governance and nominating committee believes that Dr. Jackson's qualifications for membership on the board of directors include over 20 years of experience in academic medicine and over 25 years of experience at several pharmaceutical and biotechnology companies, with positions in both research and development and senior management. This experience allows Dr. Jackson to provide our board of directors with significant insights into the clinical development of our product candidates. Dr. Jackson served as a director of Inflazyme Pharmaceuticals Ltd. until 2007. Dr. Jackson received his Ph.D. in microbiology and his B.S. in chemistry from the University of Illinois.

*Robert Kirkman*, M.D., age 64, has served as a member of our board of directors and as our president and chief executive officer since September 2006. From 2005 to 2006, Dr. Kirkman was acting president and chief executive officer of Xcyte Therapies, Inc., which concluded a merger with Cyclacel Pharmaceuticals, Inc., both development stage biopharmaceuticals companies, in March of 2006. From 2004 to 2005, Dr. Kirkman was chief business officer and vice president of Xcyte. From 1998 to 2003, Dr. Kirkman was vice president, business development and corporate communications of Protein Design Labs, Inc., a biopharmaceuticals company. Our corporate governance and nominating committee believes that Dr. Kirkman's qualifications for membership on the board of directors include his previous experience at development stage biotechnology companies and his position as our president and chief executive officer. Dr. Kirkman's scientific understanding along with his corporate vision and operational knowledge provide strategic guidance to our management team and our board of directors. Dr. Kirkman holds an M.D. degree from Harvard Medical School and a B.A. in economics from Yale University.

#### ***Directors Continuing in Office Until the 2014 Annual Meeting of Stockholders***

*Daniel Spiegelman*, M.B.A., age 54, has been a member of our board of directors since June 2008. Mr. Spiegelman is the chairman of our audit committee and a member of our corporate governance and nominating committee. Since May 2012, Mr. Spiegelman has

been the Executive Vice President and Chief Financial Officer of Biomarin Pharmaceuticals Inc., a biopharmaceutical company focused on the development and commercialization of therapies for rare diseases. From October 2009 to May 2012, Mr. Spiegelman served as the chief executive officer of Filtini, Inc., a start-up company developing next generation circulating tumor cell capture and analysis technology. Mr. Spiegelman is also a co-founder, and from July 2009 to May 2012, served as chief financial officer of Rapidscan Pharma Solutions, Inc., a start-up company that has licensed the rights from Gilead Sciences to sell regadenoson in Europe and other select territories. From 1998 to 2009, Mr. Spiegelman was employed at CV Therapeutics, Inc., a biopharmaceutical company acquired in 2009 by Gilead, most recently as senior vice president and chief financial officer. From 1992 to 1998, Mr. Spiegelman was an employee at Genentech, Inc., a biotechnology company, serving most recently as its treasurer. Mr. Spiegelman also serves as a member of the board of directors of Affymax, Inc., a biopharmaceuticals company, and Anthera Pharmaceuticals, Inc., a development-stage biopharmaceutical company. Our corporate governance and nominating committee believes that Mr. Spiegelman's qualifications for membership on the board of directors include his extensive background in the financial and commercial issues facing growing biotechnology companies. Additionally, as chief financial officer of CV Therapeutics prior to its sale to Gilead Sciences, Mr. Spiegelman was involved in transitioning the company from a research and development focus to a commercial entity with two approved products. This experience allows Mr. Spiegelman to provide our board of directors with significant insights into financial strategy and organizational development. Mr. Spiegelman received his B.A. and M.B.A. from Stanford University.

*Douglas Williams*, Ph.D., age 54, has been a member of our board of directors since October 2009. Dr. Williams serves as a member of our audit committee. Since January 2011, Dr. Williams has served as the executive vice president of research and development at Biogen IDEC Inc., a publicly-traded biotechnology company. Dr. Williams joined ZymoGenetics, Inc. in 2004 and served as executive vice president, research and development and chief scientific officer from November 2004 to July 2007, as president and chief scientific officer from July 2007 to January 2009, and as a director and chief executive officer from January 2009 until October 2010, when ZymoGenetics was acquired by Bristol-Myers Squibb. He has held senior level positions at a number of prominent biotechnology companies, including Biogen Idec, Seattle Genetics, Inc., Immunex Corporation, and Amgen, Inc. As executive vice president and chief technology officer at Immunex, Dr. Williams played a significant role in the discovery and early development of Enbrel, the first biologic approved for the treatment of rheumatoid arthritis. Our corporate governance and nominating committee believes that Dr. Williams' qualifications for membership on the board of directors include over 20 years of experience in the biotechnology industry. During his career, Dr. Williams has been involved in the approval of three new protein therapeutics and in several label expansions. Further, through his experience as chief executive officer of ZymoGenetics, Inc., Dr. Williams provides our board of directors with significant insights into the strategic and operational issues facing our company. Dr. Williams currently serves on the board of Regulus Therapeutics Inc., a publicly-held biotechnology company, and previously served as a director of Array BioPharma Inc., a biopharmaceutical company, and Aerovance, Inc., a privately-held biopharmaceutical company, Anadys Pharmaceuticals, Inc., a biopharmaceutical company, and Seattle Genetics, a biotechnology company. Dr. Williams received a B.S. (magna cum laude) in Biological Sciences from the University of Massachusetts, Lowell and a Ph.D. in Physiology from the State University of New York at Buffalo, Roswell Park Cancer Institute Division.

***Directors Continuing in Office Until the 2015 Annual Meeting of Stockholders***

*Christopher Henney*, Ph.D., age 72, has served as the chairman of our board of directors since September 2006 and as a member of our board of directors since March 2005.

Dr. Henney is a member of our compensation and corporate governance and nominating committees. From 1995 to 2003, Dr. Henney was chairman and chief executive officer of Dendreon Corporation, a publicly-traded biotechnology company that he co-founded and from 2003 to 2005 continued as executive chairman. Dr. Henney was also a co-founder of Immunex Corporation and ICOS Corporation, both publicly-traded biotechnology companies. Our corporate governance and nominating committee believes that Dr. Henney's qualifications for membership on the board of directors include his roles as co-founder of Dendreon, Immunex and ICOS, as well as his membership on the boards of directors of several development-stage biotechnology companies. Through his experience in working with biotechnology companies from founding until commercialization of their product candidates, Dr. Henney provides our board of directors with significant insights into the strategic, operational and clinical development aspects of the company. Dr. Henney currently serves as vice-chairman of the board of directors of Cyclacel Pharmaceuticals, Inc., a development-stage biopharmaceuticals company, and chairman of the board of directors of Anthera Pharmaceuticals, Inc., a biopharmaceutical company. Dr. Henney was the chairman of SGX Pharmaceuticals, Inc., a biotechnology company acquired by Eli Lilly in 2008, and a member of the board of directors of AVI BioPharma, Inc., a biopharmaceuticals company, until June 2010. Dr. Henney received a Ph.D. in experimental pathology from the University of Birmingham, England, where he also obtained his D.Sc. for contributions in the field of immunology. In 2011, he received the honorary degree of Doctor of the University from his alma mater for contributions to the biotechnology industry. Dr. Henney is a former professor of immunology and microbiology and has held faculty positions at Johns Hopkins University, the University of Washington and the Fred Hutchinson Cancer Research Center.

*W. Vickery Stoughton*, age 67, has been a member of our board of directors since June 1997. Mr. Stoughton is a member of our audit and compensation committees. Since September 2011, Mr. Stoughton has been the president and chief executive officer of Radia Genetics, a private gene therapy company. From August 2006 until September 2007, Mr. Stoughton served as president and chief executive officer of MagneVu Corporation, a medical devices company, which filed for bankruptcy in September 2007. From 1996 to 2002, Mr. Stoughton was chairman and chief executive officer of Careside Inc., a research and development medical devices company, which filed for bankruptcy in October 2002. From October 1995 to July 1996, Mr. Stoughton was president of SmithKline Beecham Diagnostics Systems Co., a diagnostic services and product company, and prior to October 1995 he served as president of SmithKline Beecham Clinical Laboratories, Inc., a clinical laboratory company. From 1988 until May 2008, Mr. Stoughton was a member of the board of directors of Sun Life Financial Inc., a financial services company. Our corporate governance and nominating committee believes that Mr. Stoughton's qualifications for membership on the board of directors include his involvement in several medical device companies, his role as president of SmithKline Beecham Clinical Laboratories, and his broader business background. Through this experience, Mr. Stoughton provides our board of directors with significant insights into the operational aspects of the company. Mr. Stoughton received his B.S. in chemistry from St. Louis University and his M.B.A. from the University of Chicago.

#### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership of, and transactions in, our securities with the Securities and Exchange Commission and NASDAQ. Such directors, executive officers, and ten percent stockholders are also required to furnish us with copies of all Section 16(a) forms that they file.

Based solely on a review of the copies of such forms received by us, or written representations from certain reporting persons, we believe that during 2012, our directors, executive officers, and ten percent stockholders complied with all Section 16(a) filing requirements applicable to them, with the exception of Diana Hausman and Scott Peterson, each of whom filed their Form 3 late.

### **Code of Conduct**

Our board of directors adopted a Code of Business Conduct and Ethics (the “Code of Conduct”) for all our officers, directors, and employees in December 2003, which was last amended on March 13, 2008, and a Code of Ethics for the President and Chief Executive Officer, the Chief Financial Officer and Corporate Controller on March 25, 2003, which was subsequently amended on March 13, 2008, (the “Code of Ethics”). The Code of Conduct details the responsibilities of all our officers, directors, and employees to conduct our affairs in an honest and ethical manner and to comply with all applicable laws, rules, and regulations. The Code of Conduct addresses issues such as general standards of conduct, avoiding conflicts of interest, communications, financial reporting, safeguarding our assets, responsibilities to our customers, suppliers, and competitors, and dealing with governments. The Code of Ethics imposes additional requirements on our senior executive, financial and accounting officers with respect to conflicts of interest, accuracy of accounting records and periodic reports and compliance with laws. Each of the Code of Conduct and Code of Ethics is available on our website at [www.oncothyreon.com](http://www.oncothyreon.com).

### **Stockholder Nominations and Recommendations for Director Candidates**

We have not made any material changes to the procedures by which our stockholders may recommend nominees to our board of directors since we last disclosed the procedures by which stockholders may nominate director candidates under the caption “Corporate Governance and Board Matters — Committees of the Board of Directors — Corporate Governance and Nominating Committee” in our proxy statement for the 2012 annual meeting of Oncothyreon stockholders filed with the SEC on April 25, 2012.

### **Audit Committee**

We have a standing audit committee, which reviews with our independent registered public accounting firm the scope, results, and costs of the annual audit and our accounting policies and financial reporting. Our audit committee has 1) direct responsibility for the appointment, compensation, retention, and oversight of our independent registered public accounting firm, (2) establishes procedures for handling complaints regarding our accounting practices, (3) authority to engage any independent advisors it deems necessary to carry out its duties, and (4) appropriate funding to engage any necessary outside advisors. The current members of the audit committee are Daniel Spiegelman (Chairman), W. Vickery Stoughton and Douglas Williams. The board of directors has determined that Mr. Spiegelman, the chairman of the audit committee, is an “audit committee financial expert” as that term is defined in Item 407(d)(5) of Regulation S-K promulgated by the SEC and is an “independent director” as that term is defined in NASDAQ Marketplace Rule 5605(a)(2). The audit committee reviews and reassesses the adequacy of its charter on an annual basis.

## **ITEM 11. *Executive Compensation***

### **Compensation Discussion and Analysis**

This compensation discussion and analysis describes our executive compensation policies for our “named executive officers” (for example, those individuals set forth in the Summary Compensation Table below).

### ***Compensation Philosophy and Objectives***

The principal objectives of our compensation policies and programs has been to attract and retain senior executive management, to motivate their performance toward clearly defined corporate goals, and to align their long term interests with those of our stockholders. In addition, our compensation committee believes that maintaining and improving the quality and skills of our management and appropriately incentivizing their performance are critical factors affecting our stockholders' realization of long-term value.

Our compensation programs have reflected, and for the foreseeable future should continue to reflect, the fact that we are a biopharmaceutical company whose principal compounds are still in clinical trials and subject to regulatory approval. As a result, our revenues have been and will continue to be limited, and we expect to continue to incur net losses for at least the next several years. In an effort to preserve cash resources, our historical compensation programs have focused heavily on long-term equity incentives relative to cash compensation. With a relatively larger equity weighting, this approach seeks to place a substantial portion of executive compensation at risk by rewarding our executive officers, in a manner comparable to our stockholders, for achieving our business and financial objectives.

In addition to long-term equity incentives, we have also implemented a performance-based cash bonus program for our executive officers and employees. Payments under this performance-based cash bonus program have been based on achievement of pre-established corporate and individual performance goals, with the relative weighting among goals individualized to reflect each person's unique contributions. With respect to our executive officers, 100% of their goals are tied to corporate objectives to reflect the fact that our executive officers make key strategic decisions influencing our company as a whole and thus, it is more appropriate to reward performance against corporate objectives.

We design and implement compensation programs that combine both long-term equity elements and cash incentive elements based on annual performance objectives. Our compensation committee has not, however, adopted any formal or informal policies or guidelines for allocating compensation between cash and equity compensation or among different forms of non-cash compensation. The compensation committee's philosophy is that a substantial portion of an executive officer's compensation should be performance-based, whether in the form of equity or cash compensation. In that regard, we expect to continue to use options or other equity incentives as a significant component of compensation because we believe that they align individual compensation with the creation of stockholder value, and we expect any payments under cash incentive plans to be tied to annual performance targets.

Our executive compensation programs have remained substantially the same for several years. We believe our programs are effectively designed and working well in alignment with the interests of our stockholders and are instrumental to achieving our compensation objectives. In determining executive compensation for 2012, our compensation committee considered the stockholder support that the "Say-on-Pay" proposal received at our June 9, 2011 Annual Meeting of Stockholders. As a result, the compensation committee continued to apply the same effective principles and philosophy it has used in previous years in determining executive compensation and will continue to consider stockholder concerns and feedback in the future. With respect to the frequency of future "Say-on-Pay" advisory votes, consistent with the recommendation of our board of directors and the outcome of the stockholder vote regarding the proposal, we determined to hold an advisory "Say-on-Pay" vote on the compensation of our named executive officers every three years. Our next advisory "Say-on-Pay" vote will occur at our 2014 annual meeting of stockholders.

### ***Role of Our Compensation Committee***

Our compensation committee is comprised of three non-employee members of our board of directors, Dr. Henney, Dr. Jackson and Mr. Stoughton, each of whom is an independent director under the rules of The NASDAQ Global Market and a “non-employee director” for purposes of Rule 16b-3 under the Exchange Act.

Our compensation committee approves, administers, and interprets our executive compensation and benefit policies. Our compensation committee acts exclusively as the administrator of our equity incentive plans and approves all grants to employees, including our executive officers. Our compensation committee operates pursuant to a written charter under which our board of directors has delegated specific authority with respect to compensation determinations. Among the responsibilities of our compensation committee are the following:

- evaluating our compensation practices and assisting in developing and implementing our executive compensation program and philosophy;
- establishing a practice, in accordance with the rules of The NASDAQ Global Market, of determining the compensation earned, paid, or awarded to our chief executive officer independent of input from him; and
- establishing a policy, in accordance with the rules of The NASDAQ Global Market, of reviewing on an annual basis the performance of our other executive officers with assistance from our chief executive officer and determining what we believe to be appropriate compensation levels for such officers.

The compensation committee’s charter allows the committee to form subcommittees for any purpose that the committee deems appropriate and may delegate to such subcommittees such power and authority as the committee deems appropriate. For example, the compensation committee has delegated certain powers and authority to the new employee option committee as set forth in “— Share Option Plan” included elsewhere in this Annual Report on Form 10-K.

Our chief executive officer actively supports the compensation committee’s work by providing information relating to our financial plans, performance assessments of our executive officers, and other personnel related data. In particular, our chief executive officer, as the person to whom our other executive officers report, is responsible for evaluating individual officers’ contributions to corporate objectives as well as their performance relative to divisional and individual objectives. Our chief executive officer, on an annual basis at or shortly after the end of each year, makes recommendations to the compensation committee with respect to merit salary increases, cash bonuses, and stock option grants or other equity incentives for our other executive officers. Our compensation committee meets to evaluate, discuss, modify or approve these recommendations. Without the participation of the chief executive officer, the compensation committee as part of the annual review process conducts a similar evaluation of the chief executive officer’s contribution and performance and makes determinations, at or shortly after the end of each year, with respect to merit salary increases, bonus payments, stock option grants, or other forms of compensation for our chief executive officer.

Our compensation committee has the authority under its charter to engage the services of outside advisors, experts, and others for assistance. The compensation committee did not rely on any outside advisors for purposes of structuring our 2012 compensation plan but did rely on the survey data described below.

### ***Competitive Market Review for 2012***

The market for experienced management is highly competitive in the life sciences and biopharmaceutical industries. We seek to attract and retain the most highly qualified

executives to manage each of our business functions, and we face substantial competition in recruiting and retaining management from companies ranging from large and established pharmaceutical companies to entrepreneurial early stage companies. We expect competition for appropriate technical, commercial, and management skills to remain strong for the foreseeable future.

In making our executive compensation determinations for 2012, we benchmarked our compensation levels using the Radford Global Life Sciences Salary Survey 2012.

In evaluating the survey data, our compensation committee compared our compensation practices and levels for each compensation component including base salary, annual performance-based bonuses, and equity compensation with the salary survey data. This information was used to determine appropriate levels of compensation based on market benchmarks for various functional titles. Based on this data, our compensation committee believes that our levels of total compensation for our executive officers generally fell at about the 50th percentile.

#### ***Peer Group Companies for 2012***

In analyzing our executive compensation program for 2012, the compensation committee compared certain aspects of compensation, including base salary and equity incentives, to those provided by our peer group. This peer group included small biotechnology companies with which we compete for executive talent. For 2012, our peer group consisted of:

- Cell Therapeutics, Inc.;
- Omeros Corporation;
- Oncogenex Pharmaceuticals, Inc.; and
- Threshold Pharmaceuticals, Inc.

#### ***Principal Elements of Executive Compensation***

Our executive compensation program consists of five components:

- base salary;
- annual performance-based cash bonuses;
- equity-based incentives;
- benefits; and
- severance/termination protection.

We believe that each of these components, combining both short and long-term incentives, offers a useful element in achieving our compensation objectives and that collectively these components have been effective in achieving our corporate goals.

#### ***Annual Review Process***

Our compensation committee reviews data and makes executive compensation decisions on an annual basis, typically during the last quarter of the year or the first quarter of the new year. In connection with that process, executive officers are responsible for establishing and submitting for review to our chief executive officer (and in the case of our chief executive officer, directly to the compensation committee) their departmental goals and financial objectives. Our chief executive officer then compiles the information submitted and provides it, along with information relating to his own personal goals and objectives, to our compensation committee for review. Our compensation committee, including our chief executive officer with respect to all officers other than himself and excluding our chief executive officer with respect to discussions of his own compensation, reviews, considers, and may amend the terms and conditions proposed by management.

As part of the annual review process, our compensation committee makes its determinations of changes in annual base compensation for executive officers based on numerous factors, including performance over the prior year, both individually and relative to corporate or divisional objectives, established corporate and divisional objectives for the next year, our operating budgets, and a review of survey data relating to base compensation for the position at companies we have identified within our peer group. During the annual review process, our compensation committee also considered each executive's equity incentive position, including the extent to which he or she was vested or unvested in his or her equity awards and the executive's aggregate equity incentive position.

From time to time, our compensation committee may make off-cycle adjustments in executive compensation as it determines appropriate. For example, in March 2009, our compensation committee considered and approved a special cash bonus for each of our chief executive officer and chief operating officer in connection with the successful completion of the 2008 transaction with Merck KGaA.

### ***Weighting of Compensation Elements***

Our compensation committee's determination of the appropriate use and weight of each element of executive compensation is subjective, based on its view of the relative importance of each element in meeting our overall objectives and factors relevant to the individual executive. Like many biopharmaceutical companies with clinical-stage products, we seek to place a significant amount of each executive's total potential compensation "at risk" based on performance.

### ***Base Salary***

Base salary for our chief executive officer and other named executive officers reflects the scope of their respective responsibilities, their relative seniority and experience, and competitive market factors. Salary adjustments are typically based on competitive conditions, individual performance, changes in job duties, and our budget requirements.

Our compensation committee has set Dr. Kirkman's base salary based on his experience and our compensation committee's view of market compensation for chief executive officers of public, early stage biopharmaceutical companies. For 2009, Dr. Kirkman's base salary was set at \$375,000, was increased to \$386,250 for 2010, \$398,000 for 2011 and \$410,000 for 2012. On January 16, 2013, the compensation committee increased Dr. Kirkman's base salary to \$422,300 for 2013. The base salaries of our other executive officers are described in the section "— Employment Agreements and Offer Letters" included elsewhere in this Annual Report on Form 10-K. For 2012, each named executive officer received a 3% increase, based on cost-of-living and Radford survey data. Dr. Hausman received a further increase related to her promotion to chief medical officer. Dr. Peterson received a merit increase in January 2012 for work related to ONT-10 and the in-licensing of ONT-701. He received a further increase of 16% in June 2012 in connection with his promotion to chief scientific officer. In 2013 each named executive officer received a 3% increase.

### ***Variable Cash Compensation — Incentive Bonuses***

We pay performance-based bonuses to our named executive officers and other employees pursuant to our performance review policy, which we believe enhances each individual employee's incentive to contribute to corporate objectives and aligns their interests with our stockholders. Under the performance review policy, our named executive officers and employees are eligible to receive bonuses based on achievement of pre-established corporate and individual performance goals, but the weighting among the goals is individualized to each person to reflect his or her unique contributions to the company.



Each goal is assigned a percentage for each person based on the importance to us that the goal be achieved with respect to that person. Generally, achievement of a particular goal will result in the payment of the expected level of incentive compensation associated with such goal. Partial achievement can result in the payment of less or no incentive compensation and likewise, superior achievement of any performance goal may result in the payment in excess of the target level of incentive compensation; however, there is not a fixed formula for determining the amount of incentive compensation for partial or above target achievement. Rather, in all cases, the compensation committee, with respect to named executive officers, and our chief executive officer, with respect to other employees, retains discretion to increase or decrease variable cash incentive compensation as it or he determines appropriate, based on actual achievement against the goals, whether performance is at, above or below the target for the goal.

Typically, the maximum incentive compensation to which a named executive officer or employee is entitled is based on a percentage of such individual's base salary. For example, if (1) an executive's base salary is \$100,000, (2) he or she is eligible to receive a bonus up to 50% of his base salary, or \$50,000, (3) the compensation committee has established four performance goals, each weighted at 25% and (4) the compensation committee determines that the executive has achieved two of the four performance goals, then, the executive would be eligible to receive, subject to the discretion of the compensation committee, a bonus of \$25,000.

Performance goals may be both qualitative and quantitative and are designed to be specific, measurable, relevant to our company, completed within a fixed period of time and defined by significant achievements that go beyond an individual's job responsibilities. Although performance goals are intended to be achievable with significant effort, we do not expect that every goal will be actually attained in any given year.

Performance goals are generally split between corporate and personalized individual performance objectives. With respect to our named executive officers, 100% of their goals are tied to corporate objectives to reflect the fact that our executive officers make key strategic decisions influencing the company as a whole and thus, it is more appropriate to reward performance against corporate objectives.

Our compensation committee is responsible for setting performance goals, assessing whether such goals have been achieved and determining the amount of bonuses (if any) to be paid with respect to our executive officers. Performance goals for the upcoming year are typically established at or shortly after the end of the prior year. Assuming that a determination is made that a bonus has been earned, we typically pay bonuses to executive officers shortly after the first scheduled meeting of the compensation committee each year. An individual must remain actively employed by the company through the actual date of payment to receive a bonus.

The weighting of bonuses between the performance goals varies from executive officer to executive officer based on an analysis of each executive officer's role and position within the company. For example, because Dr. Hausman held a key position as our chief medical officer, we felt it appropriate to more heavily weight her bonus on achievement of certain

clinical development milestones. The allocation between the corporate performance goals for each named executive officer for 2012 is set forth in the following table:

<b>Named Executive Officer</b>	<b>Cash Position (1)</b>	<b>Market Capitalization/ Investor Perception (2)</b>	<b>Clinical Assessment (3)</b>	<b>Pre-Clinical Assessment (4)</b>	<b>Technical Operations (5)</b>	<b>Business Development (6)</b>
Robert Kirkman .....	30%	25%	10%	10%	10%	15%
Julia Eastland .....	30	25	10	10	10	15
Gary Christianson .....	10	10	10	10	50	10
Diana Hausman .....	10	10	50	10	10	10
Scott Peterson .....	10	10	10	50	10	10

- (1) Have a minimum of \$45 million in cash and investments as of December 31, 2012.
- (2) Improve investor perception of the Company.
- (3) Timely complete patient enrollment in two Phase 2 trials of PX-866, timely enroll first patient in additional Phase 1/2 trial of PX-866 and fully enroll two cohorts in Phase 1 ONT-10 study.
- (4) Timely complete evaluations of pre-clinical drug candidates and of PX-866 non-clinical studies in connection with regulatory package.
- (5) Timely complete supply, formulation and manufacturing goals.
- (6) In-license, acquire or develop internally a drug development candidate.

The target and actual bonus amounts for 2012 for our named executive officers were as follows, based on achievement against the corporate performance goals (as discussed above):

<b>Named Executive Officer</b>	<b>Base Salary (\$)</b>	<b>Annual Target as Percentage of Base Salary</b>	<b>Target Bonus (\$)</b>	<b>Target Goals Achieved</b>	<b>2012 Incentive Bonus Actually Paid (\$)</b>
Robert Kirkman .....	\$ 410,000	50%	\$205,000	78.0%(1)	\$159,900
Julia Eastland .....	260,000	30	78,000	78.0(2)	60,840(2)
Gary Christianson .....	292,000	35	102,200	86.0(3)	87,892
Diana Hausman .....	335,000	30	100,500	82.0(4)	82,410
Scott Peterson .....	255,000	30	76,500	82.0(5)	62,730

- (1) Dr. Kirkman's achievement level of 78.0% was based on achievement of the goals involving cash position, market capitalization and investor perception and pre-clinical assessment, and partial achievement of the goals involving clinical assessment and technical operations.
- (2) Ms. Eastland's achievement level of 78.0% was based on achievement of the goals involving cash position, market capitalization, investor perception and pre-clinical assessment, and partial achievement of the goals involving clinical assessment and technical operations.
- (3) Mr. Christianson's achievement level of 86.0% was based on achievement of the goals involving cash position, market capitalization and investor perception and pre-clinical assessment, and partial achievement of the goals involving clinical assessment and technical operations.
- (4) Dr. Hausman's achievement level of 82.0% was based on achievement of the goals involving cash position, market capitalization and investor perception and pre-clinical assessment, and partial achievement of the goals involving clinical assessment and technical operations.

- (5) Dr. Peterson's achievement level of 82.0% was based on achievement of the goals involving cash position, market capitalization and investor perception and pre-clinical assessment, and partial achievement of the goals involving clinical assessment and technical operations.

In January 2013, the compensation committee approved target percentages for 2013. Dr. Kirkman, Ms. Eastland, Mr. Christianson, Dr. Hausman and Dr. Peterson are eligible to receive in 2013 incentive bonuses under our performance review policy of up to 50%, 30%, 35%, 30%, 30%, respectively, of their base salary. The 2013 performance goals for our executive officers are related to various corporate objectives, including objectives related to our financial condition, development of our product candidates, technical operations and certain business development activities (although the weighting for such performance goals will differ between such executive officers).

### ***Equity-based Incentives***

We grant equity-based incentives to employees, including our named executive officers, in order to create a corporate culture that aligns employee interests with stockholder interests. We have not adopted any specific stock ownership guidelines, and our equity incentive plans have provided the principal method for our named executive officers to acquire an equity position in our company.

Historically, we have granted options to our named executive officers under our share option plan. Our share option plan permits the grant of stock options for shares of common stock. All equity incentive programs are administered by our compensation committee (other than grants of restricted share units to non-employee directors, which are overseen by the corporate governance and nominating committee and grants of stock options to certain new employees, which are overseen by the new employee option committee). To date, our equity incentive grants to employees have consisted of options under the share option plan.

The size and terms of any initial option grants to new employees, including named executive officers, at the time they join us is based largely on competitive conditions applicable to the specific position. For non-executive officer grants, our compensation committee has pre-approved a matrix showing appropriate levels of option grants for use in making offers to new employees.

In making its determination of the size of initial option grants for our current named executive officers, our board of directors relied in part on survey data and peer group comparisons. On December 12, 2012, Dr. Kirkman was granted an option to purchase 100,000 shares of our common stock at an exercise price per share of \$4.74. This grant will vest as to 25,000 shares on December 12, 2013, with the balance vesting in monthly increments for 36 months following December 12, 2013, such that the option will be fully exercisable on December 12, 2016. Our compensation committee believes that the size and terms of Dr. Kirkman's stock option grants were reasonable given our early stage of product development and skill requirements for senior management, Dr. Kirkman's industry experience and background, and equity compensation arrangements for experienced chief executive officers at comparably situated companies.

In addition, our practice has been to grant refresher options to employees, including executive officers, when our board of directors or compensation committee believes additional unvested equity incentives are appropriate as a retention incentive. For example, in March 2009, December 2009, December 2010, December 2011 and December 2012, we granted refresher options to some of our employees (including our executive officers) pursuant to the standard vesting and other terms of our share option plan. We expect to continue this practice in the future in connection with the compensation committee's annual performance review, generally conducted at the beginning of each year. In making

its determination concerning additional option grants, our compensation committee will also consider, among other factors, prior individual performance in his or her role as an executive officer of our company, and the size of the individual's equity grants in the then-current competitive environment. Where our compensation committee has approved option grants for executive officers or other employees during a regular quarterly closed trading window under our insider trading policy, we have priced the options based on the closing sales price of our common stock on the first trading day after the window opened.

To date, our equity incentives have been granted with time-based vesting. Prior to May 2010, most option grants approved by the compensation committee vest and become exercisable in four equal annual installments beginning on the first anniversary of the grant date. Beginning in May 2010, our compensation committee approved changes to our standard option grant vesting schedule. The revised vesting schedule provides that 25% of the shares of common stock underlying an option vest and become exercisable on the first anniversary of the grant date and 1/48th of the shares of common stock underlying such option vest and become exercisable on each monthly anniversary of the grant date, such that the option will be fully exercisable on the fourth anniversary of the grant date. We expect that additional option grants to continuing employees will typically vest over this same schedule. Although our practice in recent years has been to provide equity incentives principally in the form of stock option grants that vest over time, our compensation committee may consider alternative forms of equity in the future, such as performance shares, restricted share units or restricted stock awards with alternative vesting strategies based on the achievement of performance milestones or financial metrics.

During 2012, we granted, in the aggregate, the following options to our executive officers as follows:

<u>Named Executive Officer</u>	<u>Options (#)</u>
Robert Kirkman .....	100,000
Julia Eastland .....	50,000
Gary Christianson .....	50,000
Diana Hausman .....	50,000
Scott Peterson .....	50,000

In September 2011, the board approved an amendment to each outstanding option agreement with Dr. Kirkman to provide that (i) in the event of death or disability, the underlying shares will continue to vest for an additional 180 days and (ii) in such an event, each option may be exercised until expiration of such option. In December 2011, we approved an amendment to our share option plan so that all options will be treated on termination as a result of disability in the same manner as death (i.e., continue to vest for an additional 180 days).

**Benefits**

We provide the following benefits to our named executive officers, generally on the same basis provided to all of our employees:

- health, dental insurance and vision (for the employee and eligible dependents);
- flexible spending accounts for medical and dependent care;
- life insurance;
- employee assistance plan (for the employee and eligible dependents);
- short- and long-term disability, accidental death and dismemberment; and
- a 401(k) plan with an employer match into the plan.

### ***Severance/Termination Protection***

We entered into offer letters with our named executive officers when each was recruited for his or her current position. These offer letters provide for general employment terms and, in some cases, benefits payable in connection with the termination of employment or a change in control. The compensation committee considers such benefits in order to be competitive in the hiring and retention of employees, including executive officers.

In addition, these benefits are intended to incentivize and retain our officers during the pendency of a proposed change in control transaction and align the interests of our officers with our stockholders in the event of a change in control. The compensation committee believes that proposed or actual change in control transactions can adversely impact the morale of officers and create uncertainty regarding their continued employment. Without these benefits, officers may be tempted to leave the company prior to the closing of the change in control, especially if they do not wish to remain with the entity after the transaction closes. Such departures could jeopardize the consummation of the transaction or our interests if the transaction does not close and we remain independent.

All arrangements with the named executive officers and the potential payments that each of the named executive officers would have received if a change in control or termination of employment would have occurred on December 31, 2012, are described in “— Employment Agreements and Offer Letters” and “— Potential Payments Upon Termination or Change in Control” included elsewhere in this Annual Report on Form 10-K.

### ***Accounting and Tax Considerations***

Section 162(m) of the United States Internal Revenue Code of 1986, as amended, or Section 162(m), limits the amount that we may deduct for compensation paid to our chief executive officer and to each of our four most highly compensated officers to \$1,000,000 per person, unless certain exemption requirements are met. Exemptions to this deductibility limit may be made for various forms of “performance-based” compensation. In addition to salary and bonus compensation, upon the exercise of stock options that are not treated as incentive stock options, the excess of the current market price over the option price, or option spread, is treated as compensation and accordingly, in any year, such exercise may cause an officer’s total compensation to exceed \$1,000,000. Under certain regulations, option spread compensation from options that meet certain requirements will not be subject to the \$1,000,000 cap on deductibility. Our options do not meet the requirements for exemption towards the \$1,000,000 cap. While the compensation committee cannot determine with certainty how the deductibility limit may impact our compensation program in future years, the compensation committee intends to maintain an approach to executive compensation that strongly links pay to performance. While the compensation committee has not adopted a formal policy regarding tax deductibility of compensation paid to our chief executive officer and our four most highly compensated officers, the compensation committee intends to consider tax deductibility under Section 162(m) as a factor in compensation decisions.

### ***Compensation Committee Interlocks and Insider Participation***

During 2012, Richard Jackson, Christopher Henney and W. Vickery Stoughton served on our compensation committee. During 2012, no member of our compensation committee was an officer or employee or formerly an officer of our company, and no member had any relationship that would require disclosure under Item 404 of Regulation S-K of the Securities Exchange Act of 1934. None of our executive officers has served on the board of directors or the compensation committee (or other board committee performing equivalent functions) of any other entity, one of whose executive officers served on our board of directors or on our compensation committee.

## Compensation Committee Report

The information contained in this report will not be deemed to be “soliciting material” or to be “filed” with the SEC, nor will such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference in such filing.

In reliance on the reviews and discussions referred to above and the review and discussion of the section captioned “Compensation Discussion and Analysis” with our management, the compensation committee has recommended to the board of directors and the board of directors has approved, that the section captioned “Compensation Discussion and Analysis” be included in this Annual Report on Form 10-K and the proxy statement for our annual meeting of stockholders.

### COMPENSATION COMMITTEE

Richard Jackson, Chairman  
Christopher Henney  
W. Vickery Stoughton

### Summary Compensation Table – 2012, 2011, and 2010

The following table sets forth the compensation earned by or awarded to, as applicable, our principal executive officer, principal financial officer and other executive officers during each of 2010, 2011 and 2012. We refer to these officers in this Annual Report on Form 10-K as the “named executive officers.”

Name and Principal Position	Year	Salary (\$)	Option Awards (\$)(1)	Non-Equity Incentive Plan Compensation (\$)(2)	All Other Compensation (\$)(3)	Total (\$)
Robert Kirkman(4)	2012	\$ 410,000	\$ 336,000	\$159,900	\$ 12,792	\$ 918,692
President, Chief Executive Officer and Director	2011	398,000	\$484,000	192,035	11,350	1,085,385
	2010	386,250	246,000	135,188	11,923	779,361
Julia Eastland(5)	2012	260,000	168,000	60,840	8,292	497,132
Chief Financial Officer, Secretary and Vice President, Corporate Development	2011	252,500	242,000	73,098	6,517	574,115
	2010	79,647	220,600	25,000	106	325,353
Gary Christianson(6)	2012	292,000	168,000	87,892	9,252	557,144
Chief Operating Officer	2011	283,250	242,000	86,745	8,703	620,698
	2010	275,000	123,000	74,883	8,586	481,469
Diana Hausman(7)	2012	335,000	168,000	82,410	10,542	595,952
Chief Medical Officer	2011	307,750	242,000	79,861	9,438	639,049
	2010	298,700	123,000	67,476	9,297	498,473
Scott Peterson(8)	2012	239,091	168,000	62,730	7,665	477,486
Chief Scientific Officer	2011	200,000	242,000	57,900	6,205	506,105
	2010	180,250	123,000	37,312	5,743	346,305

(1) These amounts represent the aggregate grant date fair value of option awards for fiscal years 2010, 2011 and 2012. These amounts do not represent the actual amounts paid to or realized by the named executive officer for these awards during fiscal years 2010, 2011 or 2012. The value as of the grant date for stock options is recognized over the number of days of service required for the grant to become vested. For a more detailed description of the assumptions used for purposes of determining grant date fair value, see “Part II – Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates – Share-based Compensation” and “Note 7 – Share-based Compensation” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

(2) The amounts in this column represent total performance-based bonuses earned for services rendered during the year under our performance review policy, for 2010, 2011 and 2012, for executive officers, in which all employees were eligible to participate. Under

the applicable bonus plan for each year, each executive was eligible to receive a cash bonus based on achievement of a combination of corporate or divisional objectives. See “— Compensation Discussion and Analysis — Variable Cash Compensation — Incentive Bonuses” included elsewhere in this Annual Report on Form 10-K for additional information regarding our variable cash compensation policies for executive officers.

- (3) Except as disclosed in the other footnotes, the amounts in this column consist of contributions made by us pursuant to our 401(k) plan.
- (4) Amounts listed in “All Other Compensation” include life insurance premiums of \$336 for 2010, \$205 for 2011 and \$492 for 2012.
- (5) Ms. Eastland’s employment with us began on September 7, 2010. Amounts listed in “All Other Compensation” include life insurance premiums of \$106 for 2010, \$205 for 2011 and \$492 for 2012.
- (6) Amounts listed in “All Other Compensation” include life insurance premiums of \$336 for 2010, \$205 for 2011 and \$492 for 2012.
- (7) Dr. Hausman’s employment with us began on September 1, 2009. Amounts listed in “All Other Compensation” include life insurance premiums of \$336, \$205 and \$492 for 2010, 2011 and 2012, respectively.
- (8) Dr. Peterson’s employment with us began on August 1, 2009. Amounts listed in “All Other Compensation” include life insurance premiums of \$336, \$205 and \$492 for 2010, 2011 and 2012, respectively.

### Grants of Plan-Based Awards

The following table sets forth each grant of an award made to a named executive officer during 2012 under any of our incentive plans or equity plans.

Name	Grant Date (1)	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards (\$)(2)(3)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards (\$/Sh)(1)	Grant Date Fair Value of Stock and Option Awards \$(4)
Robert L. Kirkman(5) . . . . .	December 12, 2012	\$205,000	100,000	\$4.74	\$336,000
Julia Eastland(6) . . . . .	December 12, 2012	78,000	50,000	4.74	168,000
Gary Christianson(7) . . . . .	December 12, 2012	102,200	50,000	4.74	168,000
Diana Hausman(8) . . . . .	December 12, 2012	100,500	50,000	4.74	168,000
Scott Peterson(9) . . . . .	December 12, 2012	76,500	50,000	4.74	168,000

- (1) Except as otherwise noted below and consistent with the provisions of our share option plan in effect at the date of grant, options were priced at the closing sales price of our shares of common stock in trading on The NASDAQ Global Market on the grant date. All options were granted under our Share Option Plan.
- (2) Performance bonuses were earned in 2012. The actual amounts paid to each of the named executive officers for 2012 are set forth in the individual footnotes below.
- (3) There was no set “Threshold” or “Maximum” performance bonus amounts established with respect to our 2012 non-equity incentive plan awards, pursuant to the description set forth under the heading “— Compensation Discussion and Analysis — Variable Cash Compensation — Incentive Bonuses” included elsewhere in this Annual Report on Form 10-K.
- (4) These amounts represent the grant date fair value of option awards granted in 2012. These amounts do not represent the actual amounts paid to or realized by the named executive officer for these awards during fiscal year 2012. The value as of the grant date for stock options is recognized over the number of days of service required for the grant to become vested. For a more detailed description of the assumptions used for purposes of determining grant date fair value, see “Part II — Item 7 — Management’s

Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Significant Judgments and Estimates — Share-based Compensation” and “Note 7 — Share-based Compensation” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

- (5) On January 16, 2013, the compensation committee approved a performance bonus of \$159,900 under the performance review policy.
- (6) On January 16, 2013, the compensation committee approved a performance bonus of \$60,840 under the performance review policy.
- (7) On January 16, 2013, the compensation committee approved a performance bonus of \$87,892 under the performance review policy.
- (8) On January 16, 2013, the compensation committee approved a performance bonus of \$82,410 under the performance review policy.
- (9) On January 16, 2013, the compensation committee approved a performance bonus of \$62,730 under the performance review policy.

### Outstanding Equity Awards at 2012 Fiscal Year-End

The following table sets forth the equity awards outstanding at December 31, 2012 for each of the named executive officers. Except as set forth in the footnotes to the following table, each stock option is fully vested.

Name	Option Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$Cdn. or \$U.S.)(1)	Option Expiration Date
Robert Kirkman	450,000	—(2)	Cdn. \$ 7.38	August 29, 2014
	137,537	—(3)	Cdn. \$ 8.04	May 3, 2015
	45,000	—(4)	\$ 3.43	June 4, 2016
	75,000	25,000(5)	\$ 1.10	March 11, 2017
	150,000	50,000(6)	\$ 4.71	December 3, 2017
	50,000	50,000(7)	\$ 3.32	December 1, 2018
	25,000	75,000(12)	\$ 6.92	December 1, 2019
Julia Eastland	—	100,000(17)	\$ 4.74	December 12, 2020
	22,500	17,500(8)	\$ 3.31	November 10, 2018
	25,000	25,000(7)	\$ 3.32	December 1, 2018
	12,500	37,500(12)	\$ 6.92	December 1, 2019
Gary Christianson	—	50,000(13)	\$ 4.74	December 12, 2020
	16,666	—(9)	Cdn. \$ 6.72	June 29, 2015
	15,000	—(4)	\$ 3.43	June 4, 2016
	22,500	7,500(5)	\$ 1.10	March 11, 2017
	75,000	25,000(6)	\$ 4.71	December 3, 2017
	25,000	25,000(7)	\$ 3.32	December 1, 2018
Diana Hausman	12,500	37,500(12)	\$ 6.92	December 1, 2019
	—	50,000(13)	\$ 4.74	December 12, 2020
	22,500	7,500(10)	\$ 4.96	October 1, 2017
	37,500	12,500(6)	\$ 4.71	December 3, 2017
	25,000	25,500(7)	\$ 3.32	December 1, 2018
Scott Peterson	12,500	37,500(12)	\$ 6.92	December 1, 2019
	—	50,000(13)	\$ 4.74	December 12, 2020
	18,750	6,250(11)	\$ 6.56	August 1, 2017
	37,500	12,500(6)	\$ 4.71	December 3, 2017
	25,000	25,000(7)	\$ 3.32	December 1, 2018
	12,500	37,500(12)	\$ 6.92	December 1, 2019
	—	50,000(13)	\$ 4.74	December 12, 2020



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- (1) In April 2008, the board of directors approved an amendment to our amended and restated share option plan, which provided that the exercise price of any future grants would equal the closing price of our common stock traded on The NASDAQ Global Market on the date of grant. Unless otherwise indicated, all exercise prices are denominated in U.S. dollars.
  - (2) This stock option fully vested on August 29, 2009.
  - (3) This stock option fully vested on May 3, 2011.
  - (4) This stock option fully vested on June 4, 2012.
  - (5) This stock option fully vests on March 11, 2013, and vests at a rate of 1/4 annually on the anniversary of grant.
  - (6) This stock option fully vests on December 3, 2013, and vests at a rate of 1/4 annually on the anniversary of grant.
  - (7) This stock option fully vests on December 1, 2014, and 1/4 vests on the first anniversary of grant, with the balance vesting in monthly increments for 36 months following the first anniversary of grant.
  - (8) This stock option fully vests on September 7, 2014, and 1/4 vests on September 7, 2011, with the balance vesting in monthly increments for 36 months following September 7, 2011.
  - (9) This stock option fully vested on June 29, 2011.
  - (10) This stock option fully vests on September 1, 2013, and vests at a rate of 1/4 annually on the anniversary of grant.
  - (11) This stock option fully vests on August 1, 2013, and vests at a rate of 1/4 annually on the anniversary of grant.
  - (12) This stock option fully vests on December 1, 2015, and 1/4 vests on the first anniversary of grant, with the balance vesting in monthly increments for 36 months following the first anniversary of grant.
  - (13) This stock option fully vests on December 12, 2016, and 1/4 vests on the first anniversary of grant, with the balance vesting in monthly increments for 36 months following the first anniversary of grant.

#### **Option Exercises and Stock Vested**

None of our named executive officers exercised stock options during 2012. We have not granted any stock awards to date to any of our named executive officers.

#### **Employment Agreements and Offer Letters**

Unless stated otherwise, all compensation data in the section below are expressed in U.S. dollars.

##### ***Employee Benefit Plans***

Our share option plan, in which our employees and officers participate, provides for the acceleration of vesting of awards in connection with or following a change in control of the company. A “change in control” shall be deemed to have occurred if (i) our board of directors passes a resolution to the effect that, for purposes of the share option plan, a change in control has occurred or (ii) any person or any group of two or more persons acting jointly or in concert becomes the beneficial owner, directly or indirectly, or acquires the right to control or direct, 25% or more of our outstanding voting securities or any successor entity in any manner, including without limitation as a result of a takeover bid or an amalgamation with any other corporation or any other business combination or reorganization. See “— Share Option Plan” included elsewhere in this Annual Report on Form 10-K.

### **Robert Kirkman**

On August 29, 2006, we entered into an offer letter with Robert Kirkman, M.D., our president and chief executive officer. In consideration for his services, Dr. Kirkman was initially entitled to receive a base salary of \$320,000 per year, subject to increases as may be approved by the compensation committee. In January 2009, the compensation committee increased Dr. Kirkman's base salary to \$375,000 for 2009, to \$386,250 for 2010, to \$398,000 for 2011 and to \$410,000 for 2012. On January 16, 2013, the compensation committee increased Dr. Kirkman's salary to \$422,300 for 2013. Dr. Kirkman is also entitled to receive a performance bonus of up to 50% of his base salary based on his achievement of predetermined objectives and on January 16, 2013, Dr. Kirkman received a performance bonus of \$159,900. In addition, the compensation committee may award, in its sole discretion, Dr. Kirkman additional performance bonuses in recognition of his performance and on March 6, 2009, Dr. Kirkman received a special bonus of \$120,000 for the successful completion of our December 2008 transaction with Merck KGaA.

In December 2009, we entered into an amendment to Dr. Kirkman's offer letter. Pursuant to the terms of the amendment, Dr. Kirkman will receive the following benefits if we undergo a change of control transaction (as defined in the share option plan), in addition to the stock option vesting acceleration described above:

- lump sum payment of two year's base salary, less required withholding; and
- lump sum payment of two year's equivalent of performance review bonus at target, less required withholding.

Additionally, if Dr. Kirkman is terminated without cause (as defined in the December 2009 amendment), he will receive the following benefits:

- lump sum payment of one year's base salary, less required withholding; and
- lump sum payment of one year's equivalent of performance review bonus at target, less required withholding.

### **Julia Eastland**

We are parties to an offer letter dated August 17, 2010 with Julia Eastland, our chief financial officer, secretary and vice president, corporate development. In consideration for her services, Ms. Eastland was initially entitled to receive a base salary of \$250,000 per year, subject to increases as may be approved by the compensation committee. In January 2011, Ms. Eastland's base salary was increased to \$252,500 for 2011 and to \$260,000 for 2012. On January 16, 2013, the compensation committee increased Ms. Eastland's salary to \$267,800. Ms. Eastland is also entitled to receive a performance bonus of up to 30% of her base salary based on her achievement of predetermined objectives and on January 16, 2013, Ms. Eastland received a performance bonus of \$60,840.

In accordance with the offer letter, Ms. Eastland was granted an option to purchase 40,000 shares of our common stock at a price of \$3.31 per share and 100% of these shares will vest if there is a change of control transaction.

Pursuant to the terms of the offer letter, Ms. Eastland will receive the following benefits if we undergo a change of control transaction (as defined in the share option plan), in addition to the stock option vesting acceleration described above:

- lump sum payment of one year's base salary, less required withholding; and
- lump sum payment of one year's equivalent of performance review bonus at target, less required withholding.

Additionally, if Ms. Eastland is terminated without cause (as defined in the offer letter), she will receive the following benefits:

- lump sum payment of nine month's base salary, less required withholding; and

- lump sum payment of nine month's equivalent of performance review bonus at target, less required withholding.

***Gary Christianson***

We are parties to an offer letter dated June 29, 2007 with Gary Christianson, our chief operating officer. In consideration for his services, Mr. Christianson was initially entitled to receive a base salary of \$240,000 per year, subject to increases as may be approved by the compensation committee. In March 2009, December 2009 and January 2011, Mr. Christianson's base salary was increased to \$275,000 for 2010, \$283,250 for 2011, and \$292,000 for 2012, respectively. In January 2013, Mr. Christianson's base salary was increased to \$300,760 for 2013. Mr. Christianson is also entitled to receive a performance bonus of up to 35% of his base salary based on his achievement of predetermined objectives and on January 16, 2013, Mr. Christianson received a performance bonus of \$87,892. In addition, the compensation committee may award, in its sole discretion, Mr. Christianson additional performance bonuses in recognition of his performance and on March 6, 2009, Mr. Christianson received a special bonus of \$20,000 for the successful completion of our December 2008 transaction with Merck KGaA.

In accordance with the offer letter of June 29, 2007, Mr. Christianson was granted an option to purchase 16,666 shares of our common stock at a price of Cdn.\$6.72 per share and 100% of these shares will vest if there is a change of control transaction.

In December 2009, we entered into an amendment to Mr. Christianson's offer letter. Pursuant to the terms of the amendment, Mr. Christianson will receive the following benefits if we undergo a change of control transaction (as defined in the share option plan), in addition to the stock option vesting acceleration described above:

- lump sum payment of one year's base salary, less required withholding; and
- lump sum payment of one year's equivalent of performance review bonus at target, less required withholding.

Additionally, if Mr. Christianson is terminated without cause (as defined in the June 2007 offer letter), he will receive the following benefits:

- lump sum payment of nine month's base salary, less required withholding;
- lump sum payment of nine month's equivalent of performance review bonus at target, less required withholding; and
- health insurance coverage for a period of nine months.

***Diana Hausman***

We are parties to an offer letter dated July 6, 2009 with Diana Hausman, M.D., our chief medical officer and vice president of clinical development. In consideration for her services, Dr. Hausman was initially entitled to receive a base salary of \$290,000 per year, subject to increases as may be approved by the compensation committee. In December 2009, Dr. Hausman's base salary was increased to \$298,700 for 2010. In January 2011, Dr. Hausman's base salary was increased to \$307,750 for 2011, in January, 2012, Dr. Hausman's base salary was increased to \$335,000 for 2012, associated with her promotion to chief medical officer, and on January 16, 2013, Dr. Hausman's base salary was increased to \$345,050. Dr. Hausman is also entitled to receive a performance bonus of up to 30% of her base salary based on her achievement of predetermined objectives and on January 16, 2013, Dr. Hausman received a performance bonus of \$82,410.

In accordance with the offer letter of July 6, 2009, Dr. Hausman was granted an option to purchase 30,000 shares of our common stock at a price of \$4.96 per share and 100% of these shares will vest if there is a change of control transaction.

In December 2009, we entered into an amendment to Dr. Hausman's offer letter. Pursuant to the terms of the amendment, Dr. Hausman will receive the following benefits if we undergo a change of control transaction (as defined in the share option plan), in addition to the stock option vesting acceleration described above:

- lump sum payment of one year's base salary, less required withholding; and
- lump sum payment of one year's equivalent of performance review bonus at target, less required withholding.

Additionally, if Dr. Hausman is terminated without cause (as defined in the July 2009 offer letter), she will receive the following benefits:

- lump sum payment of six month's base salary, less required withholding; and
- lump sum payment of six month's equivalent of performance review bonus at target, less required withholding.

### **Scott Peterson**

We are parties to an offer letter dated June 4, 2009 with Scott Peterson, Ph.D., our chief scientific officer and vice president of research and development. In consideration for his services, Dr. Peterson was initially entitled to receive a base salary of \$175,000 per year, subject to increases as may be approved by the compensation committee. In December 2009, Dr. Peterson's base salary was increased to \$180,250 for 2010. In January 2011, Dr. Peterson's base salary was increased to \$200,000 for 2011, on January 4, 2012, Mr. Peterson's base salary was increased to \$220,000 for 2012 and in June 2012, the compensation committee increased Dr. Peterson's salary to \$255,000, associated with his promotion to chief scientific officer. On January 16, 2013, Mr. Peterson's base salary was increased to \$262,650 for 2013. Dr. Peterson's salary was increased so that his compensation would fall at about the 50th percentile for similarly situated employees at companies against which we benchmark ourselves, consistent with the treatment for our executive officers generally. Dr. Peterson is also entitled to receive a performance bonus of up to 30% of his base salary based on his achievement of predetermined objectives and on January 16, 2013, Dr. Peterson received a performance bonus of \$62,730.

In accordance with the offer letter of June 4, 2009, Dr. Peterson was granted an option to purchase 25,000 shares of our common stock at a price of \$6.56 per share and 100% of these shares will vest if there is a change of control transaction.

In December 2009, we entered into an amendment to Dr. Peterson's offer letter. Pursuant to the terms of the amendment, Dr. Peterson will receive the following benefits if we undergo a change of control transaction (as defined in the share option plan), in addition to the stock option vesting acceleration described above:

- lump sum payment of one year's base salary, less required withholding; and
- lump sum payment of one year's equivalent of performance review bonus at target, less required withholding.

### **Potential Payments Upon Termination or Change in Control**

The tables below describe the payments and benefits our named executive officers would be entitled to receive assuming the occurrence on December 31, 2012 of either a change of control transaction or termination of their employment without "cause" (as defined below). For additional details regarding the payments and benefits our named executive officers are entitled to, please see "— Employment Agreements and Offer Letters" included elsewhere in this Annual Report on Form 10-K.

**Robert L. Kirkman**

<u>Name</u>	<u>Change of Control</u>			<u>Termination Other Than for Cause(3)</u>		
	<u>Equity Acceleration (1)</u>	<u>Salary (2)</u>	<u>Insurance Benefits</u>	<u>Equity Acceleration (4)</u>	<u>Salary (5)</u>	<u>Insurance Benefits</u>
Robert L. Kirkman .....	\$20,500	\$1,230,000	\$—	\$—	\$615,000	\$—

- (1) The amount shown in this column is calculated as the spread value of all unvested stock options held by Dr. Kirkman on December 31, 2012, assuming a stock price of \$1.92 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 31, 2012.
- (2) The amount shown in this column is a lump sum payment equal to two times Dr. Kirkman's base salary for 2012 plus two year's equivalent of his performance review bonus at target. Such payments will be made within 60 days following a change of control, provided that, within 45 days of a change of control, Dr. Kirkman signs a separation agreement in a form reasonably satisfactory to us, which shall include a general release of all claims against us.
- (3) For purposes of Dr. Kirkman's offer letter, "cause" includes, among other things
  - (a) willful engaging in illegal conduct or gross misconduct which is injurious to us,
  - (b) being convicted of, or entering a plea of *nolo contendere* or guilty to, a felony or a crime of moral turpitude, (c) engaging in fraud, misappropriation, embezzlement or any other act or acts of dishonesty resulting or intended to result directly or indirectly in a gain or personal enrichment of him at our expense, (d) material breach of any of our written policies, or (e) willful and continual failure substantially to perform his duties, which failure has continued for a period of at least 30 days after written notice by us.
- (4) Pursuant to the terms of our share option plan, there is no acceleration of vesting if Dr. Kirkman is terminated without cause.
- (5) The amount shown in this column is a lump sum payment equal to Dr. Kirkman's base salary for 2012 plus one year's equivalent of his performance review bonus at target. Such payments will be made within 60 days following termination other than for cause, subject to any payment delay in order to comply with Section 409A of the Internal Revenue Code.

**Julia Eastland**

<u>Name</u>	<u>Change of Control</u>			<u>Termination Other Than for Cause(3)</u>		
	<u>Equity Acceleration (1)</u>	<u>Salary (2)</u>	<u>Insurance Benefits</u>	<u>Equity Acceleration (4)</u>	<u>Salary (5)</u>	<u>Insurance Benefits</u>
Julia Eastland .....	\$—	\$338,000	\$—	\$—	\$253,500	\$—

- (1) The amount shown in this column is calculated as the spread value of all unvested stock options held by Ms. Eastland on December 31, 2012, assuming a stock price of \$1.92 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 31, 2012.
- (2) The amount shown in this column is a lump sum payment equal to Ms. Eastland's base salary for 2012 plus one year's equivalent of her performance review bonus at target. Such payments will be made within 60 days following a change of control, provided that, within 45 days of a change of control, Ms. Eastland signs a separation agreement in a form reasonably satisfactory to us, which shall include a general release of all claims against us.
- (3) For purposes of Ms. Eastland's offer letter, "cause" includes, among other things
  - (a) willful engaging in illegal conduct or gross misconduct which is injurious to us,

(b) being convicted of, or entering a plea of *nolo contendere* or guilty to, a felony or a crime of moral turpitude, (c) engaging in fraud, misappropriation, embezzlement or any other act or acts of dishonesty resulting or intended to result directly or indirectly in a gain or personal enrichment of her at our expense, (d) material breach of any of our written policies, or (e) willful and continual failure substantially to perform her duties, which failure has continued for a period of at least 30 days after written notice by us.

- (4) Pursuant to the terms of our share option plan, there is no acceleration of vesting if Ms. Eastland is terminated without cause.
- (5) The amount shown in this column is a lump sum payment equal to nine months of Ms. Eastland's base salary for 2012 plus nine month's equivalent of her performance review bonus at target.

**Gary Christianson**

Name	Change of Control			Termination Other Than for Cause(3)		
	Equity Acceleration (1)	Salary (2)	Insurance Benefits	Equity Acceleration (4)	Salary (5)	Insurance Benefits
Gary Christianson	\$6,150	\$394,200	\$—	\$—	\$295,650	\$18,835

- (1) The amount shown in this column is calculated as the spread value of all unvested stock options held by Mr. Christianson on December 31, 2012, assuming a stock price of \$1.92 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 31, 2012.
- (2) The amount shown in this column is a lump sum payment equal to Mr. Christianson's base salary for 2012 plus one year's equivalent of his performance review bonus at target. Such payments will be made within 60 days following a change of control, provided that, within 45 days of a change of control, Mr. Christianson signs a separation agreement in a form reasonably satisfactory to us, which shall include a general release of all claims against us.
- (3) For purposes of Mr. Christianson's offer letter, "cause" includes, among other things (a) willful engaging in illegal conduct or gross misconduct which is injurious to us, (b) being convicted of, or entering a plea of *nolo contendere* or guilty to, a felony or a crime of moral turpitude, (c) engaging in fraud, misappropriation, embezzlement or any other act or acts of dishonesty resulting or intended to result directly or indirectly in a gain or personal enrichment of him at our expense, (d) material breach of any of our written policies, or (e) willful and continual failure substantially to perform his duties, which failure has continued for a period of at least 30 days after written notice by us.
- (4) Pursuant to the terms of our share option plan, there is no acceleration of vesting if Mr. Christianson is terminated without cause.
- (5) The amount shown in this column is a lump sum payment equal to nine months of Mr. Christianson's base salary for 2012 plus nine month's equivalent of his performance review bonus at target. If Mr. Christianson is a "specified employee" within the meaning of Section 409A of the Internal Revenue Code and any final regulations and official guidance promulgated thereunder, at the time of his separation from service, then, if required, the amounts shown in this column, which are otherwise due on or within the six-month period following the separation from service will accrue, to the extent required, during such six-month period and will become payable in a lump sum payment six months and one day following the date of separation from service.

**Diana Hausman**

Name	Change of Control			Termination Other Than for Cause(3)		
	Equity Acceleration (1)	Salary (2)	Insurance Benefits	Equity Acceleration (4)	Salary (5)	Insurance Benefits
Diana Hausman .....	\$—	\$435,500	\$—	\$—	\$217,750	\$—

- (1) The amount shown in this column is calculated as the spread value of all unvested stock options held by Dr. Hausman on December 31, 2012, assuming a stock price of \$1.92 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 31, 2012.
- (2) The amount shown in this column is a lump sum payment equal to Dr. Hausman's base salary for 2012 plus one year's equivalent of her performance review bonus at target. Such payments will be made within 60 days following a change of control, provided that, within 45 days of a change of control, Dr. Hausman signs a separation agreement in a form reasonably satisfactory to us, which shall include a general release of all claims against us.
- (3) For purposes of Dr. Hausman's offer letter, "cause" includes, among other things (a) willful engaging in illegal conduct or gross misconduct which is injurious to us, (b) being convicted of, or entering a plea of *nolo contendere* or guilty to, a felony or a crime of moral turpitude, (c) engaging in fraud, misappropriation, embezzlement or any other act or acts of dishonesty resulting or intended to result directly or indirectly in a gain or personal enrichment of her at our expense, d) material breach of any of our written policies, or (e) willful and continual failure substantially to perform her duties, which failure has continued for a period of at least 30 days after written notice by us.
- (4) Pursuant to the terms of our share option plan, there is no acceleration of vesting if Dr. Hausman is terminated without cause.
- (5) The amount shown in this column is a lump sum payment equal to six months of Dr. Hausman's base salary for 2012 plus six month's equivalent of her performance review bonus at target.

**Scott Peterson**

Name	Change of Control		
	Equity Acceleration(1)	Salary(2)	Insurance Benefits
Scott Peterson .....	\$—	\$331,500	\$—

- (1) The amount shown in this column is calculated as the spread value of all unvested stock options held by Dr. Peterson on December 31, 2012, assuming a stock price of \$1.92 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 31, 2012.
- (2) The amount shown in this column is a lump sum payment equal to Dr. Peterson's base salary for 2012 plus one year's equivalent of his performance review bonus at target. Such payments will be made within 60 days following a change of control, provided that, within 45 days of a change of control, Dr. Peterson signs a separation agreement in a form reasonably satisfactory to us, which shall include a general release of all claims against us.

**Share Option Plan**

Our board of directors adopted our share option plan on December 9, 1992 and our stockholders approved it on May 26, 1993. Our share option plan was amended and restated as of May 3, 2007, April 3, 2008, October 22, 2009, March 14, 2011 and December 1, 2011. Unless further amended by our stockholders, our share option plan will terminate on May 3, 2017. Our share option plan provides for the grant of nonstatutory

stock options to selected employees, directors and persons or companies engaged to provide ongoing management or consulting services for us, or any entity controlled by us. The employees, directors and consultants who have been selected to participate in our share option plan are referred to below as “participants.”

### ***Share Reserve***

The total number of shares of common stock issuable pursuant to options granted under our share option plan shall, at any time, be 10% of our issued and outstanding shares of common stock. We had reserved a total of 4,804,980 shares of our common stock for issuance pursuant to our share option plan as of December 31, 2012. As of December 31, 2012, options to purchase 2,934,453 shares of our common stock were outstanding and 1,852,606 shares of our common stock were available for future grant under our share option plan. As of the filing date of this Form 10-K, 5,721,623 shares of our common stock were reserved for issuance pursuant to our share option plan.

### ***Administration***

The compensation committee of our board of directors administers our share option plan. Under our share option plan, the plan administrator has the power, subject to certain enumerated restrictions in our share option plan, to determine the terms of the awards, including the employees, directors and consultants who will receive awards, the exercise price of the award, the number of shares subject to each award, the vesting schedule and exercisability of each award and the form of consideration payable upon exercise.

In addition, the compensation committee has delegated to the new employee option committee the authority to approve grants of stock options to newly hired employees who are not our chief executive officer, president, chief financial officer (or principal financial officer, if no person holds the office of chief financial officer), vice president or a Section 16 officer (as determined pursuant to the rules promulgated under the Securities Exchange Act of 1934). The new employee option committee is composed of our chief executive officer, our principal financial officer and our head of human resources. The new employee option committee meets during the last full week of each month and may only grant stock option awards. The stock options granted by the new employee option committee must have an exercise price equal to the closing sales price of our common stock as reported by The NASDAQ Global Market on the last trading day of the month in which such grants were approved. These grants must fall within a predetermined range approved by the compensation committee and may not deviate from the standard vesting terms (i.e., awards vest over a four year period, with 25% of the shares subject to an award vesting on the first anniversary of the optionee’s commencement of employment and the balance vesting in equal monthly increments for 36 months following the first anniversary of the commencement of employment).

### ***Share Options***

The exercise price of the shares subject to options granted under our share option plan shall be determined by our compensation committee or board of directors, but shall not be less than the fair market value of the shares. Generally, the exercise price will be the closing price of our common stock on the day of the option grant. Until April 3, 2008, for purposes of our share option plan, the fair market value meant the closing price of our common stock as reported by the Toronto Stock Exchange on the day preceding the day on which the option is granted. If no trade of shares of our common stock was reported on the Toronto Stock Exchange that day, then the fair market value was not less than the mean of the bid and ask quotations for our common stock on the Toronto Stock Exchange at the close of business on such preceding day. On April 3, 2008, our board of directors amended our option plan to provide that options granted pursuant to the plan be priced at the closing price of our shares of common stock on The NASDAQ Global Market on the day of the option grant. If the grant



date would otherwise occur during a closed quarterly trading window under our insider trading policy, the compensation committee or board of directors will identify a future date as the grant date (which typically will be the first day the trading window opens after a closed quarterly trading window). Effective October 22, 2009, in connection with our voluntary delisting from the Toronto Stock Exchange, the share option plan was amended and restated to remove references to the Toronto Stock Exchange and to make certain other housekeeping changes necessitated by the voluntary delisting.

#### ***Termination of Service Provider Relationship***

Upon the termination without cause of a participant's employment or service with us (or any of our subsidiaries), other than a termination due to death or retirement (as such terms are defined in our share option plan), the participant's option will continue to vest and may be exercised at any time up to and including, but not after, the date which is 180 days after the date of the termination or the date prior to the close of the business on the expiry date of the option, whichever is the earlier. If termination is for cause, the option will immediately terminate in its entirety. An option may never be exercised after the expiration of its term.

For our president or any of our vice presidents, in the event of a termination of the participant's service or employment with us (or any of our subsidiaries) without cause, any option granted to the participant will continue to vest and may be exercised at any time up to and including, but not after, the date which is the second anniversary of the date of his or her termination or the date before the close of business on the expiry date of his or her option, whichever is the earlier.

In the event of the retirement, as such term is defined in our share option plan, of the participant while in the employment of us (or any of our subsidiaries), any option granted to the participant will continue to vest and may be exercised by the participant in accordance with the terms of the option at any time up to and including, but not after, the expiry date of the option.

In the event of the death of the participant (other than Dr. Kirkman) while in the employment or service of us (or any of our subsidiaries), the option will continue to vest and may be exercised by a legal representative of the participant at any time up to and including, but not after, the date which is 180 days after the date of the death of the optionee or before the close of business on the expiry date of the option, whichever is earlier.

In the event of the termination of service on account of disability of the participant (other than Dr. Kirkman) while in the employment or service of us (or any of our subsidiaries), the option will continue to vest and may be exercised by participant at any time up to and including, but not after, the date which is 180 days after the date of the disability of the participant or before the close of business on the expiry date of the option, whichever is earlier. In the event of Dr. Kirkman's death or disability, options would continue to vest for 180 days, but would be exercisable at any time prior to the close of business on the expiry date of the option.

#### ***Effect of a Change in Control***

Our share option plan provides that, if a change in control occurs, as such term is defined in our share option plan, including our merger with or into another corporation or the sale of all or substantially all of our assets, or if there is an offer to purchase, a solicitation of an offer to sell, or an acceptance of an offer to sell our shares of common stock made to all or substantially all of the holders of shares of common stock, a participant, who at the time of the change of control is an employee, director or service provider, shall have the right to immediately exercise his or her option as to all shares of common stock subject to such option, including as to those shares of common stock with respect to which such option cannot be exercised immediately prior to the occurrence of the change of control, and the participant shall have 90 days from the date of the change of control to exercise his or her option (unless the option expires prior to such date).

### ***Transferability***

Unless otherwise determined by the plan administrator, our share option plan generally does not allow for the sale or transfer of awards under our share option plan other than by will or the laws of descent and distribution, and awards may be exercised only during the lifetime of the participant and only by that participant or by the participant's legal representative for up to 180 days following the participant's death.

### ***Additional Provisions***

Our board of directors has the authority to amend (subject to stockholder approval in some circumstances) or discontinue our share option plan, so long as that action does not materially and adversely affect any option rights granted to a participant without the written consent of that participant.

During the period from January 1 to December 31, 2012, options to purchase 554,500 shares of common stock were granted under our share option plan at a weighted average exercise price of \$4.82 per share.

### ***Restricted Share Unit Plan***

Our board of directors adopted our RSU plan on May 18, 2005 and our stockholders approved it on May 18, 2005. Our RSU plan was amended and restated as of June 12, 2009 to add additional shares to the plan and again as of October 22, 2009 to remove references to the Toronto Stock Exchange and make certain other housekeeping changes necessitated by our voluntary delisting from the TSX. Our RSU plan provides for the grant of RSUs to non-employee members of our board of directors. Pursuant to an October 2011 amendment to the RSU plan, we are required to settle 25% of the shares of our common stock otherwise deliverable in connection with the vesting of any RSU and deliver to each non-employee director an amount in cash equal to the fair market value of the shares on the vesting date. The amendment is designed to facilitate satisfaction of the non-employee directors' income tax obligation with respect to the vested RSUs. The directors who receive RSUs under our restricted share unit plan are referred to below as participants.

### ***Share Reserve***

We have reserved a total of 466,666 of our shares of common stock for issuance pursuant to our restricted share unit plan. As of December 31, 2012, grants covering 140,968 shares of our common stock were outstanding, 170,898 shares of our common stock were available for future grant under our restricted share unit plan and 154,800 shares had been issued upon conversion of RSUs.

### ***Administration***

The corporate governance and nominating committee of our board of directors administers our restricted share unit plan. Under our restricted share unit plan, the plan administrator has the power, subject to certain enumerated restrictions in our restricted share unit plan, to determine the terms of the grants, including the directors who will receive grants, the grant period (as such term is defined in our restricted share unit plan) of any awards, and any applicable vesting terms in order for the restricted share units to be issued, and such other terms and conditions as the board of directors deems appropriate.

Each grant of restricted share units will be evidenced by a written notice, which we call the notice of grant, with such notice, in connection with our restricted share unit plan, governing the terms and conditions of the grant. Each notice of grant will state the number of restricted share units granted to the participant and state that each restricted share unit, subject to and in accordance with the terms of our restricted share unit plan, will entitle the participant to receive one share of our common stock in settlement of a restricted share unit granted pursuant to our restricted share unit plan.

***Right to Restricted Share Units in the event of Death, Disability, Retirement, or Resignation***

In the event of the death or disability of a participant while a director of us, and with respect to each grant of restricted share units for which the grant period has not ended and for which the restricted share units have not been otherwise issued prior to the date of death, all unvested restricted share units will immediately vest and the shares of our common stock subject to such restricted share units will be issued by the later of the end of the calendar year of the date of death, or by the 15th day of the third calendar month following the participant's date of death.

In the event the participant's service as a director terminates for any reason other than death or disability, and provided such participant is not a specified employee (as such term is defined in our restricted share unit plan) on the date of his or her termination, with respect to the restricted share units as to which the release date (as such term is defined in our restricted share unit plan) has not occurred, and for which shares of our common stock have not been issued, the participant will receive such shares as if the grant period had ended and such shares will be issued by the later of the end of the calendar year of the date of termination or by the 15th day of the third calendar month following the date of the termination. If the participant is a specified employee on the date of his or her termination, and if such termination is for any reason other than death, with respect to the restricted share units as to which the release date has not occurred, and for which shares of our common stock have not been issued, the participant will receive such shares as if the grant period had ended and such shares will be delivered by the 30th day of the date following the date which is six months following the participant's date of termination.

***Effect of a Change in Control***

In the event of a change in control (as such term is defined in our restricted share unit plan), with respect to all grants of restricted share units that are outstanding as of the date of such change in control, all unvested restricted share units will immediately vest and each participant who has received any such grants will be entitled to receive, on the date that is ten business days following the change in control date, an amount in full settlement of each restricted share unit covered by the grant. Such amount will be either one share of our common stock for each restricted share unit, or if so specified in a written election by the participant, a cash payment equal to the special value (as such term is defined in our restricted share unit plan) for each covered restricted share unit.

***Transferability***

The rights or interests of a participant under our restricted share unit plan will not be assignable or transferable, other than by will or the laws governing the devolution of property in the event of death and such rights or interests will not be encumbered.

***Additional Provisions***

Our board of directors has the authority to amend (subject to stockholder approval in some circumstances), suspend or terminate our restricted share unit plan in whole or in part from time to time.

***Risk Analysis of Compensation Plans***

The mix and design of the elements of executive compensation do not encourage management to assume excessive risks. Any risks arising from our compensation policies and practices for our employees are not reasonably likely to have a material adverse effect on the company.

The compensation committee extensively reviewed the elements of executive compensation to determine whether any portion of executive compensation encouraged excessive risk taking and concluded:

- significant weighting towards long-term incentive compensation discourages short-term risk taking; and
- several categories of goals generally apply, so that if any particular goal is not achieved, then a disproportionate amount of total compensation is not forfeited.

### Compensation of Directors

We pay our non-employee directors an annual cash fee of \$50,000 for their service on our board of directors and its committees. We also pay the chairman of our board an additional annual fee of \$50,000, the Chairman of our audit committee an additional annual fee of \$25,000, and the Chairmen of our other standing committees of the board of directors an additional annual fee of \$5,000 each. In addition, each non-employee member of our board is entitled to an annual restricted share unit grant equal to \$30,000 divided by the closing price of our common stock on The NASDAQ Global Market on the date of grant. On March 11, 2009 and June 12, 2009, each board member (excluding Dr. Williams who did not join the board of directors until October 2009) received 19,352 RSUs and 2,076 RSUs, respectively, for fiscal year 2008. On December 4, 2009 each board member was awarded 6,185 RSUs for fiscal year 2009. On June 3, 2010 each board member was awarded 8,086 RSUs for fiscal year 2010. On June 9, 2011 each board member was awarded 4,538 RSUs for fiscal year 2011 and on June 7, 2012 each board member was awarded 8,174 RSUs for fiscal year 2012. In recognition of Dr. Henney taking on additional responsibilities during our chief executive officer's medical leave of absence, the board awarded Dr. Henney 25,000 RSUs on December 1, 2011, which RSUs were immediately vested. On December 1, 2011, the compensation policy for our non-employee directors was changed such that each non-employee director is entitled to annual restricted share grant equal to the greater of (1) 7,500 and (2) \$30,000 divided by the closing price of our common stock on the NASDAQ Global Market on the date of grant. Board members receive cash compensation in U.S. dollars. We also reimburse our directors for travel and other necessary business expenses incurred in the performance of their services for us.

### Fiscal Year 2012 Director Compensation

The following table sets forth compensation information for our non-employee directors for the year ended December 31, 2012. The table excludes Dr. Kirkman who did not receive any compensation from us in his role as director in the year ended December 31, 2012. All compensation numbers are expressed in U.S. dollars.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Stock Awards (\$) (1)(2)(3)</u>	<u>Total (\$)</u>
Christopher Henney .....	\$105,000	\$30,000	\$135,000
Richard Jackson .....	55,000	30,000	85,000
Daniel Spiegelman .....	75,000	30,000	105,000
W. Vickery Stoughton .....	50,000	30,000	80,000
Douglas Williams .....	50,000	30,000	80,000

(1) These amounts represent the aggregate grant date fair value of RSUs granted in 2012.

(2) As of December 31, 2012, our non-employee directors held RSUs and outstanding options to purchase the number of shares of common stock as follows: Dr. Henney (53,602 options, 32,064 RSUs); Dr. Jackson (1,257 options, 32,064 RSUs); Mr. Stoughton (5,759 options, 32,064 RSUs); Mr. Spiegelman (zero options, 32,064 RSUs); Dr. Williams (zero options, 12,712 RSUs).

- (3) Each RSU may be converted into one share of our common stock at the end of the grant period, which is five years for each of the RSUs granted prior to June 12, 2009 and two years for each of the RSUs granted on or after June 12, 2009.

**ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

**Equity Compensation Plan Information as of December 31, 2012**

The following table sets forth the securities authorized for issuance under Oncothyreon's equity compensation plans.

<u>Plan Category</u>	<u>(A) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>(B) Weighted Average Price of Outstanding Options, Warrants and Rights</u>	<u>(C) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A))(1)</u>
Equity compensation plans approved by security holders:			
Share option plan (\$Cdn.)(2) .....	729,817	\$7.79	—
Share option plan (\$U.S.)(2) .....	2,204,636	\$4.58	1,852,606
RSU plan .....	140,968	N.A.	170,898
Equity compensation plans not approved by security holders .....	—	N.A.	—
<b>Total .....</b>	<b>3,075,421</b>	<b>N.A.</b>	<b>2,023,504</b>

- (1) All of these are available for grants of restricted stock, restricted share units and other full-value awards, as well as for grants of stock options and stock appreciation rights.
- (2) Under the terms of the Amended and Restated Share Option Plan, the total number of shares issuable pursuant to options under the plan is 10% of the issued and outstanding shares. Shares issued upon the exercise of options do not reduce the percentage of shares which may be issuable pursuant to options under the Plan.

For more information regarding our Amended and Restated Share Option Plan and Amended and Restated Restricted Share Unit Plan, see Note 7 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

## Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding beneficial ownership of our capital stock as of February 28, 2013 by (i) each person known by us to be the beneficial owner of more than 5% of any class of our voting securities, (ii) each of our directors, (iii) each of our “named executive officers” and (iv) our directors and executive officers as a group, including shares they had the right to acquire within 60 days after February 28, 2013.

<u>Name of Beneficial Owner(1)</u>	<u>Common Stock Beneficially Owned</u>	
	<u>Number of Shares(2)</u>	<u>Percent of Class(3)</u>
5% Stockholders:		
BlackRock, Inc.(4) .....	3,732,063	6.52%
Steven T. Newby (5) .....	3,639,000	6.36%
Viking Global Investors LP(6) .....	3,361,315	5.87%
BVF, Inc.(7) .....	2,885,914	5.04%
Directors and Named Executive Officers:		
Christopher Henney(8) .....	153,331	*
Richard Jackson(9) .....	24,736	*
W. Vickery Stoughton(10) .....	28,404	*
Daniel Spiegelman(11) .....	12,780	*
Douglas Williams(12) .....	8,384	*
Robert Kirkman(13) .....	982,536	1.69%
Gary Christianson(14) .....	190,771	*
Julia Eastland(15) .....	87,098	*
Diana Hausman(16) .....	105,834	*
Scott Peterson(17) .....	112,508	*
All directors and executive officers as a group (10 persons)(18) .....		2.91%

\* Represents less than 1% of class or combined classes.

- (1) Except as otherwise indicated, the address of each stockholder identified is c/o Oncothyreon Inc., 2601 Fourth Avenue, Suite 500, Seattle, Washington 98121. Except as indicated in the other footnotes to this table, each person named in this table has sole voting and investment power with respect to all shares of stock beneficially owned by that person.
- (2) Options and warrants exercisable within 60 days after February 28, 2013 are deemed outstanding for the purposes of computing the percentage of shares owned by that person, but are not deemed outstanding for purposes of computing the percentage of shares owned by any other person.
- (3) Based on 57,216,237 shares of common stock issued and outstanding as of February 28, 2013.
- (4) Based on information of beneficial ownership as of December 31, 2012, included in a Schedule 13G filed with the SEC on January 30, 2013. The address of the BlackRock Inc. is 40 East 52<sup>nd</sup> Street, New York, NY 10022.
- (5) Based on information of beneficial ownership as of December 31, 2012, included in a Schedule 13G/A filed with the SEC on April 5, 2012. The address of Steven T. Newby is 12716 Split Creek Court, North Potomac, MD 20878.
- (6) Based on information of beneficial ownership as of December 31, 2012, included in a Schedule 13G/A filed with the SEC on February 14, 2013. Includes shares of common

stock beneficially owned by Viking Global Investors L.P. and various affiliated entities and individuals. The address of Viking Global Investors L.P. is 55 Railroad Avenue, Greenwich, CT 06830.

- (7) Based on information of beneficial ownership as of December 31, 2012, included in a 13G filed with the SEC on February 15, 2013. Includes shares of common stock beneficially owned by BVF Inc. and various affiliated entities and individual. The address of BVF Inc. is 900 North Michigan Avenue, Suite 1100, Chicago, Ill 60611.
- (8) Includes 53,602 shares of common stock that Dr. Henney has the right to acquire under outstanding options exercisable within 60 days after February 28, 2013. Shares attributable to RSUs owned are not reflected as none of the shares underlying the RSUs have vested or will vest within 60 days after February 28, 2013.
- (9) Includes 1,257 shares of common stock that Dr. Jackson has the right to acquire under outstanding options exercisable within 60 days after February 28, 2013. Shares attributable to RSUs owned are not reflected as none of the shares underlying the RSUs have vested or will vest within 60 days after February 28, 2013.
- (10) Includes 5,759 shares of common stock that Mr. Stoughton has the right to acquire under outstanding options exercisable within 60 days after February 28, 2013. Shares attributable to restricted stock units owned are not reflected as none of the shares underlying the RSUs have vested or will vest within 60 days after February 28, 2013.
- (11) Shares attributable to RSUs owned are not reflected as none of the shares underlying the RSUs have vested or will vest within 60 days after February 28, 2013.
- (12) Shares attributable to restricted stock units owned are not reflected as none of the shares underlying the RSUs have vested or will vest within 60 days after February 28, 2013.
- (13) Includes 974,203 shares of common stock that Dr. Kirkman has the right to acquire under outstanding options exercisable within 60 days after February 28, 2013.
- (14) Includes 182,500 shares of common stock that Mr. Christianson has the right to acquire under outstanding options exercisable within 60 days after February 28, 2013.
- (15) Includes 71,667 shares of common stock that Ms. Eastland has the right to acquire under outstanding options exercisable within 60 days after February 28, 2013.
- (16) Includes 105,834 shares of common stock that Dr. Hausman has the right to acquire under outstanding options exercisable within 60 days after February 28, 2013.
- (17) Includes 102,084 shares of common stock that Dr. Peterson has the right to acquire under outstanding options exercisable within 60 days after February 28, 2013.
- (18) Includes 1,496,906 shares of common stock that can be acquired under outstanding options exercisable within 60 days after February 28, 2013.

### **ITEM 13. *Certain Relationships and Related Transactions and Director Independence***

#### **Certain Relationships and Related Transactions**

In addition to the arrangements described below, we have also entered into the arrangements which are described where required under the heading titled “Part III – Item 11 – Executive Compensation – Employment Agreements and Offer Letters” and “Part III – Item 11 – Executive Compensation – Potential Payments Upon Termination or Change in Control” included elsewhere in this Annual Report on Form 10-K.

#### ***Approval of Related Party Transactions***

We have adopted a formal, written policy that our executive officers, directors (including director nominees), holders of more than 5% of any class of our voting securities, or any member of the immediate family of or any entities affiliated with any of the foregoing persons, are not permitted to enter into a related party transaction with us without the prior approval or, in the case of pending or ongoing related party transactions, ratification

of our audit committee. For purposes of our policy, a related party transaction is a transaction, arrangement or relationship where the company was, is or will be involved and in which a related party had, has or will have a direct or indirect material interest. Certain transactions with related parties, however, are excluded from the definition of a related party transaction including, but not limited to (1) transactions involving the purchase or sale of products or services in the ordinary course of business, not exceeding \$20,000, (2) transactions where a related party's interest derives solely from his or her service as a director of another entity that is a party to the transaction, (3) transactions where a related party's interest derives solely from his or her ownership of less than 10% of the equity interest in another entity that is a party to the transaction, and (4) transactions where a related party's interest derives solely from his or her ownership of a class of our equity securities and all holders of that class received the same benefit on a pro rata basis. No member of the audit committee may participate in any review, consideration or approval of any related party transaction where such member or any of his or her immediate family members is the related party. In approving or rejecting the proposed agreement, our audit committee shall consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to (1) the benefits and perceived benefits to the company, (2) the materiality and character of the related party's direct and indirect interest, (3) the availability of other sources for comparable products or services, (4) the terms of the transaction, and (5) the terms available to unrelated third parties under the same or similar circumstances. In reviewing proposed related party transactions, the audit committee will only approve or ratify related party transactions that are in, or not inconsistent with, the best interests of the company and our stockholders. We have determined that there were no new related party transactions to disclose in 2012.

#### ***Indebtedness of Directors and Officers***

None of our or any of our subsidiaries' current or former directors or executive officers is indebted to us or any our subsidiaries, nor are any of these individuals indebted to another entity which indebtedness is the subject of a guarantee, support agreement, letter of credit or other similar arrangement or understanding provided by us, or any of our subsidiaries.

#### **Determinations Regarding Director Independence**

The board of directors has determined that each of our current directors, except Dr. Kirkman, is an "independent director" as that term is defined in NASDAQ Marketplace Rule 5605(a)(2). The independent directors generally meet in executive session at each quarterly board of directors meeting.

The board of directors has also determined that each member of the audit committee, the compensation committee, and the corporate governance and nominating committee meets the independence standards applicable to those committees prescribed by the NASDAQ, the SEC, and the Internal Revenue Service.

Finally, the board of directors has determined that Mr. Spiegelman, the chairman of the audit committee, is an "audit committee financial expert" as that term is defined in Item 407(d)(5) of Regulation S-K promulgated by the SEC.

#### **ITEM 14. *Principal Accountant Fees and Services***

##### ***Audit Fees***

Fees and related expenses for the 2012 audit by Ernst & Young LLP of our annual financial statements, its review of the financial statements included in our 2012 quarterly reports and other services, which include comfort letters, consents and accounting consultations, that are provided in connection with statutory and regulatory filings totaled \$524,811. Fees and related expenses for 2011 totaled \$494,654.



### ***Audit-Related Fees***

For the years 2012 and 2011, Ernst & Young LLP billed us \$1,735 and \$1,995, respectively, for a subscription to their technical accounting database.

### ***Tax Fees***

For the years 2012 and 2011, Ernst & Young LLP billed us \$55,884 and \$0, respectively, for professional services related to preparation of our tax return and tax consultations on tax related matters.

### ***All Other Fees***

None.

### **Policy on Audit Committee Pre Approval of Fees**

In its pre-approval policy, the audit committee has authorized our chief executive officer or our chief financial officer to engage the services of Ernst & Young LLP with respect to the following:

- audit related services that are outside the scope of our annual audit and generally are (1) required on a project, recurring, or on a one-time basis, (2) requested by one of our business partners (for example, a review or audit of royalty payments), or (3) needed by us to assess the impact of a proposed accounting standard;
- audits of the annual statutory financial statements required by the non-U.S. governmental agencies for our overseas subsidiaries;
- accounting services related to potential or actual acquisitions or investment transactions that if consummated would be reflected in our financial results or tax returns (this does not include any due diligence engagements, which must be pre-approved by the audit committee separately); and
- other accounting and tax services, such as routine consultations on accounting and/or tax treatments for contemplated transactions.

Notwithstanding this delegation of authorization, the audit committee pre-approves all audit and non-audit related services performed by Ernst & Young LLP. On an annual basis prior to the completion of the audit, the audit committee will review a listing prepared by management of all proposed non-audit services to be performed by the external auditor for the upcoming fiscal year, such listing to include scope of activity and estimated budget amount. The audit committee, if satisfied with the appropriateness of the services, will provide pre-approval of such services. If non-audit services are required subsequent to the annual pre-approval of services, management will seek approval of such services at the next regularly scheduled audit committee meeting. If such services are required prior to the next audit committee meeting, management will confer with the audit committee chairman regarding either conditional approval subject to full audit committee ratification or the necessity to reconvene a meeting. The audit committee has considered the non-audit services provided to us by our independent registered public accountants and has determined that the provision of such services is compatible with their independence.

All audit-related, tax and other fees were approved by the audit committee.

**PART IV**

**ITEM 15. Exhibits and Financial Statement Schedules**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. *Financial Statements:*

Our consolidated financial statements are contained in Item 8 of this annual report on Form 10-K.

2. *Financial Statement Schedules:*

All financial statement schedules have been omitted because the required information is either included in the financial statements or notes thereto, or is not applicable.

3. *Exhibits:*

The exhibits required by Item 601 of Regulation S-K are listed in paragraph (b) below.

(b) Exhibits:

The following exhibits are filed herewith or are incorporated by reference to exhibits previously filed with the SEC:

Exhibit No.	Exhibit Description	Incorporated by Reference		
		Form	Exhibit No.	Filing Date
2.1(a)	Agreement and Plan of Reorganization among ProIX Pharmaceuticals Corporation, D. Lynn Kirkpatrick, Garth Powis and Biomira Inc., dated October 30, 2006. ....	S-4/A	2.1	October 29, 2007
2.1(b)	Amendment No. 1 to Agreement and Plan of Reorganization dated November 7, 2007. ....	10-K	2.1(b)	May 6, 2010
3.1	Amended and Restated Certificate of Incorporation of Oncothyreon Inc. ....	S-4/A	3.1	September 27, 2007
3.2	Bylaws of Oncothyreon Inc. ....	10-Q	3.1	August 14, 2009
4.1	Form of registrant's common stock certificate. ....	S-4/A	4.1	September 27, 2007
4.2	Form of Warrant. ....	FWP	Annex A	May 20, 2009
4.3	Form of Warrant issued pursuant to the terms of the Securities Purchase Agreement, dated September 23, 2010, by and among Oncothyreon Inc. and the signatories thereto, as amended. ....	S-1	10.49	October 4, 2010
4.4	Form of Warrant to Purchase Common Stock issued by Oncothyreon Inc. to the Lenders pursuant to the terms of the Loan and Security Agreement. ....	8-K	10.3	February 9, 2011

Exhibit No.	Exhibit Description	Incorporated by Reference			Filed/ Furnished Herewith
		Form	Exhibit No.	Filing Date	
4.5	Registration Rights Agreement, dated September 28, 2010 by and among Oncothyreon Inc. and the signatories thereto. ....	8-K	4.1	September 27, 2010	
10.1*	Amended and Restated Share Option Plan. ....	10-K	10.1	March 9, 2012	
10.2*	Form of Stock Option Agreement under the Amended and Restated Share Option Plan. ....	10-K	10.2	March 9, 2012	
10.3*	Amended and Restated Restricted Share Unit Plan. ....	10-K	10.3	March 9, 2012	
10.4*	Form of Restricted Share Unit Agreement under the Amended and Restated Restricted Share Unit Plan. ....	10-K	10.4	March 9, 2012	
10.5*	2010 Employee Stock Purchase Plan. ....	8-K	10.1	June 8, 2010	
10.6*	Form of Subscription Agreement and Notice of Withdrawal under the 2010 Employee Stock Purchase Plan. ....	8-K	10.2	June 8, 2010	
10.7*	Form of Indemnification Agreement. ....	S-4/A	10.1	September 27, 2007	
10.8*	Offer letter with Robert Kirkman, dated August 29, 2006. ....	S-4	10.27	September 12, 2007	
10.8(a)*	Amendment to Robert Kirkman Offer Letter dated December 31, 2008. ....	10-K	10.18(a)	March 30, 2009	
10.8(b)*	Amendment to Robert Kirkman Offer Letter dated December 3, 2009. ....	8-K	10.1	December 7, 2009	
10.9*	Offer Letter with Gary Christianson, dated June 29, 2007. ....	10-Q	10.1	November 10, 2008	
10.9(a)*	Amendment to Gary Christianson Offer Letter dated December 31, 2008. ....	10-K	10.40(a)	March 30, 2009	
10.9(b)*	Amendment to Gary Christianson Offer Letter dated December 3, 2009. ....	8-K	10.2	December 7, 2009	
10.10*	Offer Letter dated June 9, 2009 between Oncothyreon Inc. and Scott Peterson, Ph.D. ....	8-K	10.2	June 15, 2009	
10.10(a)*	Amendment to Scott Peterson Offer Letter dated December 3, 2009. ....	8-K	10.4	December 7, 2009	

Exhibit No.	Exhibit Description	Incorporated by Reference			Filed/ Furnished Herewith
		Form	Exhibit No.	Filing Date	
10.11*	Offer Letter dated July 6, 2009 between Oncothyreon Inc. and Diana Hausman, M.D. ....	8-K	10.1	August 4, 2009	
10.11(a)*	Amendment to Diana Hausman Offer Letter dated December 3, 2009. ....	8-K	10.3	December 7, 2009	
10.12*	Offer letter with Julia M. Eastland, dated August 17, 2010. ....	8-K	10.1	August 31, 2010	
10.13	Lease Agreement between Selig Holdings Company and Oncothyreon Inc., dated May 9, 2008. ....	10-Q	10.3	November 10, 2008	
10.14	Securities Purchase Agreement, dated September 23, 2010, by and among Oncothyreon Inc. and the signatories thereto. ....	8-K	10.1	September 27, 2010	
10.15(a)	Amendment No. 1 to the Securities Purchase Agreement, dated September 28, 2010. ....	8-K	10.1	September 30, 2010	
10.16 <sup>+</sup>	License Agreement between Biomira Inc. and the Dana-Farber Cancer Institute, Inc., dated November 22, 1996. ....	S-4	10.6	September 12, 2007	
10.17 <sup>+</sup>	Amended and Restated License Agreement between Imperial Cancer Research Technology Limited and Biomira Inc., dated November 14, 2000. ....	S-4/A	10.11	September 27, 2007	
10.18	Consent and Acknowledgement among Biomira Inc., Biomira International Inc., Biomira Europe B.V., Imperial Cancer Research Technology Limited and Merck KGaA, dated February 5, 2002. ....	S-4	10.13	September 12, 2007	
10.19 <sup>+</sup>	License Agreement between the Governors of the University of Alberta and Biomira Inc., dated December 1, 2001. ....	S-4/A	10.14	September 27, 2007	
10.20 <sup>+</sup>	Letter Agreement between Biomira Inc. and Cancer Research Technology Limited (formerly Imperial Cancer Research Technology Limited), dated March 9, 2004. ....	S-4/A	10.16	September 27, 2007	

Exhibit No.	Exhibit Description	Incorporated by Reference			Filed/ Furnished Herewith
		Form	Exhibit No.	Filing Date	
10.21 <sup>†</sup>	Exclusive License Agreement between the University of Arizona and ProIX Pharmaceuticals Corporation, dated July 29, 2004. ....	S-4	10.18	September 12, 2007	
10.22(a)	First Amendment to Exclusive License Agreement between University of Arizona and Oncothyreon Inc., dated September 27, 2010. ....	10-K	10.7(a)	March 14, 2011	
10.23 <sup>†</sup>	Adjuvant License Agreement between Biomira International Inc. and Corixa Corporation, dated October 20, 2004. ....	S-4/A	10.19	September 27, 2007	
10.24 <sup>†</sup>	Adjuvant Supply Agreement between Biomira International Inc. and Corixa Corporation, dated October 20, 2004. ....	S-4/A	10.20	September 27, 2007	
10.25 <sup>†</sup>	Exclusive Patent License Agreement between the University of Arizona and ProIX Pharmaceuticals Corporation, dated September 15, 2005. ....	S-4	10.21	September 12, 2007	
10.26(a)	First Amendment to Exclusive Patent License Agreement between the University of Arizona and Oncothyreon Inc., dated November 28, 2008. ....	10-K	10.10(a)	March 14, 2011	
10.26(b)	Second Amendment to Exclusive Patent License Agreement between the University of Arizona and Oncothyreon Inc., dated August 13, 2010. ....	10-K	10.10(b)	March 14, 2011	
10.27 <sup>†</sup>	Letter Agreement between the University of Arizona and Biomira Inc., dated October 6, 2006. ....	S-4	10.28	September 12, 2007	
10.28	Amendment Number 1 to Adjuvant License Agreement and Adjuvant Supply Agreement between Corixa Corporation, d/b/a GlaxoSmithKline Biologicals N.A. and Biomira Management Inc., dated August 8, 2008. ....	10-Q	10.4	November 10, 2008	
10.29 <sup>†</sup>	Amended and Restated License Agreement between Biomira Management, Inc. and Merck KGaA, dated December 18, 2008. ....	10-Q	10.1	May 15, 2009	

<u>Exhibit No.</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>			<u>Filed/ Furnished Herewith</u>
		<u>Form</u>	<u>Exhibit No.</u>	<u>Filing Date</u>	
10.30	Common Stock Purchase Agreement by and among Biomira Inc., Biomira International Inc. and Merck KGaA dated May 2, 2001. . . .	10-K	10.41	May 6, 2010	
10.31	Tax Indemnity Agreement by and between Biomira International Inc. and Merck KGaA dated May 3, 2001. . . . .	10-K	10.42	May 6, 2010	
21.1	Subsidiaries of Oncothyreon Inc. . . .				X
23.1	Consent of Independent Registered Public Accounting Firm. . . . .				X
24.1	Power of Attorney (included on signature page). . . . .				X
31.1	Certification of Robert L. Kirkman, M.D., President and Chief Executive Officer, pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. . . . .				X
31.2	Certification of Julia Eastland, Chief Financial Officer, pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. . . . .				X
32.1	Certification of Robert L. Kirkman, M.D., 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(1). . . . .				X
32.2	Certification of Julia Eastland, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(1). . . . .				X
101.INS	XBRL Instance Document(2). . . . .				X
101.SCH	XBRL Taxonomy Extension Schema Document(2). . . . .				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document(2). . . . .				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document(2). . . . .				X

<u>Exhibit No.</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>			<u>Filed/ Furnished Herewith</u>
		<u>Form</u>	<u>Exhibit No.</u>	<u>Filing Date</u>	
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document(2). . . . .				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document(2). . . . .				X

- (1) This certification is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, or Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or Securities Act or the Exchange Act.
- (2) Pursuant to applicable securities laws and regulations, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, are deemed not filed for purposes of section 18 of the Exchange Act and otherwise are not subject to liability under these sections.
- \* Executive Compensation Plan or Agreement.
- † Confidential treatment has been granted for portions of this exhibit.

## 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 in the City of Seattle, County of King, State of Washington on March 14, 2013.

ONCOTHYREON INC.

By: /s/ Robert L. Kirkman, M.D.

Robert L. Kirkman, M.D.  
President, CEO and Director  
(Principal Executive Officer)

## POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints Robert L. Kirkman and Julia M. Eastland and each of them, his or her true and lawful attorneys-in-fact and agents, with full power to act without the other and with full power of substitution and resubstitution, to execute in his or her name and on his or her behalf, individually and in each capacity stated below, any and all amendments and supplements to this Report, and any and all other instruments necessary or incidental in connection herewith, and to file the same with the Commission.

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ Robert L. Kirkman, M.D. Robert L. Kirkman, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2013
/s/ Julia M. Eastland Julia M. Eastland	Chief Financial Officer, Secretary and Vice President of Corporate Development (Principal Financial and Accounting Officer)	March 14, 2013
/s/ Christopher S. Henney, Ph.D. Christopher S. Henney, Ph.D.	Chairman and Director	March 14, 2013
/s/ Richard L. Jackson, Ph.D. Richard L. Jackson, Ph.D.	Director	March 14, 2013
/s/ Daniel K. Spiegelman Daniel K. Spiegelman	Director	March 14, 2013
/s/ W. Vickery Stoughton W. Vickery Stoughton	Director	March 14, 2013
/s/ Douglas Williams, Ph.D. Douglas Williams, Ph.D.	Director	March 14, 2013



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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
Oncothyreon Inc.

We have audited the accompanying consolidated balance sheets of Oncothyreon Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, stockholders' 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 Oncothyreon 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 have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Oncothyreon 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 14, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington  
March 14, 2013

**ONCOTHYREON INC.**

**Consolidated Balance Sheets**

	As of December 31,	
	2012	2011
	(In thousands, except share and per share amounts)	
<b>ASSETS</b>		
Current:		
Cash and cash equivalents .....	<b>\$ 22,266</b>	\$ 11,609
Short-term investments .....	<b>58,988</b>	52,267
Accounts and other receivables .....	<b>323</b>	321
Prepaid and other current assets .....	<b>840</b>	610
Total current assets .....	<b>82,417</b>	64,807
Long-term investments .....	<b>2,502</b>	2,531
Property and equipment, net .....	<b>1,887</b>	1,643
Goodwill .....	<b>2,117</b>	2,117
Other assets .....	<b>512</b>	441
Total assets .....	<b>\$ 89,435</b>	\$ 71,539
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current		
Accounts payable .....	<b>\$ 1,133</b>	\$ 459
Accrued and other liabilities .....	<b>852</b>	1,475
Accrued compensation and related liabilities .....	<b>1,042</b>	858
Current portion of notes payable .....	<b>—</b>	1,749
Current portion of restricted share unit liability .....	<b>44</b>	329
Total current liabilities .....	<b>3,071</b>	4,870
Notes payable .....	<b>—</b>	3,059
Deferred rent .....	<b>533</b>	617
Restricted share unit liability .....	<b>227</b>	759
Warrant liability .....	<b>3,251</b>	28,771
Class UA preferred stock, 12,500 shares authorized, 12,500 shares issued and outstanding .....	<b>30</b>	30
	<b>7,112</b>	38,106
Commitments and contingencies		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, no shares issued or outstanding .....	<b>—</b>	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized, 57,216,237 and 43,613,107 shares issued and outstanding .....	<b>353,853</b>	353,851
Additional paid-in capital .....	<b>126,832</b>	74,537
Accumulated deficit .....	<b>(393,326)</b>	(389,911)
Accumulated other comprehensive loss .....	<b>(5,036)</b>	(5,044)
Total stockholders' equity .....	<b>82,323</b>	33,433
Total liabilities and stockholders' equity .....	<b>\$ 89,435</b>	\$ 71,539

See accompanying notes to the consolidated financial statements

**ONCOTHYREON INC.**

**Consolidated Statements of Operations**

	Years Ended December 31,		
	2012	2011	2010
	(In thousands, except share and per share amounts)		
<b>Revenues</b>			
Licensing revenue from collaborative and license agreements .....	\$ —	\$ 145	\$ 18
<b>Operating Expenses</b>			
Research and development .....	<b>22,001</b>	17,915	11,601
General and administrative .....	<b>6,498</b>	6,929	7,901
Total operating expenses .....	<b>28,499</b>	24,844	19,502
Loss from operations .....	<b>(28,499)</b>	(24,699)	(19,484)
<b>Other income (expense)</b>			
Investment and other income (expense), net ..	<b>(127)</b>	305	636
Interest expense .....	<b>(309)</b>	(631)	—
Change in fair value of warrant liability .....	<b>25,520</b>	(17,631)	3,030
Total other income (expense), net .....	<b>25,084</b>	(17,957)	3,666
<b>Loss before income taxes</b> .....	<b>(3,415)</b>	(42,656)	(15,818)
Income tax benefit .....	—	—	200
<b>Net loss</b> .....	<b>\$ (3,415)</b>	<b>\$ (42,656)</b>	<b>\$ (15,618)</b>
<b>Loss per share — basic</b> .....	<b>\$ (0.06)</b>	<b>\$ (1.12)</b>	<b>\$ (0.58)</b>
<b>Loss per share — diluted (Note 6)</b> .....	<b>\$ (0.53)</b>	<b>\$ (1.12)</b>	<b>\$ (0.72)</b>
<b>Shares used to compute basic loss per share</b> ...	<b>53,728,672</b>	38,197,666	26,888,588
<b>Shares used to compute diluted loss per share</b> ...	<b>54,899,955</b>	38,197,666	26,972,969

See accompanying notes to the consolidated financial statements

**ONCOTHYREON INC.**

**Consolidated Statements of Comprehensive Loss**

	Years Ended December 31,		
	2012	2011	2010
	(In thousands)		
<b>Net loss</b> .....	<b>\$ (3,415)</b>	\$(42,656)	\$(15,618)
<b>Other comprehensive income:</b>			
Available-for-sale securities:			
Unrealized gains during the period , net .....	<b>9</b>	22	—
Reclassification adjustment .....	<b>(1)</b>	—	—
Other comprehensive income .....	<b>8</b>	22	—
<b>Comprehensive loss</b> .....	<b><u>\$ (3,407)</u></b>	<u>\$(42,634)</u>	<u>\$(15,618)</u>

See accompanying notes to the consolidated financial statements

**ONCOTHYREON INC.**

**Consolidated Statements of Stockholders' Equity**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Stockholders' Equity
	Shares	Amount				
	(In thousands, except share amounts)					
<b>Balance at December 31, 2009</b> ...	<b>25,753,405</b>	<b>\$345,836</b>	<b>\$ 16,285</b>	<b>\$ (331,637)</b>	<b>\$(5,066)</b>	<b>\$ 25,418</b>
Net loss .....	—	—	—	(15,618)	—	(15,618)
Common stock issued, net of offering costs of \$1.2 million ....	4,302,791	7,849	—	—	—	7,849
Issuances under employee stock purchase plan .....	20,434	58	—	—	—	58
Restricted stock units converted .....	9,498	80	(80)	—	—	—
Restricted stock units granted ....	—	—	150	—	—	150
Share-based compensation expense .....	—	—	973	—	—	973
Stock options exercised .....	2,500	—	—	—	—	—
Warrants expiration .....	—	27	—	—	—	27
<b>Balance at December 31, 2010</b> ...	<b>30,088,628</b>	<b>353,850</b>	<b>17,328</b>	<b>(347,255)</b>	<b>(5,066)</b>	<b>18,857</b>
Net loss .....	—	—	—	(42,656)	—	(42,656)
Unrealized gains on available-for-sale securities .....	—	—	—	—	22	22
Common stock issued, net of offering costs of \$3.1 million ....	12,944,579	1	52,031	—	—	52,032
Issuances under employee stock purchase plan .....	71,969	—	207	—	—	207
Restricted stock units granted ....	—	—	323	—	—	323
Restricted stock units converted .....	93,122	—	(55)	—	—	(55)
Share-based compensation expense .....	—	—	1,204	—	—	1,204
Stock options exercised .....	12,708	—	48	—	—	48
Warrants issued .....	—	—	114	—	—	114
Warrants exercised .....	402,101	—	1,901	—	—	1,901
Reclassification of fair value of warrants exercised from liability to equity .....	—	—	1,843	—	—	1,843
Reclassification of fair value of outstanding RSUs from equity to liability .....	—	—	(407)	—	—	(407)
<b>Balance at December 31, 2011</b> ....	<b>43,613,107</b>	<b>353,851</b>	<b>74,537</b>	<b>(389,911)</b>	<b>(5,044)</b>	<b>33,433</b>
Net loss .....	—	—	—	(3,415)	—	(3,415)
Unrealized gains on available-for-sale securities .....	—	—	—	—	8	8
Common stock issued, net of offering costs of \$3.8 million ....	13,512,500	2	50,283	—	—	50,285
Issuances under employee stock purchase plan .....	55,424	—	182	—	—	182
Restricted stock units converted .....	32,551	—	231	—	—	231
Share-based compensation expense .....	—	—	1,590	—	—	1,590
Stock options exercised .....	2,655	—	9	—	—	9
<b>Balance at December 31, 2012</b> ....	<b>57,216,237</b>	<b>\$353,853</b>	<b>\$126,832</b>	<b>\$(393,326)</b>	<b>\$(5,036)</b>	<b>\$ 82,323</b>

See accompanying notes to the consolidated financial statements

**ONCOTHYREON INC.**

**Consolidated Statements of Cash Flows**

	Years Ended December 31,		
	2012	2011	2010
	(In thousands)		
<b>Cash flows from operating activities</b>			
Net loss .....	\$ (3,415)	\$(42,656)	\$ (15,618)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	520	457	462
Amortization of discount and deferred financing costs on notes payable .....	78	149	—
Share-based compensation expense .....	1,041	2,342	1,123
Provision for notes receivable, employees .....	—	—	154
Change in fair value of warrant liability .....	(25,520)	17,631	(3,030)
Recognition of deferred revenue .....	—	(145)	(22)
Derecognition of debt .....	—	(199)	—
Cash settled on conversion of restricted share units .....	(39)	(189)	—
Other .....	255	13	206
Net changes in assets and liabilities:			
Accounts and other receivables .....	11	(203)	(58)
Government grants receivable .....	—	489	(489)
Prepaid and other current assets .....	(302)	(31)	(434)
Other long-term assets .....	(307)	(27)	148
Accounts payable .....	674	(165)	(2)
Accrued and other liabilities .....	(435)	942	(120)
Accrued compensation and related liabilities .....	184	172	(118)
Deferred rent .....	(83)	229	93
Net cash used in operating activities .....	<u>(27,338)</u>	<u>(21,191)</u>	<u>(17,705)</u>
<b>Cash flows from investing activities</b>			
Purchases of investments .....	(72,037)	(88,118)	(29,331)
Redemption of investments .....	65,353	56,705	20,212
Purchases of property and equipment .....	(752)	(142)	(324)
Net cash used in investing activities .....	<u>(7,436)</u>	<u>(31,555)</u>	<u>(9,443)</u>
<b>Cash flows from financing activities</b>			
Proceeds from issuance of common stock and warrants, net of issuance costs .....	50,466	52,239	13,688
Proceeds from stock options exercised .....	9	48	—
Proceeds from warrants exercised .....	—	1,901	—
Proceeds from debt financing, net of issuance cost .....	—	4,804	—
Principal payment on notes payable .....	(909)	(151)	—
Repayment on notes payable .....	(4,135)	—	—
Net cash provided by financing activities .....	<u>45,431</u>	<u>58,841</u>	<u>13,688</u>
<b>Increase (decrease) in cash and cash equivalents .....</b>	<b>10,657</b>	<b>6,095</b>	<b>(13,460)</b>
<b>Cash and cash equivalents, beginning of year .....</b>	<b>11,609</b>	<b>5,514</b>	<b>18,974</b>
<b>Cash and cash equivalents, end of year .....</b>	<b><u>\$ 22,266</u></b>	<b><u>\$ 11,609</u></b>	<b><u>\$ 5,514</u></b>
<b>Supplemental disclosure of cash flow information</b>			
Interest paid .....	<u>\$ 276</u>	<u>\$ 437</u>	<u>\$ —</u>

See accompanying notes to the consolidated financial statements

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

#### 1. DESCRIPTION OF BUSINESS

Oncothyreon Inc. (the "Company") is a clinical-stage biopharmaceutical company incorporated in the State of Delaware on September 7, 2007. The Company is focused primarily on the development of therapeutic products for the treatment of cancer. The Company's goal is to develop and commercialize novel synthetic vaccines and targeted small molecules that have the potential to improve the lives and outcomes of cancer patients. The Company's operations are not subject to any seasonality or cyclicity factors.

#### 2. SIGNIFICANT ACCOUNTING POLICIES

##### *Basis of presentation*

These consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America ("U.S. GAAP") and reflect the following significant accounting policies.

##### *Reclassifications*

Certain prior year amounts have been reclassified to conform to the current classifications in the Consolidated Balance Sheets. These reclassifications relate to the presentation of deferred tax assets and liabilities (presented as part of other assets and accrued liabilities, respectively) as of December 31, 2011 to conform to the December 31, 2012 presentation. These reclassifications did not have a material impact on total assets and total liabilities, and had no impact on loss before income taxes, net loss, loss per share, or total equity.

##### *Basis of consolidation*

The Company's consolidated financial statements include the accounts of the company and its wholly-owned subsidiaries, including Oncothyreon Canada Inc., Biomira Management Inc., ProIX Pharmaceuticals Corporation, Biomira BV and Oncothyreon Luxembourg. All intercompany balances and transactions have been eliminated upon consolidation.

##### *Accounting estimates*

The preparation of financial statements in accordance with U.S. GAAP requires management to make complex and subjective judgments and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. By their nature, these judgments are subject to an inherent degree of uncertainty and as a consequence actual results may differ from those estimates.

##### *Cash and cash equivalents*

Cash equivalents include short-term, highly liquid investments that are readily convertible to known amounts of cash with original maturities of 90 days or less at the time of purchase. At December 31, 2012, cash and cash equivalents was comprised of \$2.4 million in cash, and \$19.9 million in money market funds. As of December 31, 2011, cash and cash equivalents was comprised of \$4.8 million in cash and \$3.9 million in certificates of deposit and \$2.9 million in money market funds. The carrying value of cash equivalents approximates their fair value.

##### *Investments*

Investments are classified as available-for-sale securities and are carried at fair value with unrealized temporary holding gains and losses, where applicable, excluded from net income or loss and reported in other comprehensive income or loss and also as a net



**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements – (Continued)**

amount in accumulated other comprehensive income or loss until realized. Available-for-sale securities are written down to fair value through income or loss whenever it is necessary to reflect an other-than-temporary impairment. All asset classes purchased for short-term investment are limited to a final maturity of less than one year from the reporting date. The Company's long-term investments are investments with maturities exceeding 12 months but less than five years from the reporting date. The Company is exposed to credit risk on its cash equivalents, short-term investments and long-term investment in the event of non-performance by counterparties, but does not anticipate such non-performance and mitigates exposure to concentration of credit risk through the nature of its portfolio holdings. If a security falls out of compliance with the Company's investment policy, it may be necessary to sell the security before its maturity date in order to bring the investment portfolio back in to compliance.

The fair value of available-for-sale securities is based on prices obtained from a third-party pricing service. The Company utilizes third-party pricing services for all of its marketable debt security valuations. The Company reviews the pricing methodology used by the third-party pricing services including the manner employed to collect market information. On a periodic basis, the Company also performs review and validation procedures on the pricing information received from the third-party pricing services. These procedures help ensure that the fair value information used by the Company is determined in accordance with applicable accounting guidance. The amortized cost, unrealized gains or losses and fair value of the Company's cash, cash equivalents and investments for the periods presented are summarized below:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
	(In thousands)			
As of December 31, 2012:				
Cash .....	\$ 2,407	\$ —	\$—	\$ 2,407
Money market funds .....	19,859	—	—	19,859
Debt securities of U.S. government agencies ..	52,415	29	—	52,444
Corporate bonds .....	9,045	1	—	9,046
Total .....	<u>\$83,726</u>	<u>\$30</u>	<u>\$—</u>	<u>\$ 83,756</u>
As of December 31, 2011:				
Cash .....	\$ 4,841	\$ —	\$—	\$ 4,841
Money market funds .....	2,869	—	—	2,869
Certificates of deposits .....	10,633	—	—	10,633
Debt securities of U.S. government agencies ..	16,378	2	—	16,380
Corporate bonds .....	31,664	20	—	31,684
Total .....	<u>\$66,385</u>	<u>\$22</u>	<u>\$—</u>	<u>\$ 66,407</u>

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

The following table summarizes the Company's available for sale securities by contractual maturity:

	As of December 31, 2012		As of December 31, 2011	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
	<i>(In thousands)</i>			
Less than one year .....	\$78,819	\$78,847	\$59,012	\$59,035
Greater than one year but less than five years .....	<u>2,500</u>	<u>2,502</u>	2,532	2,531
Total .....	<u>\$ 81,319</u>	<u>\$ 81,349</u>	<u>\$61,544</u>	<u>\$ 61,566</u>

**Warrants**

Warrants issued in connection with the Company's May 2009 and September 2010 financings are recorded as liabilities as both have the potential for cash settlement upon the occurrence of a fundamental transaction (as defined in the warrant; see "Note 6 — Share Capital"). Changes in the fair value of the warrants are recognized as other income (expense) in the consolidated statements of operations.

**Accounts and other receivables**

Accounts and other receivables are reviewed whenever circumstances indicate that the carrying amount of the receivable may not be recoverable. At this time, the Company does not deem an allowance to be necessary.

**Property and equipment, depreciation and amortization**

Property and equipment are recorded at cost and depreciated over their estimated useful lives on a straight-line basis, as follows:

Scientific and office equipment .....	5 years
Computer software and equipment .....	3 years
Leasehold improvements and leased equipment .....	Shorter of useful life or the term of the lease

**Long-lived assets**

Long-lived assets, such as property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset be tested for impairment, the Company first compares the undiscounted cash flows expected to be generated by the asset to the carrying value of the asset. If the carrying value of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying value exceeds its estimated fair value. Fair value is determined by management through various valuation techniques, including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. There were no impairment charges recorded for any of the periods presented.

**Goodwill**

Goodwill is not amortized, but is reviewed annually for impairment on October 1 of each year or more frequently when events or changes in circumstances indicate that the asset may be impaired. In the event that the carrying value of goodwill exceeds its fair value, an impairment loss would be recognized. There were no impairment charges recorded for any of the periods presented.

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

#### ***Deferred rent***

Rent expense is recognized on a straight-line basis over the term of the lease. Lease incentives, including rent holidays provided by lessors, and rent escalation provisions are accounted for as deferred rent.

#### ***Revenue recognition***

The Company recognizes revenue when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured. In accordance with ASC Topic 605-25, the Company evaluates revenue from arrangements with multiple deliverables to determine whether the deliverables represent one or more units of accounting. Revenue arrangements entered into, or materially modified, through December 31, 2010 have been accounted for in accordance with accounting standards that state that a delivered item is considered a separate unit of accounting if the following separation criteria are met: (1) the delivered item has stand-alone value to the customer; (2) there is objective and reliable evidence of the fair value of any undelivered items; and (3) if the arrangement includes a general right of return relative to the delivered item, the delivery of undelivered items is probable and substantially in the Company's control. The relevant revenue recognition accounting policy is then applied to each unit of accounting.

Effective January 1, 2011, the Company adopted new accounting guidance on a prospective basis and will no longer rely on objective and reliable evidence of the fair value of the elements in a revenue arrangement in order to separate a deliverable into a separate unit of accounting. The Company will instead use a selling price hierarchy for determining the selling price of a deliverable, which will be used to determine the allocation of consideration to each unit of accounting under an arrangement. The selling price used for each deliverable will be based on vendor-specific objective evidence if available, third-party evidence if vendor-specific objective evidence is not available or estimated selling price if neither vendor-specific objective evidence nor third-party evidence is available. This new guidance will be applied by the Company to revenue arrangements entered into, or materially modified, beginning January 1, 2011. As of December 31, 2012, the Company had not entered into any new revenue arrangements, or materially modified any of its existing, revenue arrangements and as such, these provisions do not apply.

The Company has historically generated revenue from the following activity:

*Licensing revenue from collaborative and license agreements.* Revenue from collaborative and license agreements consists of (1) up-front cash payments for initial technology access or licensing fees and (2) contingent payments triggered by the occurrence of specified events or other contingencies derived from the Company's collaborative and license agreements. Royalties from the commercial sale of products derived from the Company's collaborative and license agreements are reported as licensing, royalties, and other revenue.

If the Company has continuing obligations under a collaborative agreement and the deliverables within the collaboration cannot be separated into their own respective units of accounting, the Company utilizes a Multiple Attribution Model for revenue recognition as the revenue related to each deliverable within the arrangement should be recognized upon the culmination of the separate earnings processes and in such a manner that the accounting matches the economic substance of the deliverables included in the unit of accounting. As such, up-front cash payments are recorded as deferred revenue and recognized as revenue ratably over the period of performance under the applicable agreement.

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

If the Company has no continuing obligations under a license agreement, or a license deliverable qualifies as a separate unit of accounting included in a collaborative arrangement, license payments that are allocated to the license deliverable are recognized as revenue upon commencement of the license term and contingent payments are recognized as revenue upon the occurrence of the events or contingencies provided for in such agreement, assuming collectability is reasonably assured.

Effective January 1, 2011, the Company adopted new accounting guidance for recognizing milestone revenue, which will be applied on a prospective basis. Consideration that is contingent upon achievement of a milestone for research or development deliverables will be recognized in its entirety as revenue in the period in which the milestone is achieved if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the arrangement, such that it: (i) is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company's performance to achieve the milestone; (ii) relates solely to past performance; and (iii) is reasonable relative to all deliverables and payment terms in the arrangement.

The provisions of the new milestone revenue guidance apply only to those milestones payable for research or development activities and do not apply to contingent payments for which payment is either contingent solely upon the passage of time or the result of a collaborative partner's performance. The Company's existing collaboration agreements entail no performance obligations on the part of the Company, and milestone payments would be earned based on the collaborative partner's performance; therefore, milestone payments under existing agreements are considered contingent payments to be accounted for outside of the new milestone revenue guidance. The Company will recognize contingent payments as revenue upon the occurrence of the specified events, assuming the payments are deemed collectible at that time.

#### ***Government grants***

Funds received pursuant to government grants are recognized when the related research and development expenditures that qualify for grants are made and the Company has complied with the conditions for the receipt of the government grants. Government grants are recorded as other income or applied to reduce eligible expenses incurred, depending upon the circumstances surrounding timing of grant funding. In 2010, the Company was awarded a federal grant for \$0.5 million under the U.S. Government's Qualifying Therapeutic Discovery Project program for expenses incurred in 2009 and 2010, and recorded the funding received as other income in 2010.

#### ***Research and development costs***

Research and development expenses include personnel and facility related expenses, which includes depreciation and amortization, outside contract services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Research and development costs are expensed as incurred. In instances where the Company enters into agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities, costs are expensed as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

The Company's accruals for clinical trials are based on estimates of the services received and pursuant to contracts with numerous clinical trial centers and clinical research

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements – (Continued)

organizations. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful accrual of patients, and the completion of portions of the clinical trial or similar conditions. The objective of the Company's accrual policy is to match the recording of expenses in its consolidated financial statements to the actual services received. As such, expense accruals related to clinical trials are recognized based on its estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

#### ***Income or loss per share***

Basic net income or loss per share is calculated by dividing net income or loss by the weighted average number of shares outstanding for the period. Diluted net income or loss per share is calculated by adjusting the numerator and denominator of the basic net income or loss per share calculation for the effects of all potentially dilutive common shares. Potential dilutive shares of the Company's common stock include stock options, restricted shares units, warrants and shares under the 2010 Employee Stock Purchase Plan. Basic net loss per share equaled the diluted loss per share for the year ended December 31, 2011, since the effect of the shares potentially issuable upon the exercise or conversion was anti-dilutive. For additional information regarding the income or loss per share, see "Note 6 – Share Capital."

#### ***Income taxes***

The Company follows the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future income tax consequences attributable to differences between the carrying amounts and tax bases of assets and liabilities and losses carried forward and tax credits. Deferred tax assets and liabilities are measured using enacted tax rates and laws applicable to the years in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided to the extent that it is more likely than not that deferred tax assets will not be realized.

The Company recognizes the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. The Company does not believe any uncertain tax positions currently pending will have a material adverse effect on its consolidated financial statements nor expects any material change in its position in the next twelve months. Penalties and interest, of which there are none, would be reflected in income tax expense. Tax years are open to the extent the Company has net operating loss carryforwards available to be utilized currently.

#### ***Accumulated other comprehensive income (loss)***

Comprehensive income or loss is comprised of net income or loss and other comprehensive income or loss. Other comprehensive income or loss includes unrealized gains and losses on the Company's available-for-sale investments. In addition to the unrealized gains and losses on investments, accumulated other comprehensive income or loss consists of foreign currency translation adjustments that arose from the conversion of the Canadian dollar functional currency consolidated financial statements to the U.S. dollar functional currency consolidated financial statements prior to January 1, 2008. Should the Company

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

liquidate or substantially liquidate its investments in its foreign subsidiaries, the Company would be required to recognize the related cumulative translation adjustments pertaining to the liquidated or substantially liquidated subsidiaries, as a charge to earnings in the Company's consolidated statement of operations and comprehensive income (loss).

The balance of accumulated other comprehensive loss as reported on the Company's Consolidated Balance Sheets consists of the following components:

	<b>As of December 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(In thousands)</b>	
Unrealized gains on available-for-sale securities, net .....	<b>\$ 30</b>	\$ 22
Foreign currency translation adjustment .....	<b>(5,066)</b>	(5,066)
Accumulated other comprehensive loss .....	<b><u>\$(5,036)</u></b>	<u>\$(5,044)</u>

***Share-based compensation***

The Company recognizes in the statements of operations the estimated grant date fair value of share-based compensation awards granted to employees over the requisite service period. Share-based compensation expense in the consolidated statements of operations is recorded on a straight-line basis over the requisite service period for the entire award, which is generally the vesting period, with the offset to additional paid-in capital. The Company uses the Black-Scholes option pricing model to estimate the fair value of stock options granted to employees. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

For non-employee directors, the Company sponsors a Restricted Share Unit Plan, or RSU Plan that was established in 2005. An amendment to the RSU Plan in October 2011 requires the Company to settle 25% of the shares of its common stock otherwise deliverable in connection with the vesting of any restricted stock unit, or RSU and deliver to each non-employee director an amount in cash equal to the fair market value of the shares on the vesting date to satisfy the non-employee directors' tax obligations. This amendment resulted in the RSUs being classified as a liability. The outstanding RSU awards are required to be remeasured at each reporting date until settlement of the award, and changes in valuation are recorded as compensation expense for the period. To the extent that the liability recorded in the balance sheet is less than the original award value, the difference is recognized in equity. The Company uses the closing share price of its shares on the NASDAQ Global Market at the reporting or settlement date to determine the fair value of RSUs.

The Company maintains an Employee Stock Purchase Plan, or ESPP under which a total of 900,000 shares of common stock were reserved for sale to employees of the Company. The Company recognizes the estimated fair value of the ESPP which determined by the Black-Scholes option pricing model in the statement of operations.

For additional information regarding the share-based compensation, see "Note 7 — Share-based Compensation."

***Segment information***

The Company operates in a single business segment — research and development of therapeutic products for the treatment of cancer.

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

#### ***Recent accounting pronouncements***

In September 2011, FASB issued guidance on testing goodwill for impairment. The guidance simplifies how an entity tests goodwill for impairment. It allows an entity the option to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. An entity is no longer required to calculate the fair value of a reporting unit unless the entity determines, based on a qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The guidance was effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this accounting pronouncement on January 1, 2012 had no impact on the Company's financial position or results of operations.

In June 2011, FASB and the IASB issued guidance on presentation of items within other comprehensive income. The guidance requires an entity to present components of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive statements. The option to report other comprehensive income and its components in the statement of stockholders' equity has been eliminated. Although the guidance changes the presentation of comprehensive income, there are no changes to the components that are recognized in net income or other comprehensive income under existing guidance. The Company adopted these standards using the two separate but consecutive statements approach on January 1, 2012 for all periods presented, which impacted presentation only and had no effect on the Company's financial position or results of operations.

In May 2011, FASB and the IASB published converged standards on fair value measurement and disclosure. The standards do not require additional fair value measurements and are not intended to establish valuation standards or affect valuation practices outside of financial reporting. The standards clarified some existing rules and provided guidance for additional disclosures: (1) the concepts of "highest and best use" and "valuation premise" in a fair value measurement are relevant only when measuring the fair value of nonfinancial assets and are not relevant when measuring the fair value of financial assets or of liabilities; (2) when measuring the fair value of instruments classified in equity (e.g., equity issued in a business combination), the entity should measure it from the perspective of a market participant that holds that instrument as an asset; and (3) quantitative information about the unobservable inputs used in Level 3 measurements should be included. The amendments in this update are applied prospectively. For public entities, the amendments are effective during interim and annual periods beginning after December 15, 2011. The adoption of this accounting pronouncement on January 1, 2012 only impacted the disclosures within the Company's financial statements, and not its financial position or results of operations.

### **3. FAIR VALUE MEASUREMENTS**

The Company measures certain financial assets and liabilities at fair value in accordance with a hierarchy which requires an entity to maximize the use of observable inputs which reflect market data obtained from independent sources and minimize the use of unobservable inputs. There are three levels of inputs that may be used to measure fair value:

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

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

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

The Company's financial assets and liabilities measured at fair value on a recurring basis consisted of the following as of December 31, 2012 and 2011:

	December 31, 2012				December 31, 2011			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
	(In thousands)							
Financial Assets:								
Money market funds .....	\$19,859	\$ —	\$ —	\$ 19,859	\$ 2,869	\$ —	\$ —	\$ 2,869
Certificates of deposits .....	—	—	—	—	—	10,633	—	10,633
Debt securities of U.S. government agencies .....	—	52,444	—	52,444	—	16,380	—	16,380
Corporate bonds .....	—	9,046	—	9,046	—	31,684	—	31,684
	<u>\$19,859</u>	<u>\$ 61,490</u>	<u>\$ —</u>	<u>\$ 81,349</u>	<u>\$ 2,869</u>	<u>\$ 58,697</u>	<u>\$ —</u>	<u>\$ 61,566</u>

Financial Liability:

Restricted Share Units .....	\$ 271	\$ —	\$ —	\$ 271	\$ 1,088	\$ —	\$ —	\$ 1,088
Warrants .....	—	—	3,251	3,251	—	—	28,771	28,771

If quoted market prices in active markets for identical assets are not available to determine fair value, then the Company uses quoted prices of similar instruments and other significant inputs derived from observable market data obtained from third-party data providers.

These investments are included in Level 2 and consist of debt securities of U.S government agencies, corporate bonds and certificates of deposits denominated at or below \$250,000 issued by banks insured by the Federal Deposit Insurance Corporation.

There were no transfers between Level 1 and Level 2 during 2012.

The Company classifies its warrant liability within Level 3 because the warrant liability is valued using valuation models with significant unobservable inputs. The estimated fair value of warrants accounted for as liabilities was determined on the issuance date and are subsequently remeasured to fair value at each reporting date. The change in fair value of the warrants is recorded in the statement of operations as other income or other expense estimated by using the Black-Scholes option-pricing model with the following inputs:

	As of December 31, 2012	
	May 2009 Warrants	September 2010 Warrants
Exercise price .....	\$3.74	\$4.24
Market value of stock at end of period .....	\$ 1.92	\$ 1.92
Expected dividend rate .....	0.0%	0.0%
Expected volatility .....	99.2%	81.1%
Risk-free interest rate .....	0.2%	0.3%
Expected life (in years) .....	1.40	2.78



**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

	As of December 31, 2011	
	May 2009 Warrants	September 2010 Warrants
Exercise price .....	\$3.74	\$4.24
Market value of stock at end of period .....	\$7.58	\$7.58
Expected dividend rate .....	0.0%	0.0%
Expected volatility .....	63.4%	80.4%
Risk-free interest rate .....	0.3%	0.5%
Expected life (in years) .....	2.40	3.75

The table below shows the reconciliation of warrant liability measured and recorded at fair value on a recurring basis, using significant unobservable inputs (Level 3):

	Years Ended December 31,	
	2012	2011
	(In thousands)	
Balance at beginning of period .....	<b>\$ 28,771</b>	\$12,983
Change in fair value of warrant liability included in:		
Other expense (income) .....	<b>(25,520)</b>	17,631
Reclassified to equity upon exercise of warrants .....	<b>—</b>	(1,843)
Balance at the end of period .....	<b>\$ 3,251</b>	\$28,771

Expected volatility is an unobservable input that is inter-related to the market value or price of the Company's stock, since the calculation for volatility is based on the Company's historical closing prices. If volatility were to change by 10%, the value of the warrant liability would change by approximately \$0.6 million.

**4. PROPERTY AND EQUIPMENT**

The table below outlines the cost, accumulated depreciation and amortization and net carrying value of the Company's property and equipment for the years ended December 31, 2012 and 2011:

	2012		
	Cost	Accumulated Depreciation and Amortization (In thousands)	Net Carrying Value
<b>Leasehold improvements</b> .....	<b>\$ 1,580</b>	<b>\$ 604</b>	<b>\$ 976</b>
<b>Scientific equipment</b> .....	<b>2,095</b>	<b>1,212</b>	<b>883</b>
<b>Office equipment</b> .....	<b>34</b>	<b>20</b>	<b>14</b>
<b>Computer software and equipment</b> .....	<b>325</b>	<b>311</b>	<b>14</b>
	<b><u>\$4,034</u></b>	<b><u>\$2,147</u></b>	<b><u>\$1,887</u></b>

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

	2011		
	Cost	Accumulated Depreciation and Amortization	Net Carrying Value
	(In thousands)		
Leasehold improvements .....	\$ 1,574	\$ 412	\$ 1,162
Scientific equipment .....	1,373	927	446
Office equipment .....	34	13	21
Computer software and equipment .....	319	305	14
	<u>\$3,300</u>	<u>\$1,657</u>	<u>\$1,643</u>

Depreciation and leasehold improvement amortization expense was \$0.5 million for each of the years ended December 31, 2012, 2011 and 2010, respectively.

**5. NOTES PAYABLE**

On February 8, 2011, the Company entered into a Loan and Security Agreement with General Electric Capital Corporation, or GECC, and with the other financial institutions that may become parties to the Loan and Security Agreement (GECC and such other financial institutions together, the "Lenders"), pursuant to which the Lenders agreed to make a term loan in an aggregate principal amount of \$5.0 million, or Term Loan, subject to the terms and conditions set forth in the Term Loan. On February 8, 2011, the Lenders funded a Term Loan in the principal amount of \$5.0 million on a total facility of \$12.5 million. The Term Loan accrued interest at a fixed rate of 10.64% per annum and was payable over a 42-month period. In connection with the Term Loan, on February 8, 2011, the Company issued to an affiliate of GECC a warrant to purchase up to an aggregate of 48,701 shares of common stock at an exercise price of \$3.08 per share. This warrant, classified as equity, is immediately exercisable and will expire on February 8, 2018.

On June 29, 2012, the Company paid approximately \$4.1 million to extinguish the outstanding balance of its term loan with GECC prior to its scheduled maturity. During the year ended December 31, 2012, the Company incurred a \$0.3 million loss on early extinguishment of debt, which consisted of a prepayment penalty of 3% on the outstanding principal, the write-off of unamortized deferred financing costs and unamortized debt discount and legal expenses related to extinguishment of debt. As of December 31, 2012, the outstanding balance of the debt, the unamortized deferred financing costs and unamortized debt discount is zero.

Interest expense for the years ended December 31, 2012 and 2011, all of which related to the Term Loan, was \$308,745 and \$631,132, respectively. No interest expense was incurred for the years ended December 31, 2010. Interest expense is calculated using the effective interest method and includes non-cash amortization of debt discount and capitalized loan fees in the amount of \$77,504 and \$149,287 for the years ended December 31, 2012 and 2011, respectively.

**6. SHARE CAPITAL**

***Class UA preferred stock***

As of December 31, 2012 and 2011, the Company had 12,500 shares of Class UA preferred stock authorized, issued and outstanding. The Class UA preferred stock has the following rights, privileges, and limitations:

*Voting.* Each share of Class UA preferred stock will not be entitled to receive notice of, or to attend and vote at, any Stockholder meeting unless the meeting is called to consider any

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements – (Continued)

matter in respect of which the holders of the shares of Class UA preferred stock would be entitled to vote separately as a class, in which case the holders of the shares of Class UA preferred stock shall be entitled to receive notice of and to attend and vote at such meeting. Amendments to the certificate of incorporation of Oncothyreon that would increase or decrease the par value of the Class UA preferred stock or alter or change the powers, preferences or special rights of the Class UA preferred stock so as to affect them adversely would require the approval of the holders of the Class UA preferred stock.

*Conversion.* The Class UA preferred stock is not convertible into shares of any other class of Oncothyreon capital stock.

*Dividends.* The holders of the shares of Class UA preferred stock will not be entitled to receive dividends.

*Liquidation preference.* In the event of any liquidation, dissolution or winding up of the Company, the holders of the Class UA preferred stock will be entitled to receive, in preference to the holders of the Company's common stock, an amount equal to the lesser of (1) 20% of the after tax profits ("net profits"), determined in accordance with Canadian generally accepted accounting principles, where relevant, consistently applied, for the period commencing at the end of the last completed financial year of the Company and ending on the date of the distribution of assets of the Company to its stockholders together with 20% of the net profits of the Company for the last completed financial year and (2) CDN \$100 per share.

Holders of Class UA preferred stock are entitled to mandatory redemption of their shares if the Company realizes "net profits" in any year. For this purpose, "net profits . . ." means the after tax profits determined in accordance with generally accepted accounting principles, where relevant, consistently applied." The Company has taken the position that this applies to Canadian GAAP and accordingly there have been no redemptions to date.

*Redemption.* The Company may, at its option and subject to the requirements of applicable law, redeem at any time the whole or from time to time any part of the then-outstanding shares of Class UA preferred stock for CDN \$100 per share. The Company is required each year to redeem at CDN \$100 per share that number of shares of Class UA preferred stock as is determined by dividing 20% of the net profits by CDN \$100.

The difference between the redemption value and the book value of the Class UA preferred stock will be recorded at the time that the fair value of the shares increases to redemption value based on the Company becoming profitable as measured using Canadian GAAP.

#### ***Preferred stock***

As of December 31, 2012 and 2011, the Company had 10,000,000 shares of undesignated preferred stock, \$0.0001 par value per share, authorized, with none outstanding. Shares of preferred stock may be issued in one or more series from time to time by the board of directors of the Company, and the board of directors is expressly authorized to fix by resolution or resolutions the designations and the powers, preferences and rights, and the qualifications, limitations and restrictions thereof, of the shares of each series of preferred stock. Subject to the determination of the board of directors of the Company, the preferred stock would generally have preferences over common stock with respect to the payment of dividends and the distribution of assets in the event of the liquidation, dissolution or winding up of the Company.

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

**Common stock**

As of December 31, 2012, the Company had 100,000,000 shares of common stock, \$0.0001 par value per share, authorized. The holders of common stock are entitled to receive such dividends or distributions as are lawfully declared on the Company's common stock, to have notice of any authorized meeting of stockholders, and to exercise one vote for each share of common stock on all matters which are properly submitted to a vote of the Company's stockholders. As a Delaware corporation, the Company is subject to statutory limitations on the declaration and payment of dividends. In the event of a liquidation, dissolution or winding up of the Company, holders of common stock have the right to a ratable portion of assets remaining after satisfaction in full of the prior rights of creditors, including holders of the Company's indebtedness, all liabilities and the aggregate liquidation preferences of any outstanding shares of preferred stock. The holders of common stock have no conversion, redemption, preemptive or cumulative voting rights.

Amounts pertaining to issuances of common stock are classified as common stock on the consolidated balance sheet, approximately \$5,722 and \$4,360 of which represents par value of common stock as of December 31, 2012 and 2011 respectively. Additional paid-in capital primarily relates to amounts for share-based compensation (see "Note 7 — Share-based Compensation").

**Equity Financings and Warrants**

In connection with certain equity and debt financings, the Company issued warrants to purchase shares of its common stock. In May 2009 and September 2010, the Company issued warrants to purchase 2,909,244 and 3,182,147 shares of its common stock respectively in connection with a registered direct offering of its common stock and warrants. These warrants are classified as liabilities, as opposed to equity, due to the potential cash settlement upon the occurrence of certain transactions specified in the warrant agreement.

In February 2011, the Company issued 48,701 warrants, which have been classified as equity, to purchase shares of common stock in connection with a Loan and Security Agreement entered into with GECC.

A summary of outstanding warrants as of December 31, 2012 and 2011 and changes during the years is presented below.

	<u>2012</u>	<u>2011</u>
	<u>Shares</u> <u>Underlying</u> <u>Warrants</u>	<u>Shares</u> <u>Underlying</u> <u>Warrants</u>
Balance, beginning of year .....	<b>5,922,089</b>	6,819,641
Warrants issued with term loan .....	—	48,701
Exercise of warrants .....	—	(402,103)
Expiration of warrants .....	—	(544,150)
Balance, end of year .....	<b><u>5,922,089</u></b>	<b><u>5,922,089</u></b>

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements – (Continued)**

The following table summarizes information regarding warrants outstanding at December 31, 2012:

<u>Exercise Prices</u>	<u>Shares Underlying Outstanding Warrants</u>	<u>Expiry Date</u>
\$3.08 .....	48,701	February 8, 2018
\$3.74 .....	2,691,241	May 26, 2014
\$4.24 .....	3,182,147	October 12, 2015
	<u>5,922,089</u>	

	<u>Years Ended December 31,</u>	
	<u>2012</u>	<u>2011</u>
Shares underlying warrants outstanding classified as liabilities .....	5,873,388	5,873,388
Shares underlying warrants outstanding classified as equity .....	48,701	48,701

On May 4, 2011, the Company closed an underwritten public offering of 11,500,000 shares of its common stock at a price to the public of \$4.00 per share for gross proceeds of \$46.0 million. The net proceeds from the sale of the shares, after deducting the underwriters' discounts and other estimated offering expenses payable were approximately \$43.1 million.

On October 4, 2011, the Company sold an aggregate of 639,071 shares of its common stock pursuant to the Company's committed equity line financing facility, at a per share purchase price of approximately \$6.43 resulting in aggregate proceeds of \$4.1 million. The per share purchase price was established under the financing facility by reference to the volume weighted average prices of the Company's common stock on The NASDAQ Global Market during a 10-day pricing period, net a discount of 5% per share. The Company received net proceeds from the sale of these shares of approximately \$4.1 million after deducting the Company's estimated offering expenses of approximately \$49,000, including a placement agent fee of \$41,000.

On November 10, 2011, the Company sold an aggregate of 805,508 shares of its common stock pursuant to the Company's committed equity line financing facility, at a per share purchase price of approximately \$6.21 resulting in aggregate proceeds of \$5.0 million. The per share purchase price was established under the financing facility by reference to the volume weighted average prices of the Company's common stock on The NASDAQ Global Market during a 10-day pricing period, net a discount of 5% per share. The Company received net proceeds from the sale of these shares of approximately \$4.9 million after deducting the Company's estimated offering expenses of approximately \$50,000.

In connection with the entry into the Sales Agreement with Cowen to sell shares of the Company's common stock, the Company terminated its committed equity line financing facility effective February 3, 2012.

On February 3, 2012, the Company entered into an agreement, or Sales Agreement with Cowen and Company, LLC ("Cowen"), to sell shares of the Company's common stock, having aggregate gross sales proceeds up to \$50,000,000, from time to time, through an

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

“at the market” equity offering program under which Cowen will act as sales agent. Under the Sales Agreement, the Company will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. The Sales Agreement provides that Cowen will be entitled to compensation for its services that will not exceed, but may be lower than, 3.0% of the gross sales price per share of all shares sold through Cowen under the Sales Agreement. The Company has no obligation to sell any shares under the Sales Agreement, and may at any time suspend solicitation and offers under the Sales Agreement. No shares have been sold under the Sales Agreement as of the date hereof.

On April 3, 2012, the Company closed an underwritten public offering of 13,512,500 shares of its common stock at a price to the public of \$4.00 per share for gross proceeds of approximately \$54.1 million. The net proceeds from the sale of the shares, after deducting the underwriters' discounts and other estimated offering expenses payable by the Company, were approximately \$50.3 million.

#### ***Loss per share***

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding for the period. Diluted net loss per share is calculated by adjusting the numerator and denominator of the basic net loss per share calculation for the effects of all potentially dilutive common shares. Potential dilutive shares of the Company's common stock include stock options, restricted shares units, warrants and shares under the 2010 Employee Stock Purchase Plan. The calculation of diluted income (loss) per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of such securities are dilutive to income (loss) per share for the period, adjustments to net income or net loss used in the calculation are required to remove the change in fair value of the warrants for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares.

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**Notes to the Consolidated Financial Statements – (Continued)**

The following is a reconciliation of the numerators and denominators used in the calculation of basic and diluted loss per share computations for the years ended December 31, 2012, 2011 and 2010:

	Years Ended December 31,		
	2012	2011	2010
		(in thousands, except share and per share amounts)	
<b>Numerator:</b>			
Net loss used to compute net loss per share			
Basic .....	\$ (3,415)	\$ (42,656)	\$ (15,618)
Adjustments for change in fair value of warrant liability .....	(25,520)	—	(3,887)
Diluted .....	<u>\$ (28,935)</u>	<u>\$ (42,656)</u>	<u>\$ (19,505)</u>
<b>Denominator:</b>			
Weighted average shares outstanding used to compute loss per share:			
Basic .....	53,728,672	38,197,666	26,888,588
Dilutive effect of warrants .....	1,171,283	—	84,381
Diluted .....	<u>54,899,955</u>	<u>38,197,666</u>	<u>26,972,969</u>
Loss per share — basic .....	<u>\$ (0.06)</u>	<u>\$ (1.12)</u>	<u>\$ (0.58)</u>
Loss per share — diluted .....	<u>\$ (0.53)</u>	<u>\$ (1.12)</u>	<u>\$ (0.72)</u>

The following table presents the number of shares that were excluded from the number of shares used to calculate diluted net loss per share, since the effect of shares potentially issuable upon the exercise or conversion was anti-dilutive:

	Years Ended December 31,		
	2012	2011	2010
Director and employee stock options .....	2,934,453	2,441,725	2,075,025
Warrants .....	48,701	5,922,089	3,866,297
Non-employee director restricted share units ...	140,968	143,495	217,198
Employee stock purchase plan .....	4,758	1,067	2,604

For all periods presented, shares contingently issuable in connection with an agreement with Merck KGaA agreement (discussed below) and contingently issuable shares in connection with the October 30, 2006 ProIX acquisition, have been excluded from the calculation of diluted loss per share because the effect would have been anti-dilutive.

Under the terms of a common stock purchase agreement with Merck KGaA, upon the first submission of a biologics license application, or BLA for L-BLP25, if any, the Company is required to sell and Merck KGaA is required to purchase from the Company a number of shares of Company common stock equal to (1) \$1.5 million divided by (2) 115% of the 90-day weighted average per share price of such shares immediately prior to such submission date. During periods presented, no additional common shares were issued to Merck KGaA under such agreement.

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

**7. SHARE-BASED COMPENSATION**

***Share option plan***

The Company sponsors a Share Option Plan, or Option Plan under which a maximum fixed reloading percentage of 10% of the issued and outstanding common shares of the Company may be granted to employees, directors, and service providers. Prior to April 1, 2008, options were granted with a per share exercise price, in Canadian dollars, equal to the closing market price of the Company's shares of common stock on the Toronto Stock Exchange on the date immediately preceding the date of the grant. After April 1, 2008, options were granted with a per share exercise price, in U.S. dollars, equal to the closing price of the Company's shares of common stock on The NASDAQ Global Market on the date of grant. Canadian dollar amounts reflected in the tables below, which approximates their U.S. dollar equivalents as differences between the U.S. dollar and Canadian dollar exchange rates for the periods reflected below are not material. Prior to January 2010, options granted under the Option Plan begin to vest after one year from the date of the grant, are exercisable in equal amounts over four years on the anniversary date of the grant, and expire eight years following the date of grant. After January 2010, options granted under the Option Plan begin to vest 25% on the first anniversary of the hiring date, with the balance vesting in monthly increments for 36 months following the first anniversary of hiring, and expire eight years following the date of grant. The current maximum number of shares of common stock reserved for issuance under the Option Plan is 4,804,980. As of December 31, 2012, 1,852,606 shares of common stock remain available for future grant under the Option Plan.

A summary of option activity under the Option Plan as of December 31, 2012, and changes during such year is presented below. As described above, prior to April 1, 2008, exercise prices were denominated in Canadian dollars and in U.S. dollars thereafter. The weighted average exercise prices listed below are in their respective dollar denominations.

<u>Options</u>	<u>Stock Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
<b>In Canadian dollars (\$CDN):</b>				
Outstanding at January 1, 2012 .....	769,683	\$ 8.07		
Granted .....	—	—		
Exercised .....	—	—		
Forfeited .....	—	—		
Expired .....	(39,866)	13.06		
Outstanding at December 31, 2012 .....	<u>729,817</u>	\$ 7.79	1.77	\$—
Vested or expected to vest at December 31, 2012 .....	<u>729,817</u>	\$ 7.79	1.77	\$—
Vested and exercisable at December 31, 2012 .....	<u>729,817</u>	\$ 7.79	1.77	\$—



**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

<u>Options</u>	<u>Stock Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
<b>In US dollars (\$US):</b>				
Outstanding at January 1, 2012 .....	1,672,042	\$ 4.50		
Granted .....	554,500	4.82		
Exercised .....	(2,655)	3.57		
Forfeited .....	<u>(19,251)</u>	4.56		
Outstanding at December 31, 2012 .....	<u>2,204,636</u>	\$ 4.58	6.11	\$134,070
Vested or expected to vest at December 31, 2012 .....	<u>2,142,885</u>	\$ 4.57	5.14	\$134,070
Vested and exercisable at December 31, 2012 .....	<u>952,793</u>	\$ 4.10	6.08	\$100,553

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's common stock for all options that were in-the-money at December 31, 2012. The total fair value of stock options vested during the years ended December 31, 2012, 2011 and 2010 was \$2.93 million, \$1.57 million and \$0.68 million, respectively. Cash received from stock option exercises during the years ended December 31, 2012, 2011 and 2010 was immaterial. The total intrinsic value of option exercised during 2012, 2011 and 2010 was immaterial. There were 2,655, 12,708 and 2,500 stock options exercised during 2012, 2011 and 2010, respectively. As of December 31, 2012, there were 122,625 exercisable, in-the-money stock options based on the Company's closing share price of \$1.92 on The NASDAQ Global Market.

Share-based compensation expense related to the stock option plan of \$1.4 million, \$1.1 million and \$0.9 million was recognized for the years ended December 31, 2012, 2011 and 2010, respectively. Total compensation cost related to non-vested stock options not yet recognized was \$3.3 million as of December 31, 2012, which is expected to be recognized over the next 36 months on a weighted-average basis.

The Company uses the Black-Scholes option pricing model to value options upon grant date, under the following weighted average assumptions:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Weighted average grant-date fair value per stock option \$US .....	<b>\$ 3.41</b>	\$ 4.76	\$ 2.49
Expected dividend rate .....	—	—	—
Expected volatility .....	<b>84.68%</b>	82.63%	89.11%
Risk-free interest rate .....	<b>0.89%</b>	1.29%	2.00%
Expected life of options in years .....	<b>6.0</b>	6.0	6.0

The expected term represents the period that the Company's stock options are expected to be outstanding and was determined based on the simplified method, which calculates the expected life as the average of the vesting term and the contractual term of the option. The Company's historical stock option exercise data was impacted by a restructuring of its business in 2008. Because the Company does not have sufficient historical stock option exercise data to accurately estimate the expected term used for its valuation of stock

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

options, the Company continues to use the simplified method to calculate the expected term of new stock option grants. As the Company accumulates more data and history related to the exercises of stock option awards, the Company will reassess its use of the simplified method to determine the expected term. The expected volatility is based on the historical volatility of the Company's common stock for a period equal to the stock option's expected life. The risk-free interest rate is based on the yield at the time of grant of a U.S. Treasury security with an equivalent expected term of the option. The Company does not expect to pay dividends on its common stock. The amounts estimated according to the Black-Scholes option pricing model may not be indicative of the actual values realized upon the exercise of these options by the holders.

Share-based compensation guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. The Company estimates forfeitures based on its historical experience.

***Restricted share unit plan***

The Company also sponsors a RSU Plan for non-employee directors that was established in 2005. The RSU Plan provides for grants to be made from time to time by the Board of Directors or a committee thereof. Each grant will be made in accordance with the RSU Plan and terms specific to that grant and will be converted into one common share of common stock at the end of the grant period (not to exceed five years) without any further consideration payable to the Company in respect thereof. The current maximum number of common shares of the Company reserved for issuance pursuant to the RSU Plan is 466,666. As of December 31, 2012, 170,898 shares of common stock remain available for future grant under the RSU Plan. The fair value of the restricted share units has been determined to be the equivalent of the Company's common share closing trading price on the date of grant as quoted on the NASDAQ Global Market.

Upon vesting, RSUs of 43,397, 121,393 and 9,498 with a weighted average fair value of \$3.55, \$7.47 and \$8.46 were converted into 43,397, 121,393 and 9,498 shares of common stock during 2012, 2011 and 2010, respectively. Pursuant to an October 2011 amendment to the Company's RSU Plan, the Company withheld 10,846 shares of the 43,397 RSUs during 2012 and 28,271 shares of the 121,393 RSUs during 2011. The Company delivered to non-employee directors cash totaling \$38,544 and \$189,354, which was equal to the fair value of the shares withheld on the vesting date in order to facilitate satisfaction of the non-employee directors' income tax obligation with respect to the vested RSUs for the years ended December 31, 2012 and 2011, respectively.

A summary of the RSU activity under the Company's RSU Plan as of December 31, 2012, and changes during such year is presented below:

<u>Restricted Share Units</u>	<u>Restricted Share Units</u>	<u>Weighted Average Fair Value per Unit</u>
Outstanding at January 1, 2012 .....	143,495	\$7.58
Granted .....	40,870	3.67
Converted .....	<u>(43,397)</u>	3.55
Outstanding at December 31, 2012 .....	<u>140,968</u>	\$ 1.92
Expected to vest at December 31, 2012 .....	<u>140,968</u>	\$ 1.92

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

As a result of the October 2011 amendment discussed above, an additional \$0.8 million in share-based compensation expense was recorded in general and administrative expenses for the year ended December 31, 2011.

As of December 31, 2012, there was no unrecognized compensation cost related to unvested RSUs. A reduction of share-based compensation expense of \$0.5 million was recognized on the RSU Plan in 2012 and share-based compensation expense of \$1.1 million and \$0.1 million was recognized on the RSU Plan in 2011 and 2010, respectively.

#### ***Employee Stock Purchase Plan***

The Company adopted an the ESPP on June 3, 2010, pursuant to which a total of 900,000 shares of common stock were reserved for sale to employees of the Company. The ESPP is administered by the compensation committee of the board of directors and is open to all eligible employees of the Company. Under the terms of the ESPP, eligible employees may purchase shares of the Company's common stock at six month intervals during 18-month offering periods through their periodic payroll deductions, which may not exceed 15% of any employee's compensation and may not exceed a value of \$25,000 in any calendar year, at a price not less than the lesser of an amount equal to 85% of the fair market value of the Company's common stock at the beginning of the offering period or an amount equal to 85% of the fair market value of the Company's common stock on each purchase date. The maximum aggregate number of shares that may be purchased by each eligible employee during each offering period is 15,000 shares of the Company's common stock.

Fair value of shares purchases under the Company's ESPP was estimated at subscription dates using a Black-Scholes valuation model, which requires the input of highly subjective assumptions including expected stock price volatility and expected term. The expected volatility is based on the historical volatility of the Company's common stock for a period equal to the ESPP's expected life, which is determined by length of time between the subscription date and the purchase date. The risk-free interest rate is based on the yield at the time of grant of a U.S. Treasury security with an equivalent expected term of the ESPP. The Company does not expect to pay dividends on its common stock.

For the year ended December 31, 2012, 2011 and 2010, expense related to this plan was \$184,960, \$153,000 and \$54,000, respectively. Under the ESPP, the Company issued 49,086 and 6,338 shares to employees at a purchase price of \$3.33 and \$2.82 per share respectively during 2012. The Company issued 70,934 and 1,035 shares to employees at a purchase price of \$2.82 and \$6.27 per share respectively during 2011. There are 752,173 shares reserved for future purchases as of December 31, 2012. As of December 31, 2012, there was \$84,469 of unrecognized compensation cost related to the ESPP, which is expected to be recognized over an estimated weighted-average period of one year.

## **8. COLLABORATIVE AND LICENSE AGREEMENTS**

### ***2001 Merck KGaA Agreements***

On May 3, 2001, the Company entered into a collaborative arrangement with Merck KGaA to pursue joint global product research, clinical development, and commercialization of two of the Company's product candidates, L-BLP25 and Theratope. The collaboration covered the entire field of oncology for these two product candidates and was documented in collaboration and supply agreements (the "2001 Agreements"). The Company's deliverables under the 2001 Agreements included (1) the license of rights to the product

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

candidates, (2) collaboration with Merck KGaA, including shared responsibilities for the clinical development and post-commercialization promotion of the product candidates, (3) participation in a joint steering committee, (4) participation in a manufacturing/CMC Project team, (5) delivery of any improvements of L-BLP25 to Merck and (6) manufacturing of the product candidates.

Pursuant to the 2001 collaboration agreement, the Company granted a co-exclusive license to Merck KGaA with respect to the clinical development and commercialization of such product candidates in North America and an exclusive license with respect to the clinical development and commercialization of such product candidates in the rest of the world. Merck KGaA did not obtain the right to sublicense the rights licensed to it pursuant to the 2001 collaboration agreement. The license term commenced as of the effective date of the 2001 collaboration agreement. The exclusivity provisions of such license were to remain in effect during the period beginning on the effective date of such license agreement and ending, on a product-by-product and country-by-country basis, on the latter of (1) the expiration of patent rights with respect to the applicable product candidate and (2) the 15th anniversary of the product launch. After the expiration of such period, such license would be perpetual and non-exclusive.

Under the 2001 Agreements, the parties agreed to collaborate in substantially all aspects of the clinical development and commercialization of the product candidates and coordinate their activities through a joint steering committee. Pursuant to the 2001 collaboration agreement, the parties agreed to share the responsibilities and obligations, for the clinical development and commercialization of the product candidates in North America (other than with respect to the right to promote product candidates in Canada, which was retained by the Company). In the rest of the world, Merck KGaA was responsible for the clinical development of the product candidates (although the Company agreed to reimburse Merck KGaA for 50% of the clinical development and regulatory costs) and commercialization of the product candidates. The 2001 collaboration agreement's term corresponded with the exclusivity period of the Company's license to the product candidates. Additionally, Merck KGaA was, and is, entitled to terminate the agreements with the Company with respect to a particular product candidate upon 30 days prior written notice to the Company, if, in the exercise of Merck KGaA's reasonable judgment, it determined that there were issues concerning the safety or efficacy of such product candidate that would materially adversely affect the candidate's medical, competitive or economic viability. If the agreements are terminated by Merck KGaA in accordance with their terms, the Company does not have legal recourse against Merck KGaA with respect to contingent or other future payments.

Pursuant to the 2001 supply agreement, the Company was responsible for the manufacturing of the clinical and commercial supply of the product candidates for which Merck KGaA agreed to reimburse the Company for its manufacturing costs. The 2001 supply agreement's term corresponded to the exclusivity period of the Company's license to the product candidates.

In connection with the execution of the 2001 collaboration agreement and supply agreement, the Company received up-front cash payments of \$2.8 million (\$1.0 million for executing the agreement and \$1.8 million as reimbursement of pre-agreement clinical development expenses incurred by the Company) and \$4.0 million, respectively. In addition, under the 2001 Agreements the Company was entitled to receive (1) a \$5.0 million payment contingent upon enrollment of the first patient in a Phase 3 clinical trial, (2) various additional contingent payments, up to a maximum of \$90.0 million in the

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

aggregate (excluding payments payable with respect to Theratope, the development of which was discontinued in 2004), tied to BLA submission for first and second cancer indications, for regulatory approval for first and second cancer indications, and for various sales milestones, and (3) royalties in the low twenties based on net sales outside of North America. Under the 2001 supply agreement, the Company was entitled to receive reimbursements from Merck KGaA for a portion of the L-BLP25 manufacturing costs.

The Company recorded the payments received in connection with the execution of the 2001 Agreements as deferred revenue and initially recognized such revenue ratably over the period from the date of the 2001 Agreements to 2011. The Company determined that the estimated useful life of the products and estimated period of its ongoing obligations corresponded to the estimated life of the issued patents for such products. The Company chose that amortization period because, at the time, the Company believed it reflected an anticipated period of “market exclusivity” based upon the Company’s expectation of the life of the patent protection, after which the market entry of competitive products would likely occur. The Company did not receive any contingent payments or royalties under the 2001 Agreements. For more information regarding the Company’s revenue recognition policies, see “Note 2 — Significant Accounting Policies — Revenue Recognition.”

In June 2004, following the failure of Theratope in a Phase 3 clinical trial, Merck KGaA returned to the Company all rights to Theratope and development of Theratope was discontinued; however, the parties continued to collaborate under the terms of the 2001 Agreements with respect to the development of L-BLP25, which in 2004 had shown positive results in a Phase 2 clinical trial. In connection with the discontinuation of Theratope, the Company accelerated recognition of approximately \$4.5 million in previously deferred revenue, which corresponded to the portion of the up-front cash payments under the 2001 Agreements that was allocated to Theratope. The remaining deferred revenue related to L-BLP25 was then amortized over a period to end in 2018, the period estimated by management to represent the estimated useful life of the product and estimated period of its ongoing obligations, which corresponded to the estimated life of the issued patents for L-BLP25.

#### **2006 Merck KGaA LOI**

On January 26, 2006, the parties entered into a binding letter of intent (the “LOI”) pursuant to which the 2001 Agreements were amended in part and the parties agreed to negotiate in good faith to amend and restate the 2001 collaboration and supply agreements, as necessary, to implement the provisions contemplated by the LOI. The Company’s deliverables under the 2001 Agreements, as amended by the LOI, remained (1) the license of rights to L-BLP25, (2) participation in a joint steering committee, (3) participation in a manufacturing/CMC Project team, (4) delivery of any improvements of L-BLP25 to Merck and (5) manufacturing of the product candidate.

Pursuant to the LOI, in addition to the rights granted pursuant to the 2001 Collaboration Agreement, the Company granted to Merck KGaA an exclusive license with respect to the clinical development and commercialization of L-BLP25 in the United States and, subject to certain conditions, to act as a secondary manufacturer of L-BLP25. The Company’s right to commercialize L-BLP25 in Canada remained unchanged. The license grant was effective as of March 1, 2006. The exclusivity period of such license corresponded to that under the 2001 collaboration agreement.

Pursuant to the LOI, the joint steering committee continued to meet and served as the vehicle through which Merck KGaA provided updates and shared information regarding

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

clinical development and marketing; however, it ceased to be a decision-making body. The Company continued to have responsibility for manufacturing. Further, the parties' collaboration, including the term of the 2001 collaboration agreement, was not otherwise affected.

Pursuant to the LOI, the Company continued to be responsible for the manufacturing of the clinical supply of L-BLP25 for which Merck KGaA agreed to pay the Company its cost of manufacturing. The 2001 supply agreement's term was not modified by the LOI.

Further, under the LOI, the \$5.0 million contingent payment payable to the Company under the 2001 Agreements upon enrollment of the first patient in a Phase 3 clinical trial was amended such that the Company was entitled to receive a \$2.5 million contingent payment upon the execution of the amended and restated collaboration and supply agreements contemplated by the LOI and a \$2.5 million contingent payment upon enrollment of the first patient in such Phase 3 clinical trial. In addition, under the LOI the Company was entitled to receive (1) various additional contingent payments tied to the same events and up to the same maximum amounts as under the 2001 Agreements, (2) royalties based on net sales outside of North America at the same rates as under the 2001 Agreements and (3) royalties based on net sales inside of the North America ranging from a percentage in the high-twenties to the mid-twenties, depending on the territory in which the net sales occur. The royalty rate was higher in North America than in the rest of the world in return for the Company relinquishing its rights to L-BLP25 in the United States. In February 2007, the Company announced that the first patient had been enrolled in the global Phase 3 L-BLP25 clinical trial for non-small cell lung cancer ("NSCLC"), triggering the contingent payment by Merck KGaA to the Company of \$2.5 million. This payment was received in March 2007.

The Company assessed whether objective and reliable evidence of fair value of the undelivered elements under the 2001 Agreements, as amended by the LOI, existed as the manufacturing deliverable was shipped, and concluded such evidence did not exist. As a result, it was concluded that all deliverables in the arrangement were to be considered a single unit of accounting.

The Company recorded the payments received under the LOI as deferred revenue and recognized such revenue ratably over the remaining estimated product life of L-BLP25, which was until 2018. The Company did not receive any royalties under the LOI. For more information regarding the Company's revenue recognition policies, see "Note 2 — Significant Accounting Policies — Revenue recognition."

#### **2007 Merck KGaA Agreements**

On August 8, 2007, the parties amended and restated the collaboration and supply agreements (as amended and restated, the "2007 Agreements"), which restructured the 2001 Agreements and formalized the terms set forth in the LOI. The Company's deliverables under the 2007 Agreements remained (1) the license of rights to L-BLP25, (2) participation in a joint steering committee, (3) participation in a manufacturing/CMC Project team, (4) delivery of any improvements of L-BLP25 to Merck and (5) manufacturing of the product candidates.

Under the 2007 collaboration agreement, in addition to the rights granted pursuant to the 2001 collaboration agreement (as modified by the LOI), the Company granted to Merck KGaA an exclusive license to develop and commercialize L-BLP25 in Canada. For accounting purposes, the license grant to develop L-BLP25 in Canada was effective as of

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

the date of the 2007 collaboration agreement. As a result, Merck KGaA obtained an exclusive world-wide license with respect to the development and commercialization of L-BLP25. The exclusivity period of such license corresponded to that under the 2001 collaboration agreement; however, whereas the license was perpetual and was subject to termination by Merck KGaA the Company believed that the appropriate amortization period, and therefore the period of performance under the agreements, for amounts arising under the contract corresponds to the estimated product life of L-BLP25, or until 2018.

Under the 2007 collaboration agreement, the joint steering committee continued to meet and serve as the vehicle through which Merck KGaA provided updates and shared information regarding clinical development and marketing; however, it ceased to be a decision-making body. The Company continued to have responsibility for the development of the manufacturing process and plans for the scale-up for commercial manufacturing and the parties' collaboration was not otherwise materially affected from the LOI. The 2007 collaboration agreement's term corresponded to that under the 2001 collaboration agreement.

Under the 2007 supply agreement, the Company continued to be responsible for the manufacturing of the clinical and commercial supply of L-BLP25 for which Merck KGaA agreed to pay the Company its cost of goods (which included amounts owed to third parties) and provisions for certain contingent payments to the Company related to manufacturing scale-up and process transfer were added. The 2007 supply agreement's term corresponded to that under the 2001 collaboration agreement.

The entry into the 2007 Agreements triggered a payment to the Company of \$2.5 million. Such payment was received in September 2007 and recorded as deferred revenue and recognized ratably over the remaining estimated product life of L-BLP25, which was until 2018. In addition, under the 2007 Agreements, the Company was entitled to receive (1) a \$5.0 million payment tied to the transfer of certain assays and methodology related to the manufacturing of L-BLP25, a \$3.0 million payment tied to the transfer of certain L-BLP25 manufacturing technology and a \$2.0 million payment tied to the receipt of the first manufacturing run at commercial scale of L-BLP25 (provided that, in each case, such payments would have been payable by December 31, 2009, regardless of whether the applicable triggering event had been met), (2) various additional contingent payments tied to the same events and up to the same maximum amounts as under the 2001 Agreements, (3) royalties based on net sales outside of North America at the same rates as under the 2001 Agreements and (4) royalties based on net sales inside of North America with percentages in the mid-twenties, depending on the territory in which the net sales occur. If the manufacturing process payments due by December 31, 2009 were paid in full, the royalty rates would be reduced in all territories by 1.25%, relative to the 2001 Agreements and the LOI. In December 2007 and May 2008, the Company received from Merck KGaA a \$5.0 million and a \$3.0 million payment, respectively, related to the transfer of certain manufacturing information and technology.

The Company assessed whether objective and reliable evidence of fair value of the undelivered elements under the 2007 Agreements existed as the manufacturing deliverable was shipped, and concluded such evidence did not exist. As a result, it was concluded that all deliverables in the arrangement was to be considered a single unit of accounting.

The Company recorded the manufacturing process transfer payments received under the 2007 Agreements as deferred revenue and recognized such revenue ratably over the remaining estimated product life of L-BLP25. After execution of the 2007 supply agreement, the Company reported revenue and associated clinical trial material costs

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

related to the supply of L-BLP25 separately in the consolidated statements of operations as contract manufacturing revenue and manufacturing expense, respectively. Under the 2007 supply agreement, the Company was entitled to invoice and receive a specified upfront payment on the contractual purchase price for L-BLP25 clinical trial material after the receipt of Merck KGaA's quarterly 12-month rolling forecast requirements. The Company invoiced the remaining balance of the contractual purchase price after shipment of the clinical trial material to Merck KGaA. The upfront entitlements were recorded as deferred revenue and such entitlements and the remaining balance of the purchase price were recognized as contract manufacturing revenue after shipment to Merck KGaA upon the earlier of (1) the expiration of a 60-day return period (since returns could not be reasonably estimated) and (2) formal acceptance of the clinical trial material by Merck KGaA. Concurrently, the associated costs of the clinical trial material was removed from inventory and recorded as manufacturing expense. The Company did not receive any royalties under the 2007 Agreements. For more information regarding the Company's revenue recognition policies, see "Note 2 — Significant Accounting Policies — Revenue recognition."

#### **2008 Merck KGaA Agreements**

On December 18, 2008, the Company entered into a license agreement with Merck KGaA which replaced the 2007 Agreements. Pursuant to the 2008 license agreement, in addition to the rights granted pursuant to the 2007 collaboration agreement, the Company granted to Merck KGaA the exclusive right to manufacture L-BLP25 and the right to sublicense to other persons all such rights licensed to Merck KGaA. The license grant was effective as of the date of the 2008 license agreement. The exclusivity period of such license corresponded to that under the 2007 collaboration agreement.

In addition, (1) the joint steering committee was abolished, (2) the Company transferred certain manufacturing know-how to Merck KGaA, (3) the Company agreed not to develop any product that is competitive with L-BLP25, other than its product candidate ONT-10, (4) the Company granted to Merck KGaA a right of first negotiation in connection with any contemplated collaboration or license agreement with respect to the development or commercialization of ONT-10 and (5) the Company sold other L-BLP25-related assets as described in further detail below.

The only deliverable under the 2008 license agreement was the license grant. Upon the execution of the agreements with Merck KGaA in December 2008, all future Company performance obligations related to the collaboration for the clinical development and development of the manufacturing process of L-BLP25 were removed and continuing involvement by the Company in the development and manufacturing of L-BLP25 ceased (although the Company continues to be entitled to certain information rights with respect to clinical testing, development and manufacture of L-BLP25).

In return for the license of manufacturing rights and transfer of manufacturing know-how under the 2008 license agreement, the Company received an up-front cash payment of approximately \$10.5 million. In addition, under the 2008 license agreement (1) the provisions with respect to contingent payments under the 2007 Agreements remained unchanged and (2) the Company is entitled to receive royalties based on net sales of L-BLP25 ranging from a percentage in mid-teens to high single digits, depending on the territory in which the net sales occur. The royalties rates under the 2008 license agreement were reduced by a specified amount which management believes is consistent with the estimated costs of goods, manufacturing scale up costs and certain other expenses assumed by Merck KGaA. Since the Company had no further deliverables under the 2008



## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements — (Continued)

License Agreement, the Company (1) recognized as revenue the balance of all previously deferred revenue of \$13.2 million relating to the Merck KGaA collaboration and (2) the final \$2.0 million manufacturing process transfer payment was recognized as revenue when received in December 2009. For more information regarding the Company's revenue recognition policies, see "Note 2 — Significant Accounting Policies — Revenue recognition."

Under the 2008 license agreement, the Company may receive potential payments of up to \$90 million upon the occurrence of certain specified events. The payments entail no performance obligation on the part of the Company and are tied solely to regulatory and specific achievements of sales levels. Accordingly, these payments will not be accounted for under the milestone method of revenue recognition, but rather will be recognized as revenue upon the occurrence of the events specified in the 2008 license agreement, assuming the payments are deemed collectible at that time.

In connection with the entry into the 2008 license agreement, the Company also entered into an asset purchase agreement pursuant to which the Company sold to Merck KGaA certain assets related to the manufacture of, and inventory of, L-BLP25, placebo and raw materials, and Merck KGaA agreed to assume certain liabilities related to the manufacturing of L-BLP25 and the Company's obligations related to the lease of the Company's Edmonton, Alberta, Canada facility.

The plant and equipment in the Edmonton facility and inventory of raw materials, work-in-process and finished goods were sold for a purchase price of \$0.6 million (including the assumption of lease obligation of \$0.1 million) and \$11.2 million, respectively. The purchase price of the inventory was first offset against advances made in prior periods resulting in net cash to the company of \$2.0 million. The Company recorded the net gain from the sale of the plant and equipment of \$0.1 million in other income and \$11.2 million as contract manufacturing revenue in 2008.

#### ***Sanford-Burnham Medical Research Institute Agreement***

In September 2011, the Company entered into an exclusive, worldwide license agreement with the Sanford-Burnham Medical Research Institute, or SBMRI for certain intellectual property related to SBMRI's small molecule program based on ONT-701 and related compounds. ONT-701 is a pan-inhibitor of the B-cell lymphoma-2, or Bcl-2 family of anti-apoptotic proteins and is currently in pre-clinical development. Because the Company acquired ONT-701 in an early research stage, the Company determined the compound did not have an alternate future use. Under the terms of this agreement, the Company made a payment of \$1.5 million to SBMRI, which was recorded as part of research and development expense. In addition, the Company may be required to make milestone payments of up to approximately \$26 million upon the occurrence of certain clinical development and regulatory milestones and up to \$25 million based on certain net sales targets. The Company would be required to pay a royalty in the low to mid-single digits on net sales of licensed products. In addition, if the Company generates income from a sublicense of any of the licensed rights, it must pay SBMRI a portion of certain income received from the sublicensee at a rate between mid-single digits and 30%, depending on stage of the clinical development of the rights when the sublicense is granted. Unless earlier terminated in accordance with the license agreement, the agreement shall terminate on a country-by-country basis upon the later of (i) 10 years after the first commercial sale of the first licensed product and (ii) the expiration of the last-to-expire patent within the licensed patents.

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

**9. INVESTMENT AND OTHER INCOME (EXPENSE), NET**

Net investment and other income (expense) include the following components for the periods indicated:

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In thousands)		
Government grant .....	\$ —	\$ —	\$489
Investment income, net .....	128	115	177
Loss on extinguishment of debt .....	(279)	—	—
Net foreign exchange gain (loss) .....	1	(9)	(27)
Gain (loss) on sale of equipment .....	24	—	(6)
Loss on sale of investment .....	(1)	—	—
Other income .....	—	199	3
Total investment and other income (expense), net .....	<u>\$ (127)</u>	<u>\$305</u>	<u>\$636</u>

**10. INCOME TAX**

The income tax benefit consists of the following for the year ended December 31, 2012, 2011 and 2010:

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
	(In thousands)		
Federal:			
Current .....	\$—	\$—	\$200
Deferred .....	—	—	—
Income tax benefit .....	<u>\$—</u>	<u>\$—</u>	<u>\$200</u>

In 2010, the Company recorded a current federal tax benefit of \$0.2 million for the year ended December 31, 2010, which consists of recovery of federal alternative minimum tax previously paid.

The benefit (provision) for income taxes is different from applying the statutory federal income tax rate as follows:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Tax benefit at statutory rate .....	35.0%	35.0%	35.0%
Change in fair value of warrant liability .....	259.6	(14.6)	6.8
Deferred tax adjustment .....	0.0	1.0	15.0
Other .....	(1.9)	(1.6)	4.0
Change in valuation allowance .....	(292.7)	(16.4)	(50.2)
Expiration of loss carryforwards and credits .....	(0.0)	(3.4)	(9.2)
Income tax benefit .....	<u>0.0%</u>	<u>0.0%</u>	<u>1.4%</u>

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements — (Continued)**

The Company's net deferred tax assets and deferred tax liabilities were recorded in other assets and accrued and other liabilities, respectively on the Consolidated Balance Sheets and consist of the following as of December 31, 2012 and 2011:

	<u>2012</u>	<u>2011</u>
	<u>(In thousands)</u>	
Deferred tax assets		
Current		
Accrued expenses and other .....	\$ 450	\$ 366
Valuation allowance .....	<u>(447)</u>	<u>(366)</u>
Net current deferred tax assets .....	3	0
Non-current deferred tax assets		
Tax benefits from losses carried forward and tax credits .....	149,860	139,252
Stock based compensation .....	2,027	1,783
Intangible assets .....	1,152	1,275
Other .....	<u>102</u>	<u>80</u>
	<u>153,141</u>	<u>142,390</u>
Valuation allowance .....	<u>(152,834)</u>	<u>(142,202)</u>
Net non-current deferred tax assets .....	<u>307</u>	<u>188</u>
Deferred tax liabilities		
Current		
Prepaid expenses .....	<u>310</u>	<u>188</u>
Total current deferred tax liabilities .....	<u>310</u>	<u>188</u>
Net deferred tax asset (liability) .....	<u>\$ —</u>	<u>\$ —</u>

Based on the available evidence, the Company has recorded a full valuation allowance against its net deferred income tax assets as it is more likely than not that the benefit of these deferred tax assets will not be realized. The valuation allowance increased by \$10.9 million and \$5.0 million during the years ended December 31, 2012 and 2011, respectively.

The Company has recorded the following uncertain tax positions as of December 31, 2012, 2011 and 2010:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
	<u>(In thousands)</u>		
Balance at January 1 .....	\$729	\$ —	\$—
Decrease related to prior year tax positions .....	—	—	—
Increase related to prior year tax positions .....	12	729	—
Increase related to current year tax positions .....	—	—	—
Decrease related to current year tax positions .....	—	—	—
Decrease related to settlements with tax authorities .....	—	—	—
Lapses of statute of limitations .....	<u>(79)</u>	—	—
Balance at December 31 .....	<u>\$662</u>	<u>\$729</u>	<u>\$—</u>

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements – (Continued)

None of the unrecognized tax benefits that, if recognized, would affect the effective tax rate due to valuation allowance. We are currently not under audit by the federal, state and foreign tax authorities. We do not believe that it is reasonably possible that the total amounts of unrecognized tax benefit will materially increase or decrease within the next 12 months.

#### **United States**

The Company has accumulated net operating losses of \$129 million and \$103 million for United States federal tax purposes at December 31, 2012 and 2011, respectively, some of which may be limited in their utilization pursuant to Section 382 of the Internal Revenue Code, and which may not be available entirely for use in future years. These losses expire in fiscal years 2018 through 2032.

#### **Canada**

The Company has unclaimed Canada federal investment tax credits of \$20.5 million and \$20.2 million (CAD) at December 31, 2012 and 2011, respectively that expire in fiscal years 2017 through 2028. The Company has scientific research & experimental development expenditures of \$137.5 million and \$135.3 million for Canada federal purposes and \$59.9 million and \$60.1 million for provincial purposes at December 31, 2012 and 2011 respectively. These expenditures may be utilized in any period and may be carried forward indefinitely. The Company also has Canada federal capital losses of \$185.9 million and \$182.9 million and provincial capital losses of \$186.0 million and \$182.9 million at December 31, 2012 and 2011 respectively that can be carried forward indefinitely to offset future capital gains. The Company has accumulated net operating losses of \$5.4 million and \$6.4 million at December 31, 2012 and 2011 for Canada federal tax purposes and \$4.2 million and \$4.2 million at December 31, 2012 and 2011 for provincial purposes which expire between 2026 and 2030. The Company is subject to examination by the Canada Revenue Agency for years after 2006. However carryforward attributes that were generated prior to 2006 may still be adjusted by a taxing authority upon examination if the attributes have been or will be used in a future period.

#### **Other**

The Company files federal and foreign income tax returns in the United States and abroad. For U.S. federal income tax purposes, the statute of limitations is open for 1998 and onward for the United States and Canada due to net operating loss carried forwards.

### **11. CONTINGENCIES, COMMITMENTS, AND GUARANTEES**

#### **Royalties**

In connection with the issuance of the Class UA preferred stock (See "Note 6 – Share Capital"), the Company has agreed to pay a royalty in the amount of 3% of the net proceeds of sale of any products sold by the Company employing technology acquired in exchange for the shares. None of the Company's products currently under development employ the technology acquired.

Under certain licensing arrangements for technologies incorporated into the Company's product candidates, the Company is contractually committed to payment of ongoing licensing fees and royalties, as well as contingent payments when certain milestones as defined in the agreements have been achieved.

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements – (Continued)**

***Employee benefit plan***

Under a defined contribution plan available to permanent employees, the Company is committed to matching employee contributions up to limits set by the terms of the plan, as well as limits set by U.S. tax authorities. The Company's matching contributions to the plan totaled \$0.2 million for the year ended December 31, 2012 and \$0.1 million in each of the years ended December 31, 2011 and 2010, respectively. There were no changes to the plan during the year ended December 31, 2012.

***Lease obligations – operating leases***

The Company is committed to annual minimum payments under operating lease agreements for its office and laboratory space and equipment) as follows (in thousands):

<u>Year Ending December 31,</u>	
2013 .....	\$ 590
2014 .....	600
2015 .....	608
2016 .....	617
2017 .....	622
Thereafter .....	<u>604</u>
	<u>\$3,641</u>

Rental expense for operating leases in the amount of \$0.5 million, \$0.5 million and \$0.6 million have been recorded in the consolidated statements of operations in 2012, 2011 and 2010, respectively. In May 2008, the Company entered into a lease agreement to lease office and laboratory space for its headquarters in Seattle, Washington totaling approximately 17,000 square feet. The lease, which expires in December 2018, provides for a monthly base rent of \$47,715 increasing to \$52,259 in 2018. The Company has also entered into operating lease obligations through June 2017 for certain office equipment, which are included in the table above.

***Other obligations***

In connection with the acquisition of ProlX, the Company may become obligated to issue additional shares of our common stock to the former stockholders of ProlX upon satisfaction of certain milestones. The Company may become obligated to issue shares of our common stock with a fair value of \$5.0 million (determined based on a weighted average trading price at the time of issuance) upon the initiation of the first Phase 3 clinical trial for a ProlX product that qualifies as a "subject product" as such term is defined in the ProlX acquisition agreement, which the Company refers to as a ProlX product. The Company may become obligated to issue shares of its common stock with a fair value of \$10.0 million (determined based on a weighted average trading price at the time of issuance) upon regulatory approval of a ProlX product in a major market.

***Guarantees***

The Company is contingently liable under a mutual undertaking of indemnification with Merck KGaA for any withholding tax liability that may arise from payments under the Company's agreement with them.

In the normal course of operations, the Company provides indemnities to counterparties in transactions such as purchase and sale contracts for assets or shares, service agreements,

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements – (Continued)**

director/officer contracts and leasing transactions. These indemnification agreements may require the Company to compensate the counterparties for costs incurred as a result of various events, including environmental liabilities, changes in (or in the interpretation of) laws and regulations, or as a result of litigation claims or statutory sanctions that may be suffered by the counterparties as a consequence of the transaction. The terms of these indemnification agreements vary based upon the contract, the nature of which prevents the Company from making a reasonable estimate of the maximum potential amount that could be required to pay to counterparties. Historically, the Company has not made any significant payments under such indemnities and no amounts have been accrued in the accompanying consolidated financial statements with respect to these indemnities.

**12. SUBSEQUENT EVENTS**

None.

**13. CONDENSED QUARTERLY FINANCIAL DATA (unaudited)**

The following table contains selected unaudited statement of operations information for each quarter of 2012 and 2011. The unaudited information should be read in conjunction with the Company's audited financial statements and related notes included elsewhere in this report. The Company believes that the following unaudited information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

**Quarterly Financial Data:**

	Three Months Ended,			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
<b>2012</b>				
<b>Revenues</b> .....	\$ —	\$ —	\$ —	\$ —
<b>Operating expenses</b> .....	5,741	8,103	7,685	6,970
<b>Net income (loss)(1)</b> .....	9,691	(8,735)	(8,625)	4,254
<b>Net income (loss) per share — basic</b> .....	0.22	(0.15)	(0.15)	0.07
<b>Net income (loss) per share — diluted</b> .....	(0.13)	(0.15)	(0.15)	(0.12)
<b>2011</b>				
Revenues .....	\$ 145	\$ —	\$ —	\$ —
Operating expenses .....	6,017	5,826	6,443	6,558
Net income (loss)(2) .....	(7,116)	(33,973)	9,937	(11,504)
Net income (loss) per share — basic .....	(0.24)	(0.91)	0.24	(0.27)
Net income (loss) per share — diluted .....	(0.24)	(0.91)	(0.15)	(0.27)

(1) Net income (loss) for the three months ended March 31, June 30, September 30 and December 31, 2012 includes change in fair value of warrants income (expense) of approximately \$15.6 million, \$(0.3) million, \$(1.0) million and \$11.2 million respectively (see Note 3).

(2) Net income (loss) for the three months ended March 31, June 30, September 30 and December 31, 2011 includes change in fair value of warrants income (expense) of approximately \$(1.5) million, \$(28.0) million, \$16.6 million and \$(4.8) million respectively (see Note 3).

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## **Forward-Looking Statements**

*This annual report contains statements that are forward-looking. Any statements contained in this annual report that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include Oncothyreon's expectations regarding clinical development activities, the expected timing of the release of data from clinical trials and the use and adequacy of cash resources.*

*Forward-looking statements involve risks and uncertainties related to Oncothyreon's business and the general economic environment, many of which are beyond its control. These risks, uncertainties and other factors could cause Oncothyreon's actual results to differ materially from those projected in forward-looking statements, including the risks associated with the costs and expenses of developing its product candidates, the adequacy of financing and cash, cash equivalents and investments, changes in general accounting policies, general economic factors, achievement of the results it anticipates from its clinical trials of its products candidates and its ability to adequately obtain and protect its intellectual property rights. Although Oncothyreon believes that the forward-looking statements contained herein are reasonable, it can give no assurance that its expectations are correct. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. For a detailed description of Oncothyreon's risks and uncertainties, you are encouraged to review the documents filed with the securities regulators in the United States on EDGAR and in Canada on SEDAR. Oncothyreon does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.*