



ANNUAL REPORT

2011

Dear Fellow Stockholders,

2011 was a productive and eventful year at Oncothyreon for both our partnered and internal development programs. For our most advanced therapeutic vaccine, Stimuvax<sup>®</sup>, our licensee Merck KGaA of Darmstadt, Germany, completed enrollment in the Phase 3 START trial in patients with non-small cell lung cancer (NSCLC). At Oncothyreon, we submitted an Investigational New Drug application for ONT-10, our wholly-owned follow-on therapeutic vaccine. We also initiated four Phase 2 trials for PX-866, our most advanced small molecule product candidate targeting PI-3 kinase. Finally, we expanded our small molecule pipeline by in-licensing ONT-701.

We are pleased with these achievements and the momentum that they build for exciting times to come. I welcome this opportunity to review our progress and look ahead to upcoming milestones.

### ***Stimuvax Phase 3 START Trial – Final Results Expected in 2013***

As I write this letter, it has been just over five years since the first patient was enrolled in START, a worldwide, randomized, placebo controlled trial of Stimuvax in patients with stage III NSCLC. It has been a long trial, as would be expected for a trial of this size which has overall patient survival as its primary endpoint. The end, however, is now within sight. Based on information provided by Merck KGaA, we currently expect the event that will trigger the conclusion of the START trial to occur by the end of 2012, followed by the results from the primary outcome analysis in early 2013.

It may be useful to review how we arrived at this advanced stage in the development of Stimuvax. As a reminder, Stimuvax is a therapeutic vaccine designed to induce an immune response to cancer cells that express MUC1, a glycoprotein antigen widely expressed on common cancers, including lung cancer, breast cancer, prostate cancer and colorectal cancer. Therapeutic vaccines are a form of immunotherapy, a method of cancer treatment that attempts to enlist the body's immune system to attack the cancer. Stimuvax was developed at Oncothyreon, which conducted the clinical development program through the end of Phase 2. These trials included a randomized Phase 2b study suggesting a 17.3 month survival advantage for patients with stage IIIb NSCLC who received Stimuvax versus those who did not.

Oncothyreon has had a long term partnership with Merck KGaA in immunotherapy dating back to 2001. In 2006, Merck KGaA assumed responsibility for the further clinical development of Stimuvax, leading to the initiation of the Phase 3 program. Currently, there are two Phase 3 trials for Stimuvax underway for patients with stage III NSCLC: START, which completed enrollment of more than 1,500 patients in the fall of 2011; and INSPIRE, a 420 patient trial being conducted primarily in Asia.

The START trial was designed with two event-driven interim looks, each of which included both an efficacy and futility analysis. These analyses, which are conducted by an independent Data Monitoring Committee (DMC), are intended to protect patients participating in the trial by stopping it early if Stimuvax has been statistically proven either to have efficacy, in which case the continued administration of a placebo is inappropriate, or to have no possibility of achieving the primary endpoint, in which case continued administration of Stimuvax would be unethical. The first interim look, based on 50 percent of the projected events in the trial, was announced in December of 2010, while the second interim look, based on 75 percent of the projected events, was announced in March of 2012. In both cases, the DMC determined the START trial did not meet pre-specified endpoints for either efficacy or futility and should continue to its conclusion.

These outcomes should not have been a surprise. The statistical plan for START was designed with the expectation that the trial would enroll the full number of patients and follow them until the complete number of pre-specified number of events had occurred, in order to achieve a high degree of statistical certainty. This high degree of statistical certainty is needed, as it is the intention of Merck KGaA to file marketing applications based on this single trial, should it prove successful.

We appreciate the support from our stockholders during the long course of Stimuvax development. We, like you, are eager to learn the final outcome of the START trial, now expected in early 2013.

### ***Proprietary Vaccine ONT-10 Advanced to Clinical Trials***

While progress with START is certainly important for Oncothyreon, it is by no means all that is happening at your company. During 2011 we have been diligently focused on advancing our internal product pipeline, including our follow-on cancer vaccine candidate ONT-10.

ONT-10 is similar to Stimuvax in that it targets the MUC1 antigen. However, it is distinguished by several important factors. The antigen target in ONT-10 has been designed to activate both arms of the immune response. In preclinical results presented in 2011 at the American Association of Cancer Research meeting, we demonstrated that ONT-10 stimulates both antibodies and T-cells that target tumors expressing MUC1. ONT-10 is also the first vaccine to contain our proprietary adjuvant, PET-lipid-A, which is synthesized chemically instead of being derived from a biologic source and as such may offer some manufacturing, potency and cost advantages compared to the adjuvant in Stimuvax. Finally, and very importantly, ONT-10 is fully owned by Oncothyreon.

We worked hard during 2011 in order to complete the preclinical studies that enabled us to file an Investigational New Drug Application in December. In March of 2012 we announced the initiation of the first Phase 1 trial of ONT-10 to evaluate the safety and immunogenicity of this therapeutic vaccine product candidate.

We are pleased to have this clinical trial underway. Our ultimate goal is to assess if a vaccine that induces both an antibody and cellular immune response may offer improved outcomes. We also are excited to have our novel adjuvant, PET-lipid A, included in this clinical trial. Adjuvants are widely used as immune stimulants in vaccines, and we believe we may have the opportunity to license this adjuvant to other vaccine developers once we have established its safety in man. Finally, we believe ONT-10, because it remains proprietary to Oncothyreon, will be of significant strategic value should Stimuvax prove successful in Phase 3.

### ***Broad Phase 2 Development Program Underway for Irreversible PI-3 Kinase Inhibitor PX-866***

The majority of our clinical efforts this year have been directed toward the advancement of our unique small molecule candidate PX-866, an inhibitor of phosphatidylinositol 3-kinase (PI-3K). PI-3 kinase is a critical cell signaling pathway activated in multiple types of human cancers. Mutations in PI-3K cause increased cancer proliferation and inhibit cancer cell death, making it a popular target for cancer drug development.

Our PX-866 candidate is distinguished among the field of PI-3K inhibitors in development for cancer by virtue of its irreversible inhibitory nature. Unlike competitive inhibitors, PX-866 forms a covalent bond and cannot be displaced from the target, a feature that we believe offers a number of advantages in terms of dose and schedule and, potentially, tolerability and efficacy.

We have now largely completed three Phase 1 trials of PX-866, with much of that work being done in 2011. In these early trials PX-866 was well tolerated, both alone and in combination with other agents, and we also saw evidence of prolonged disease stabilization. Based on these Phase 1 data, we have now initiated four Phase 2 clinical trials. Our Phase 2 development program for PX-866 is designed to examine a number of different tumor indications, to test PX-866 both alone and in combination with other agents, to provide further differentiation from our competition, and to provide a path forward into later stage registration trials. Two of the Phase 2 trials are randomized to evaluate the effect of PX-866 when used in combination with another agent. One is a randomized Phase 2 trial of PX-866 administered in combination with the chemotherapeutic agent docetaxel (Taxotere<sup>®</sup>) versus docetaxel alone. There are two patient groups in this study: patients with locally advanced, recurrent or metastatic non-small lung cancer receiving second or third line treatment and patients with locally advanced, recurrent or metastatic squamous cell carcinoma of the head and neck after failure of first or second line therapy. These patient groups are being randomized and evaluated independently of each other with a primary endpoint of progression free survival and secondary endpoints of objective response rate and overall survival.

The second trial is a randomized Phase 2 trial of PX-866 in combination with cetuximab (Erbix<sup>®</sup>) versus cetuximab alone in two groups of patients. The first group includes patients with metastatic colorectal carcinoma who have a history of progression or recurrence following prior treatment regimens containing irinotecan and oxaliplatin. The second group includes patients with incurable progressive, recurrent or

metastatic squamous cell carcinoma of the head and neck. Like the docetaxel trial, these two groups of patients will be randomized and evaluated independently. The primary endpoint is objective response rate based on the specified clinical criteria collectively termed RECIST.

In 2011 we also initiated two single agent Phase 2 trials of PX-866. One is enrolling approximately 40 patients with recurrent or metastatic castration-resistant prostate cancer that has not been treated with chemotherapy. The primary endpoint of this single-arm screening trial is the proportion of patients without disease progression at 12 weeks from the initiation of therapy. The second is enrolling up to 30 patients with glioblastoma multi-forme, an aggressive type of brain cancer, that has recurred during or following primary therapy. The primary endpoint of this trial is a combination of objective response rate and non-progression. These single agent trials are being conducted by the National Cancer Institute of Canada Clinical Trials Group, and we are thankful for their support of this research.

Our goal for 2012 is to enroll these trials as quickly as possible and to complete enrollment in all four trials by the end of the year. We expect to report preliminary data from the Phase 2 trial in glioblastoma multi-forme at the American Society of Clinical Oncology meeting in June 2012.

#### ***Expanded Pipeline with New Small Molecule ONT-701***

As we look to the future of Oncothyreon, it is important not only to advance current clinical programs but to consider opportunities to expand our product pipeline and pursue new targets of potential interest in the cancer therapeutics space.

As such, we were pleased to in-license from the Sanford Burnham Research Institute in 2011 a new small molecule product candidate, which we believe offers some potentially attractive clinical development avenues. ONT-701 is an inhibitor of the Bcl-2 family of anti-apoptotic proteins that are commonly over expressed in most human cancers. Importantly, ONT-701 inhibits all of the family members of BCL-2, which distinguishes it from the competitive product candidates that are currently in clinical trial. We are excited about this new opportunity and plan to begin IND enabling studies for ONT-701 during 2012 to prepare it for clinical evaluation in 2013.

## Looking forward to a Pivotal Year

The achievements of 2011, including the full enrollment of the START trial of Stimuvax, the initiation of four Phase 2 trials of PX-866 and the beginning of the first Phase 1 trial of ONT-10, have set the stage for an exciting and pivotal year for Oncothyreon. By the time I am writing this letter next year, we expect to know the outcome of the START trial, have the results of most of the Phase 2 trials of PX-866 and be nearing the completion of the Phase 1 trial for ONT-10. Rarely does a company the size of Oncothyreon have so many pivotal data points in such a short time frame, creating a unique opportunity for our investors.

We are approaching these data points with a spirit of confidence. While we cannot know the outcome of an individual trial in advance, we have worked hard to create a broad pipeline with multiple opportunities to succeed. Creating this pipeline would not have been possible without our dedicated employees, led by an experienced management team including Diana Hausman, Chief Medical Officer; Scott Peterson, Vice President of Research and Development; Gary Christianson, Chief Operating Officer; and Julie Eastland, Chief Financial Officer and Vice President Corporate Development. I am extremely grateful for their steadfast dedication to our programs and commitment to our overarching mission: to improve the lives and outcomes of cancer patients.

We are also approaching this pivotal year from a position of financial strength. As outlined in the attached financial report, we ended 2011 with approximately \$66 million in cash, cash equivalents and investments, not including the additional approximately \$50 million in net proceeds from an offering of common stock in late March 2012. This strong balance sheet will enable us to move both PX-866 and ONT-10 into the next stages of clinical development if the upcoming results are supportive. As always, we will take these steps with careful consideration of the cost-effective use of our resources and control of our headcount. We greatly value the resources with which you have entrusted us and will continue to endeavor to use them wisely.

Finally, I would like to thank you, our stockholders, for your continued support of Oncothyreon. I look forward to sharing our progress in the months ahead.

Sincerely,



Robert L. Kirkman, M.D.

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**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, 2011

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission file number: 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**

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (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 if the registrant is a shell company, as defined in Rule 12b-2 of the Exchange Act. (Check one):

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 \$383 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 43,613,107 shares of the Registrant's common stock, \$0.0001 par value, outstanding on March 9, 2012.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

**ONCOTHYREON INC.  
ANNUAL REPORT ON FORM 10-K  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2011**

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## PART I

### ITEM 1. Business

*This annual report on Form 10-K, including the “Management’s Discussion and Analysis of Financial Condition and Results of Operation” section in Item 7 of this report, and other materials accompanying this annual report on Form 10-K contain forward-looking statements or incorporate by reference 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. These forward-looking statements include, but are not limited to, statements regarding:*

- the prospects for developing, obtaining regulatory approval for, and commercializing our lead product candidate, Stimuvax;
- the results we anticipate from our pre-clinical development activities and the clinical trials of our products;
- our belief that our product candidates could potentially be useful for many different oncology indications that address large markets;
- our ability to manage our growth;
- the size of the markets for the treatment of conditions our product candidates target;
- our ability to acquire or in-license additional product candidates and technologies;
- our ability to manage our relationship with Merck KGaA to develop and commercialize Stimuvax;
- financing to support our operations, clinical trials and commercialization of our products;
- our ability to meet the obligations of our secured debt facility;
- our ability to adequately protect our proprietary information and technology from competitors and avoid infringement of proprietary information and technology of our competitors;
- the possibility that government-imposed price restrictions may make our products, if successfully developed and commercialized following regulatory approval, unprofitable;
- potential exposure to product liability claims and the impact that successful claims against us will have on our ability to commercialize our product candidates;
- our ability to obtain on commercially reasonable terms adequate product liability insurance for our commercialized products;

- the possibility that competing products or technologies may make our products, if successfully developed and commercialized following regulatory approval, obsolete;
- our ability to succeed in finding and retaining joint venture and collaboration partners to assist us in the successful marketing, distribution and commercialization of our products;
- our ability to attract and retain highly qualified scientific, clinical, manufacturing, and management personnel;
- our ability to identify and capitalize on possible collaboration, strategic partnering, acquisition or divestiture opportunities; and
- potential problems with third parties, including suppliers and key personnel, upon whom we are dependent.

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 product candidate, Stimuvax, is a cancer vaccine being evaluated in two Phase 3 clinical trials 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 Stimuvax. Merck KGaA has completed enrollment of 1514 patients in the Phase 3 START trial of Stimuvax in NSCLC and is currently expected to report the primary efficacy data in 2013. We have also filed an Investigational New Drug application for ONT-10, a proprietary cancer vaccine directed against a target similar to Stimuvax. In addition to our vaccine product candidates, we have developed novel vaccine technology we may further develop ourselves and/or license to others.

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. PX-866 is an irreversible, pan-isoform phosphatidylinositol-3-kinase (PI-3K) 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. 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: Stimuvax and PX-866, which are in clinical trials, and ONT-10 and ONT-701, which are 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 Stimuvax. 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 Stimuvax. We understand Merck KGaA plans to investigate the use of Stimuvax in multiple types of cancer, which we would not have been able to do alone. All development costs for Stimuvax 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.

*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 Sanford Burnham Medical Research Institute 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>
Stimuvax	Vaccine	Non-small cell lung cancer	Phase 3
PX-866	Small Molecule	To be determined	Phase 2
ONT-10	Vaccine	To be determined	Preclinical
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; 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 Stimuvax 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.

## *Stimuvax*

Our lead product candidate currently under clinical development is a vaccine we call Stimuvax. Stimuvax incorporates a 25 amino acid sequence of the cancer antigen MUC1, in a liposomal formulation. Stimuvax 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. Stimuvax is thought to work by stimulating the body's immune system to identify and destroy cancer cells expressing MUC1. Stimuvax is being evaluated in two Phase 3 clinical trials 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. Stimuvax 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. Stimuvax 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 the fourth quarter of 2002, we completed the enrollment of 171 patients in a Phase 2b multi-center trial of Stimuvax in patients with advanced (Stages IIIB and IV) NSCLC at 13 sites in Canada and four sites in the United Kingdom. All patients had received first line standard chemotherapy and had responded to chemotherapy treatment with either a complete response or stable disease. Patients were randomly chosen to receive either Stimuvax along with best supportive care, or best supportive care alone. Second line chemotherapy and/or palliative radiotherapy were allowed where indicated for treatment of progressive disease. The objectives of the trial were to measure safety and the possible survival benefit of Stimuvax in these patients. Secondary endpoints of the trial were quality of life and immune response.

We reported the preliminary results from our Phase 2b trial of Stimuvax in December 2004. The median survival of those patients receiving Stimuvax was 4.4 months longer than those on the control arm who did not receive the vaccine. The overall median survival was 17.4 months for patients who received the vaccine versus 13 months for the patients on the control arm who did not receive the vaccine. The two-year survival rate was 43.2% for the vaccine arm versus 28.9% for the control arm. The two-year survival rate for

patients who had locoregional Stage IIIB NSCLC cancer was 60% for the vaccine arm versus 36.7% for the control arm.

In mid-2005, we began scheduling for the manufacture of new vaccine supplies incorporating manufacturing changes intended to secure the future commercial supply of the vaccine. We began a small clinical safety study of the new formulation of Stimuvax in the second quarter of 2005. The results of this study indicated that the new formulation is equivalent to the formulation used in the Phase 2b trial. In mid-2008 Merck KGaA reported that the two-year survival rate for patients in this trial was 64%.

In April 2006, we announced that the final survival analysis of our Phase 2b trial of Stimuvax in patients with Stages IIIB and IV NSCLC showed that the median survival in the pre-stratified subset of locoregional Stage IIIB patients on the vaccine arm was 30.6 months compared to 13.3 months observed for the same stage patients who did not receive the vaccine, a difference of 17.3 months. These data were obtained through ongoing, regular follow-up of patients enrolled in the trial.

In December 2006, we reached an agreement with the U.S. Food and Drug Administration, or FDA, on a Special Protocol Assessment, or SPA, for the Phase 3 trial of Stimuvax for the treatment of NSCLC. The SPA relates to the design of the Phase 3 trial and outlines definitive clinical objectives and data analyses considered necessary to support regulatory approval of Stimuvax. However, the SPA does not guarantee approval even if the endpoints are successfully reached.

The FDA has granted Fast Track status to the investigation of Stimuvax for its proposed use in the treatment of NSCLC. The FDA's Fast Track programs are designed to facilitate the development and expedite review of drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. With Fast Track designation, there may be more frequent interactions with the FDA during the development of a product and eventually a company may be eligible to file a U.S. Biologics License Application on a rolling basis as data become available.

In January 2007, a global Phase 3 trial assessing the efficacy and safety of Stimuvax as a potential treatment for patients with unresectable, or inoperable, Stage III NSCLC was opened for enrollment. The trial, known as START, is being conducted by Merck KGaA and completed enrollment of 1,514 patients in 2011. We expect that primary efficacy data will be reported in 2012.

In June 2009, Merck KGaA initiated a global Phase 3 trial called STRIDE to assess the efficacy and safety of Stimuvax as a potential therapy for patients with hormone receptor-positive, locally advanced, recurrent or metastatic breast cancer. The trial was anticipated to enroll more than 900 patients at approximately 180 sites in over 30 countries; the primary endpoint was progression-free survival.

In December 2009, Merck KGaA initiated a Phase 3 trial of Stimuvax in Asian patients with advanced NSCLC. The trial, named INSPIRE, is anticipated to enroll approximately 420 patients in China, Hong Kong, South Korea, Singapore and Taiwan.

On March 23, 2010, we announced that Merck suspended the clinical development program for Stimuvax 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 Stimuvax 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 Stimuvax. 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, but the clinical hold on the Stimuvax trial in breast cancer remains in effect and Merck KGaA has discontinued the Phase 3 trial in breast cancer. The suspension affected the Phase 3 clinical program for Stimuvax, including the trials in NSCLC and in breast cancer. For example, we have been informed that Merck KGaA increased the planned size of the START trial of Stimuvax in NSCLC from an estimated number of 1,322 to 1,476 patients as part of a plan to maintain the statistical power of the trial. This change was agreed in consultation with the FDA, and the SPA for START has been amended to reflect the change.

### ***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 expected to be our first completely synthetic vaccine. ONT-10 includes our proprietary liposomal delivery technology. We filed an Investigational New Drug application for ONT-10 in December 2011 and expect to initiate a Phase 1 clinical trial in 2012.

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.

## **Small Molecule Drugs**

### ***General***

On October 30, 2006, we acquired ProLX Pharmaceuticals Corporation, or ProLX, 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 ProLX 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 phosphatidylinositol-3-kinase (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. Patient enrollment is complete in the Phase 1 portions of both trials, and we are currently enrolling patients in the randomized Phase 2 portions. The first trial is examining PX-866 in combination with docetaxel (Taxotere) versus docetaxel alone in patients with either non-small cell lung cancer or locally advanced, recurrent or metastatic squamous cell carcinoma of the head and neck. The second trial is randomizing patients to cetuximab (Erbix) with or without PX-866 and will include patients with either squamous cell carcinoma of the head and neck or colorectal cancer. 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.

### ***ONT-701***

In September 2011, we 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. Overexpression of one or more members of the Bcl-2 family of proteins is common in most human cancers.

### **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 \$12.9 billion in 2011. 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.

### **Research Programs/Vaccine Technology**

In addition to our pipeline of product candidates, 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 preclinical 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 also open to new collaborations to discover novel applications of these molecules as stand-alone therapeutics and as synergistic adjuvants for antibiotic and antiviral drugs.

### **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, Stimuvax 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 Stimuvax, 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 Stimuvax in the United States and, subject to certain conditions, the right to act as a secondary manufacturer of Stimuvax.

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 Stimuvax, while we retained responsibility for manufacturing process development and manufacturing the clinical and commercial supply of Stimuvax.

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

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 Stimuvax 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, Stimuvax, placebo and raw materials, and Merck KGaA agreed to assume certain liabilities related to the manufacture of Stimuvax 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 Stimuvax 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 Stimuvax 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 Stimuvax. 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 Stimuvax 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 B-cell lymphoma-2, or 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, 2011, we owned approximately 24 U.S. patents and patent applications, as well as the corresponding foreign patents and patent applications and held exclusive or partially exclusive licenses to 23 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>
Stimuvax.....	2018 (patent) – 2029 (patent application)
PX – 866.....	2022 (patent) – 2032 (patent application)
ONT - 10.....	2022 (patent applications) – 2032 (patent application)
ONT - 701.....	2028 (patent – 2030 (patent application)

In addition, our composition of matter patents for Stimuvax and PX-866 will expire in 2018 and 2022, respectively, and our composition of matter patent application, if issued, for ONT-10 will expire in 2032. 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 GMP 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 Relationship 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 Stimuvax. Prior to the entry into the 2008 license agreement, we were responsible for the manufacture of Stimuvax and Merck KGaA purchased Stimuvax 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 Stimuvax and placebo. The manufacture of Stimuvax is outsourced pursuant to agreements with Baxter (for the manufacture of Stimuvax) and Corixa, a subsidiary of GlaxoSmithKline (for the manufacture of the adjuvant used in Stimuvax). 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 Stimuvax 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 Stimuvax. 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 Stimuvax 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.

*Stimuvax.* 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. Stimuvax 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 Stimuvax. To our knowledge, these vaccines are not currently being developed in the same indications as Stimuvax. However, subsequent development of these vaccines, including Stimuvax, may result in direct competition.

*Small Molecule Products.* PX-866 is an inhibitor of PI-3-kinase and several other companies have product candidates directed at this target in clinical trials, including Novartis (Phase 1/2), Roche/Genentech (Phase 2), Bayer (Phase 1), Semafore (Phase 1), Sanofi-Aventis (Phase 2), Pfizer (Phase 1), GlaxoSmithKline (Phase 2) and Gilead (Phase 3). At least two companies have product candidates directed at Bcl-2, the target of ONT-701, including Teva (formerly Cephalon, Phase 2) and Genentech in partnership with Abbott (Phase 2). There are also several approved targeted therapies for cancer and in development against which our small molecule products 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. In December 2006, we entered into an SPA agreement with the FDA for the Phase 3 trial of Stimuvax for the treatment of NSCLC. The SPA agreement relates to the design of the Phase 3 trial and outlines definitive clinical objectives and data analyses considered necessary to support regulatory approval of Stimuvax however the SPA does not guarantee approval even if the endpoints are successfully reached.

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***

We received Fast Track designation from the FDA for Stimuvax for the treatment of NSCLC. 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, 2011, 2010 and 2009, we expended approximately \$17.9 million, \$11.6 million, and \$6.2 million, respectively, on research and development activities.

## **Employees**

As of December 31, 2011, we (including our consolidated subsidiaries) had 32 employees, 24 of whom are engaged in development activities, eight in finance and administration, and eight 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.

## **ITEM 1A. Risk Factors**

### **Factors That Could Affect Future Results**

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 also affect our results of operations and financial condition.

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

***Our near-term success is highly dependent on the success of our lead product candidate, Stimuvax, and we cannot be certain that it will be successfully developed or receive regulatory approval or be successfully commercialized.***

Our lead product candidate, Stimuvax, is being evaluated in Phase 3 clinical trials for the treatment of non-small cell lung cancer, or NSCLC. Stimuvax will require the successful completion of the ongoing NSCLC trials and possibly other clinical trials before submission of a biologic license application, or BLA, or its foreign equivalent for approval. This process can take many years and require the expenditure of substantial resources. Pursuant to our agreement with Merck KGaA, Merck KGaA is responsible for the development and the regulatory approval process and any subsequent commercialization of Stimuvax. We cannot assure you that Merck KGaA will continue to advance the development and commercialization of Stimuvax as quickly as would be optimal for our stockholders. In addition, Merck KGaA has the right to terminate the 2008 license agreement upon 30 days' prior written notice if, in its reasonable judgment, it determines there are issues concerning the safety or efficacy of Stimuvax that would materially and adversely affect Stimuvax's medical, economic or competitive viability. Clinical trials involving the number of sites and patients required for U.S. Food and Drug Administration, or FDA, approval of Stimuvax may not be successfully completed. If these clinical trials fail to demonstrate that Stimuvax is safe and effective, it will not receive regulatory approval. Even if Stimuvax receives regulatory approval, it may never be successfully commercialized. If Stimuvax does not receive regulatory approval or is not successfully commercialized, or if Merck were to terminate the 2008 license agreement, we may not be able to generate revenue, become profitable or continue our operations. Any failure of Stimuvax to receive regulatory approval or be successfully commercialized 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.

We understand that Merck KGaA intends to submit for regulatory approval of Stimuvax for the treatment of NSCLC based on the results of a single Phase 3 trial, the START study. If the FDA determines that the results of this single study do not demonstrate the efficacy of Stimuvax with a sufficient degree of statistical certainty, the FDA may require an additional Phase 3 study to be performed prior to regulatory approval. Such a trial requirement would delay or prevent commercialization of Stimuvax and could result in

the termination by Merck KGaA of our license agreement with them. In addition, there can be no guarantee that the results of an additional trial would be supportive of the results of the START trial.

***Stimuvax 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. Stimuvax 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 Stimuvax 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.

***The suspension of Merck's clinical development program for Stimuvax could severely harm our business.***

In March 2010, we announced that Merck KGaA suspended the clinical development program for Stimuvax as the result of a suspected unexpected serious adverse event reaction in a patient with multiple myeloma participating in an exploratory clinical trial. The suspension was a precautionary measure while an investigation of the cause of the adverse event was conducted, but it affected the Phase 3 clinical trials in NSCLC and in breast cancer. In June 2010, we announced that the FDA, lifted the clinical hold it had placed on the Phase 3 clinical trials in NSCLC. Merck KGaA has resumed the treatment and enrollment in these trials for Stimuvax in NSCLC. The clinical hold on the Stimuvax trial in breast cancer remains in effect and Merck KGaA has discontinued the Phase 3 trial in breast cancer.

As of the date of this report, we can offer no assurances that this serious adverse event was not caused by Stimuvax or that there are not or will not be more such serious adverse events in the future. The occurrence of this serious adverse event, or other such serious adverse events, could result in a prolonged delay, including the need to enroll more patients or collect more data, or the termination of the clinical development program for Stimuvax. For example, we have been informed that Merck KGaA plans to increase the size of the START trial of Stimuvax in NSCLC from an estimated number of 1,322 to 1,476 patients as part of a plan to maintain the statistical power of the trial. This change was agreed in consultation with the FDA and the Special Protocol Agreement, or SPA, for START has been amended to reflect the change. Another unexpected serious adverse event reaction could cause a similar suspension of clinical trials in the future. Any of these foregoing risks could materially and adversely affect our business, results of operations and the trading price of our common stock.

***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, 2011, our accumulated deficit was approximately \$389.9 million. Our losses have resulted primarily from expenses incurred in research and development of our product candidates. 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, Stimuvax, in Phase 3 clinical trials for the treatment of NSCLC. We are conducting four Phase 2 trials for PX-866. Our other product candidates remain in the pre-clinical testing stages. The results from pre-clinical testing and clinical trials that we have completed may not be predictive of results in future pre-clinical tests and clinical trials, and 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, the clinical trials for Stimuvax were suspended as a result of a suspected unexpected serious adverse event reaction in a patient. Although the clinical hold for trials in NSCLC has been lifted, it remains in effect for the trial in breast cancer and Merck KGaA has decided to discontinue the Phase 3 trial in breast cancer. Regulatory approval may not be obtained for any of our product candidates. If our product candidates are not shown to be safe and effective in clinical trials, the resulting delays in developing other product candidates and conducting related pre-clinical testing and clinical trials, as well as the potential need for additional financing, would have a material adverse effect on our business, financial condition and results of operations.

***We are dependent upon Merck KGaA to develop and commercialize our lead product candidate, Stimuvax.***

Under our license agreement with Merck KGaA for our lead product candidate, Stimuvax, Merck KGaA is entirely responsible for the development, manufacture and worldwide commercialization of Stimuvax and the costs associated with such development, manufacture and commercialization. Any future payments, including royalties to us, will depend on the extent to which Merck KGaA advances Stimuvax through development and commercialization. Merck KGaA has the right to terminate the 2008 license agreement, upon 30 days' written notice, if, in Merck KGaA's reasonable judgment, Merck KGaA determines that there are issues concerning the safety or efficacy of Stimuvax which materially adversely affect Stimuvax's medical, economic or competitive viability; provided that if we do not agree with such determination we have the right to cause the matter to be submitted to binding arbitration. Our ability to receive any significant revenue from Stimuvax is dependent on the efforts of Merck KGaA. If Merck KGaA fails to fulfill its obligations under the 2008 license agreement, we would need to obtain the capital necessary to fund the development and commercialization of Stimuvax or enter into alternative arrangements with a third party. We could also become involved in disputes with Merck KGaA, which could lead to delays in or termination of our development and commercialization of Stimuvax 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 chances of successfully developing or commercializing Stimuvax would be materially and adversely affected.

***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 Stimuvax, 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, Stimuvax, and on Corixa Corp. (now a part of GlaxoSmithKline plc, or GSK) for the manufacture of the adjuvant in Stimuvax. If Stimuvax 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 Stimuvax, which would materially harm our business.

Similarly, we rely on a single manufacturer, Fermentek, LTD for the supply of wortmannin, a key raw ingredient for PX-866. Without the timely support of Fermentek, LTD, our development program for PX-866 could suffer significant delays, require significantly higher spending or face cancellation.

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 Stimuvax) 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 Stimuvax) 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.

***Any failure or delay in commencing or completing clinical trials for our product candidates could severely harm our business.***

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 and/or our collaborators intend to sell those product candidates. Accordingly, we and/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. For example, although the suspension of the clinical development program for Stimuvax in March 2010 has been lifted for trials in NSCLC, it remains in effect for the Phase 3 breast cancer trial and, in any event, may result in a prolonged delay or in the termination of the clinical development program for Stimuvax. For example, Merck KGaA has announced that it has decided to discontinue the Phase 3 trial in breast cancer. A prolonged delay or termination of the clinical development program would have a material adverse impact on 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. For example, the suspension of the Stimuvax trials resulted in Merck KGaA enrolling additional patients which could delay such trials.

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.

***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. For example, in March 2010, Merck KGaA suspended the clinical development program for Stimuvax in both NSCLC and breast cancer as the result of a suspected unexpected serious adverse event reaction in a patient with multiple myeloma participating in an exploratory clinical trial. Although the clinical hold placed on Stimuvax clinical trials in NSCLC has been lifted, the suspension of clinical trials in breast cancer remains in effect and Merck KGaA has announced that it has decided to discontinue the Phase 3 trial in breast cancer. In addition, 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. 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 costs or delays in such 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 can involve additional testing and data review. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. 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 harm our business.

***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. 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.

***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. 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.

***The terms of our secured debt facility may restrict our current and future operations, particularly our ability to respond to changes or to take some actions, and our failure to comply with certain restrictive covenants, whether due to events beyond our control or otherwise, could result in an event of default which could materially and adversely affect our operating results and our financial condition.***

In February 2011 we borrowed \$5.0 million pursuant to the terms of a loan and security agreement, or the loan agreement, with General Electric Capital Corporation, or GECC. The loan agreement with GECC contains certain restrictive covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, or repurchase stock. The loan agreement also requires that we

have 12 months of unrestricted cash and cash equivalents (as calculated in the loan agreement) as of each December 31 during the term of the loan agreement. A breach of any of these covenants or the occurrence of certain other events of default, which are customary in similar loan facilities, would result in a default under the loan agreement. If there was an uncured event of default, GECC could cause all amounts outstanding under the loan agreement to become due and payable immediately and could proceed against the collateral securing the indebtedness, including our cash, cash equivalents and short-term investments. We cannot be certain that our assets would be sufficient to fully repay borrowings under the loan agreement, either upon maturity or acceleration upon an uncured event of default.

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

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

- obtain patent and other proprietary protection for our technology, processes and product candidates;
- defend patents once issued;
- preserve trade secrets; and
- operate without infringing the patents and proprietary rights of third parties.

As of December 31, 2011, we owned approximately nine U.S. patents and 15 U.S. patent applications, as well as the corresponding foreign patents and patent applications, and held exclusive or partially exclusive licenses to approximately 15 U.S. patents and eight 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.

Even if any or all of our patent applications issue as patents, 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. 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 no assurance that our patents, if issued, will not be infringed or successfully avoided through design innovation. Intellectual property lawsuits are expensive and would consume time and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents, if issued, are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity 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. If any of these events were to occur, our business, financial condition and results of operations would be materially and adversely effected.

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 our vaccine technology or our product candidates, including Stimuvax, 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.

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. 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.

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. 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.

***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; however, prices may become subject to controls similar to those in other countries. 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.***

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.

*Stimuvax.* 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. Stimuvax 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 Stimuvax. Of these vaccines, only Lucanix is being developed as a maintenance therapy in Stage III NSCLC, the same indication as Stimuvax. However, subsequent development of these vaccines, including Stimuvax, 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 phosphoinositide 3-kinase (PI3K). We are aware of several companies that have entered clinical trials with competing compounds targeting the same protein. Among those are compounds being developed by Novartis (Phase 1/2), Roche/Genentech (Phase 2), Bayer (Phase 1), Semafore (Phase 1), Sanofi-Aventis (Phase 2), Pfizer (Phase 1), GlaxoSmithKline (Phase 2) and Gilead Sciences, Inc. (Phase 3). 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 several companies that are developing competing drugs that target the same family, including Cephalon (Phase 2), Ascenta (Phase 2) and Abbott/Roche (Phase 1). There are also several approved targeted therapies for cancer and in development against which ONT-701 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 Stimuvax, and any problems with that relationship could delay the development and commercialization of Stimuvax. 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.

***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;
- 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, 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.

### **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. 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, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and

industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. 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.

***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 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. 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.

***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 of 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, 2011, 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 accounted for as a derivative financial instrument and classified as a derivative 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 May 2011, we generated approximately \$43.1 million of net proceeds from the sale of shares of our common stock in an underwritten public offering and in the fourth quarter of 2011 we generated approximately \$9.0 million in net proceeds from the sale of shares pursuant to our committed equity line financing facility. 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 sublease 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 sublease expired in December 2011 and we currently lease the same facility pursuant to a lease agreement entered into directly with the landlord in May 2008. 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 has been quoted on the NASDAQ Global Market under the symbol “ONTY” since December 11, 2007. Prior to that time, Biomira’s common shares were quoted on the NASDAQ Global Market under the symbol “BIOM”. Our common stock was also quoted on the Toronto Stock Exchange under the symbol “BRA” until December 11, 2007 and under the symbol “ONY” until October 14, 2009, when we announced that the Toronto Stock Exchange had granted our voluntary application to delist our shares of common stock from the TSX effective at the close of trading on October 22, 2009.

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, 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
Fiscal year ended December 31, 2010:		
First Quarter .....	\$ 5.90	\$ 3.16
Second Quarter .....	4.35	2.20
Third Quarter .....	4.73	3.10
Fourth Quarter .....	4.20	3.11

#### 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 29, 2012, there were 43,613,107 shares of our common stock outstanding held by approximately 693 stockholders of record and approximately 29,100 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.”

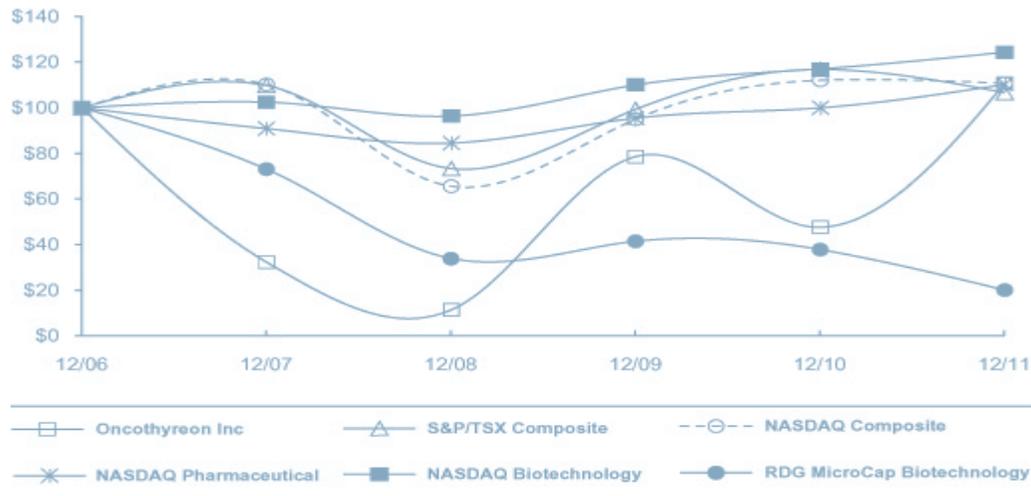
## Stock Performance Graph

Notwithstanding any statement to the contrary in any of our previous or future filings with the SEC, 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 Securities Act or the Exchange Act, 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, 2006 through December 31, 2011. 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 Oncothyreon 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 12/13/06 in stock or Index, including reinvestment of dividends. Fiscal year ending December 31  
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## Unregistered Sale of Equity Securities

As previously disclosed in our Current Report on Form 8-K filed with the SEC on July 7, 2010, we were party to a committed equity line facility with Small Cap Biotech Value, Ltd., or SCBV, which provided that, upon the terms and subject to the conditions of the purchase agreement governing the facility, SCBV would be committed to purchase shares of our common stock in transactions exempt from the registration requirements of the Securities Act of 1933, as amended. We effected two draw downs under the facility during the three months ended December 31, 2011. The per share price at which SCBV purchased these

shares was established under the purchase agreement governing the facility by reference to the volume weighted average prices of our common stock on The NASDAQ Global Market during the pricing period, net a discount of 5% per share.

In connection with the first draw down, which settled on October 4, 2011, we sold an aggregate of 639,071 shares of our common stock to SCBV, at a per share purchase price of approximately \$6.43 and an aggregate purchase price of approximately \$4.1 million. We received net proceeds from the sale of these shares of approximately \$4.1 million after deducting our estimated offering expenses, including a placement agent fee of approximately \$41,000 paid to Reedland Capital Partners, an Institutional Division of Financial West Group, member FINRA/SIPC, in connection with this draw down. In connection with the second draw down under the facility, which settled on November 10, 2011, we sold an aggregate of 805,508 shares of our common stock to SCBV, at a per share purchase price of approximately \$6.21 and an aggregate purchase price of approximately \$5.0 million. We received net proceeds from the sale of these shares of approximately \$4.9 million after deducting our estimated offering expenses, including a placement agent fee of approximately \$50,000, paid to Reedland Capital Partners in connection with this draw down.

The sale and issuance of such shares of common stock in these draw downs were exempt from registration under the Securities Act of 1933 pursuant to Section 4(2) of the Securities Act and Regulation D promulgated thereunder.

#### **Issuer Purchases of Equity Securities**

We did not make any purchases of our outstanding common stock during the three months ended December 31, 2011.

#### **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 “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	Year Ended December 31,				
	2011	2010	2009	2008(1)	2007(2)
	(Amounts in thousands, except share and per share data.)				
<b>Consolidated Statements of Operations Data:</b>					
Revenue:					
Licensing revenue from collaborative and license agreements .....	\$ 145	\$ 18	\$ 2,051	\$ 24,713	\$ 440
Contract manufacturing .....	—	—	—	15,582	2,536
Licensing, royalties and other revenue .....	—	—	27	—	103
Contract research and development .....	—	—	—	—	631
	<u>145</u>	<u>18</u>	<u>2,078</u>	<u>40,295</u>	<u>3,710</u>
Expenses:					
Research and development 33).....	17,915	11,601	6,215	9,142	9,793
Manufacturing(1)(2).....	—	—	—	13,675	2,564
General and administrative.....	6,929	7,901	6,724	10,347	12,261
Marketing and business development .....	—	—	—	—	565
Total operating expenses.....	<u>24,844</u>	<u>19,502</u>	<u>12,939</u>	<u>33,164</u>	<u>25,183</u>
Income (loss) from operations.....	(24,699)	(19,484)	7,131	(10,861)	(21,473)
Investment and other income (expense).....	305	636	(8)	298	(371)
Interest expense .....	(631)	—	—	(7)	(5)
Change in fair market value of warrant liability .....	(17,631)	3,030	(6,150)	—	1,421
Income (loss) before income taxes .....	(42,656)	(15,818)	(17,019)	7,422	(20,428)
Income tax benefit (provision).....	—	200	(200)	—	—
Net income (loss).....	<u>\$ (42,656)</u>	<u>\$ (15,618)</u>	<u>\$ (17,219)</u>	<u>\$ 7,422</u>	<u>\$ (20,428)</u>
Earnings (loss) per share - basic .....	<u>\$ (1.12)</u>	<u>\$ (0.58)</u>	<u>\$ (0.76)</u>	<u>\$ 0.38</u>	<u>\$ (1.05)</u>
Earnings (loss) per share - diluted .....	<u>\$ (1.12)</u>	<u>\$ (0.58)</u>	<u>\$ (0.76)</u>	<u>\$ 0.38</u>	<u>\$ (1.05)</u>
Weighted average number of common shares outstanding - basic.....	<u>38,197,666</u>	<u>26,888,588</u>	<u>22,739,138</u>	<u>19,490,621</u>	<u>19,485,889</u>
Weighted average number of common shares outstanding - diluted.....	<u>38,197,666</u>	<u>26,888,588</u>	<u>22,739,138</u>	<u>19,570,170</u>	<u>19,485,889</u>

	Year Ended December 31,				
	2011	2010	2009	2008(1)	2007(2)(3)
	(Amounts in thousands, except share and per share data.)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments .....	\$ 63,876	\$ 28,877	\$ 33,218	\$ 19,166	\$ 24,186
Total assets .....	\$ 71,351	\$ 34,445	\$ 38,225	\$ 24,971	\$ 36,218
Total long-term liabilities .....	\$ 33,236	\$ 13,727	\$ 10,732	\$ 578	\$ 12,823
Stockholders' equity .....	\$ 33,433	\$ 18,857	\$ 25,418	\$ 20,717	\$ 11,722
Common shares outstanding.....	\$43,613,107	\$30,088,628	\$25,753,405	\$19,492,432	\$19,485,889

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- (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 9 — Collaborative and License Agreements” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.
  - (2) In August 2007, we signed the amended and restated collaboration and supply agreements related to Stimuvax with Merck KGaA. Pursuant to the terms of the collaboration and supply agreements, from August 2007 to December 2008, with the entry into the 2008 license agreement, we retained the responsibility to manufacture Stimuvax and Merck KGaA agreed to purchase Stimuvax from us. During their term, the collaboration and supply agreements transformed what were previously reimbursements of a portion of the Stimuvax manufacturing costs to a long-term contract manufacturing arrangement. Our financial reporting during the term of the collaboration and supply agreements reflects the revenue and associated clinical trial material costs related to the supply of Stimuvax separately in the consolidated statements of operations as contract manufacturing revenue and manufacturing expense, respectively. Previously, these amounts were reported under contract research and development revenue and research and development expense, respectively.
  - (3) Depreciation and amortization expense of \$462,000, \$269,000, \$422,000 and \$246,000 was reclassified to research and development and general and administrative expenses for the years ended December 31, 2010, 2009, 2008 and 2007, respectively, to conform to current year presentation. See “Note 2 — Significant Accounting Policies — Reclassifications” elsewhere in this Annual Report on Form 10-K.

## **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 product candidate, Stimuvax, is a cancer vaccine being evaluated in two Phase 3 clinical trials 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 Stimuvax. Merck KGaA has completed enrollment of 1514 patients in the Phase 3 START trial of Stimuvax in NSCLC and is currently expected to report the primary efficacy data in 2013. We have also filed an Investigational New Drug application for ONT-10, a cancer vaccine directed against a target similar to Stimuvax, and 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.

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. PX-866 is an irreversible, pan-isoform phosphatidylinositol-3-kinase (PI-3K) inhibitor we obtained when we acquired from 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. 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. See “Note 9 — Collaborative and License Agreements” for additional information.

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 Stimuvax. 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 Stimuvax. 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 Stimuvax. We also continued to be responsible for manufacture of the clinical and commercial supply of Stimuvax 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 Stimuvax, which we received in December 2007, a \$3.0 million payment tied to the transfer of certain Stimuvax 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 Stimuvax 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 Stimuvax 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 Stimuvax 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 Stimuvax were removed and our continuing involvement in the development and manufacturing of Stimuvax 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 Stimuvax 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 which 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 of, and inventory of, Stimuvax, placebo and raw materials, and Merck KGaA agreed to assume certain liabilities related to the manufacture of Stimuvax 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 9 — 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 Stimuvax 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 Stimuvax, 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 Stimuvax 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

Stimuvax, 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, 2011, our accumulated deficit totaled \$389.9 million. We incurred a net loss of \$42.7 million for 2011 compared to a net loss of \$15.6 million for 2010. 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. We completed financings in September 2010, in which we raised approximately \$14.9 million in gross proceeds, in May 2009, in which we raised approximately \$11.0 million in gross proceeds and in August 2009, in which we raised approximately \$15.0 million in gross proceeds, from the sale of our common stock and the issuance of warrants. 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 and, subject to the satisfaction of certain conditions, may incur an additional \$7.5 million in term loan indebtedness. 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. See the section captioned “Liquidity and Capital Resources” and “Note 6 — 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***

Our revenue in 2011 and 2010 was immaterial; however, the types of revenues described in this section are relevant for 2009. Historically, our revenue has been derived from payments under our collaborative and license agreements, our contract manufacturing activities, and miscellaneous licensing, royalty and other revenues from ancillary activities. Our arrangement with Merck KGaA regarding Stimuvax has historically contributed the substantial majority of our revenue.

*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.

*Licensing, Royalties, and Other Revenue.* Licensing, royalties, and other revenue consist of revenue from sales of compounds and processes from patented technologies to third parties and royalties received pursuant to collaborative agreements and license agreements. Royalties based on reported sales, if any, of licensed products are recognized based on the terms of the applicable agreement when and if reported sales are reliably measurable and collectability is reasonably assured. For more information on revenue recognition for licensing, royalties, and other revenue, see “— Critical Accounting Policies and Significant Judgments and Estimates — Revenue Recognition — Licensing, Royalties, and Other Revenue” 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, stock-based compensation expense, benefits, and related costs; allocated facility overhead which includes depreciation and amortization; and third party supplier expenses.

For the periods covered by this report, we have recognized research and development expenses, including those paid to third parties, as they have been incurred. We credit funding received from government research and development grants against research and development expense when such funding is received in the period when incurred. These credits totaled \$0.8 million for the year ended December 31, 2009. This grant was a Small Business Innovation Research, or SBIR, grant that we assumed in connection with our acquisition of ProIX on October 30, 2006. Funding for the SBIR grants was completed in 2009. No SBIR grants were received in 2010 and 2011.

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.

As a result of these uncertainties and the other risks inherent in the drug development process, we cannot determine the duration and completion costs of current or future clinical stages of any of our product candidates. Similarly, we cannot determine when, if, or to what extent we may generate revenue from the

commercialization and sale of any product candidate. The timeframe for development of any product candidate, associated development costs, and the probability of regulatory and commercial success vary widely. As a result, we continually evaluate our product candidates and make determinations as to which programs to pursue and how much funding to direct to specific candidates. These determinations are typically made based on consideration of numerous factors, including our evaluation of scientific and clinical trial data and an ongoing assessment of the product candidate's commercial prospects. We anticipate that we will continue to develop our portfolio of product candidates, which will increase our research and development expense in future periods. We do not expect any of our current candidates to be commercially available before 2013, if at all.

*General and Administrative.* General and administrative expense consists principally of salaries, benefits, stock-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 debt securities, commercial paper 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, or QTDP, program, which was recorded as other income since the amounts pertained to expenses incurred in 2009 and 2010. Interest expense consists of interest incurred under our loan agreement with General Electric Capital Corporation. For more information, see "Note 6 — 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 7 — 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 the realization of these benefits is not reasonably assured. Our income tax provision in 2009 relates to alternative minimum tax liability on the sale of manufacturing rights and know how to Merck KGaA in December 2008 and the final process transfer payment received in 2009. In 2010 we recorded a tax benefit for recovery of taxes paid in the previous year and received payment in 2011. In 2011, no provision 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;
- stock-based compensation; and
- warrant liability.

### **Revenue Recognition**

Our revenue in 2011 and 2010 was immaterial; however, the types of revenues described in this section are relevant for 2009.

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, 2011, we have not applied these provisions to any of our revenue arrangements as we have not entered into any new, or materially modified any of our existing, revenue arrangements in 2011.

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.

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: (i) 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 the our 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. 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 Stimuvax, which was until 2018. Upon entering into the 2008 agreements, all of our future performance obligations related to our collaboration with Merck KGaA regarding Stimuvax were removed and our continuing involvement in the development and manufacturing of Stimuvax 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 currently 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.

*Licensing, Royalties, and Other Revenue.* Licensing, royalties, and other revenue consists of revenue from sales of compounds and processes from patented technologies to third parties and royalties received pursuant to collaborative agreements and license agreements. Royalties based on reported sales, if any, of licensed products are recognized based on the terms of the applicable agreement when and if reported sales are reliably measurable and collectability is reasonably assured. As of the date of this report, we have not received any royalties pursuant to our arrangement with Merck KGaA.

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.

### ***Goodwill Impairment***

Goodwill is carried at cost and 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. If the carrying value of goodwill exceeds its fair value, an impairment loss would be recognized. As of December 31, 2011, we had one reporting unit and there was a substantial excess of fair value compared to the carrying value. There were no impairment charges recorded for any of the periods presented.

### ***Stock-Based Compensation***

We maintain a share option plan under which an aggregate of 2,441,725 shares of common stock underlie outstanding options as of December 31, 2011 and an aggregate of 1,919,585 shares of common stock were available for future issuance. We maintain an Employee Stock Purchase Plan (“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, 2011, there were 807,597 shares reserved for future purchases. We maintain a restricted share unit plan under which an aggregate of 143,495 shares of common stock underlie restricted stock units, or RSUs, as of December 31, 2011 and an aggregate of 200,922 shares of common stock were available for future issuance. 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. Prior to the April 1, 2008 amendment to our share option plan, we granted options with an exercise price denominated in Canadian dollars equal to the closing price of our shares on the Toronto Stock Exchange on the trading day immediately prior to the date of grant. On and after April 1, 2008, we granted options with an exercise price denominated in U.S. dollars equal to the closing price of our shares on The NASDAQ Global Market on the date of grant.

On and after June 12, 2009 the fair value of the restricted share units has been determined to be the equivalent of our common shares closing trading price on the date immediately prior to the grant as quoted on The NASDAQ Global Market. Prior to June 12, 2009, the fair value was computed using the closing trading price on the date immediately prior to the grant as quoted in Canadian dollars on the Toronto Stock Exchange. 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, or until settlement of the award, and any changes in valuation are recorded as compensation expense for the period.

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 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. Historically we have based the risk-free interest rate for the expected term of the option on the yield available on Government of Canada benchmark bonds with an equivalent expected term. Subsequent to April 1, 2008, we use the yield at the time of grant of a U.S. Treasury security. The expected life of options in years represents the period of time stock-based awards are expected to be outstanding, giving consideration to the contractual terms of the awards, vesting schedules and historical employee behavior. The expected volatility is based on the historical volatility of our common stock for a period equal to the stock option's expected life.

### *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. Of the warrants issued in May 2009, 262,101, zero and 91,500, warrants were exercised in 2011, 2010 and 2009 respectively. These warrants are classified as liabilities due to potential cash settlement upon the occurrence of certain transactions specified in the warrant agreement related to the warrants and, in the case of the warrants issued in May 2009, certain adjustments that may be made to the terms of the warrants if we issue or sell shares below the exercise price. The September 2010 equity financing triggered certain adjustment provisions in the May 2009 warrants and, as a result, the aggregate number of shares underlying such unexercised warrants increased by 135,600 to 2,953,344 as of December 31, 2010 and the per share exercise price decreased from \$3.92 to \$3.74. Pursuant to the terms of the warrant agreement, the terms of the warrants issued in May 2009 will not be further adjusted for any future transactions. 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 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. In 2010, we changed the way we estimated volatility when determining the fair value of the warrants using the

Black-Scholes model. For more information, see “Note 3 — Fair Value Measurements” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

## Results of Operations for the years ended December 31, 2011, 2010 and 2009

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

### Overview

	Years Ended December 31,		
	2011	2010	2009
	(In millions, except per share amounts)		
Revenue .....	\$ 0.1	\$ —	\$ 2.1
Operating expenses .....	(24.9)	(19.5)	(12.9)
Other income (expense), net .....	(0.3)	0.7	—
Change in fair value of warrant liability .....	(17.6)	3.0	(6.2)
Benefit (provision) for income tax .....	—	0.2	(0.2)
Net loss .....	<u>\$ (42.7)</u>	<u>\$ (15.6)</u>	<u>\$ (17.2)</u>
Loss per share — basic and diluted .....	<u>\$ (1.12)</u>	<u>\$ (0.58)</u>	<u>\$ (0.76)</u>

We incurred a net loss of \$42.7 million in 2011 compared to a net loss of \$15.6 million in 2010. The increase in our net loss was primarily due to the increase in the fair value of our warrant liability, which was attributable principally to the increase in the price of our common stock. In addition, the increase in our net loss was also due to higher expenses in research and development related to the development of PX-866 and ONT-10. This increase was partly offset by lower general and administrative expenses due to lower professional fees incurred in 2011. The net loss of \$15.6 million in 2010 compared to a net loss of \$17.2 million in 2009 was primarily driven by the decline in the fair value of our warrant liability, which was attributable principally to the decrease in the price of our common stock. This was substantially offset by higher expenses in research and development related to the development of PX-866 and ONT-10. In addition, general and administrative expenses were higher due to higher professional fees incurred in 2010. Depreciation and amortization expense of \$0.5 million and \$0.3 million were reclassified to research and development and general and administrative expenses for the years ended December 31, 2010 and 2009 respectively, to conform to current year presentation. See “Note 2 — Significant Accounting Policies — Reclassifications” elsewhere in this Annual Report on Form 10-K for more information. Based on our development plans for our small molecule and vaccine candidates we will continue to incur operating losses for the foreseeable future.

### Revenue

	Years Ended December 31,		
	2011	2010	2009
	(In millions)		
Licensing revenues from collaborative and license agreements .....	\$ 0.1	\$ —	\$ 2.1

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 did not receive any revenues during 2010. License revenue in 2009 included a \$2.0 million contractually obligated payment from Merck KGaA. We do not expect revenue from the license of Stimuvax, if at all, until the submission by Merck KGaA of the BLA for the first indication.

### *Research and Development*

	Years Ended December 31,		
	2011	2010	2009
	(In millions)		
Research and development .....	\$ 17.9	\$ 11.6	\$ 6.2

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 also 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. As we continue with our development on PX-866 and ONT-10, we expect that our research and development costs will be higher in 2012 compared to 2011.

The \$5.4 million, or 87.1%, increase in research and development expenses for 2010 compared to 2009 was primarily driven by a \$2.8 million increase in contract laboratory services and contract manufacturing and lab supplies, related to the development of PX-866 and ONT-10. Salaries and benefits and clinical trial expenses were higher by \$1.3 million and \$0.2 million, respectively, due to increased headcount and greater clinical trial activity. Grant revenue used to offset research and development expenses decreased to zero in 2010 from \$0.8 million in 2009, since our activities related to the SBIR grant ceased in 2009.

### *General and Administrative*

	Years Ended December 31,		
	2011	2010	2009
	(In millions)		
General and administrative .....	\$ 6.9	\$ 7.9	\$ 6.7

The \$1.0 million decrease in general and administrative expenses for 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. 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, or until settlement of the award, and any changes in valuation are recorded as compensation expense for the period. For more information, see “Note 8 — Stock-based Compensation” of the audited financial statements included elsewhere in this Annual Report on Form 10-K. 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. We expect general and administrative expenses to be higher in 2012 compared to 2011; however, these expenses will be subject to fluctuations related to the changes in the fair value of the RSU liability.

The \$1.2 million increase in 2010 relative to 2009 was principally due to a \$1.3 million increase in professional fees incurred related to regulatory compliance in the first half of 2010 and a \$0.2 million increase in directors and officers insurance premiums. The increase was partially offset by lower stock based compensation expense of \$0.4 million and lower overhead allocation of \$0.4 million, which includes rent, repair and maintenance, depreciation and amortization, communication expenses and supplies.

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

	Years Ended December 31,		
	2011	2010	2009
		(In millions)	
Investment and other income (expense), net.....	\$ 0.3	\$ 0.6	\$ —

Net investment and other income (expense) decreased by \$0.3 million for 2011 compared to 2010 primarily due 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 related to the acquisition of Pro1X. For additional information, see “Note 6 — Notes payable assumed in connection with the acquisition of Pro1X”

The \$0.6 million increase in investment and other income in 2010 compared to 2009 was primarily attributable to receipt of a government grant of \$0.5 million and higher average yields on our investments in 2010.

### *Interest Expense*

	Years Ended December 31,		
	2011	2010	2009
		(In millions)	
Interest expense .....	\$ 0.6	\$ —	\$ —

Interest expense for 2011 increased by \$0.6 million compared to 2010 due to cash interest and non-cash amortization of debt issuance costs and debt discount related to the notes payable that we entered into with General Electric Capital Corporation on February 8, 2011. For additional information, see “Note 6 — Notes payable — General Electric Capital Corporation”

### *Change in Fair Value of Warrant Liability*

	Years Ended December 31,		
	2011	2010	2009
		(In millions)	
Change in fair value of warrant liability .....	\$ (17.6)	\$ 3.0	\$ (6.2)

The \$17.6 million recorded was due to the increase in fair value of warrant liability for the year ended 2011. Such increase was attributable principally to the increase in the price of our common stock and pertains to warrants issued in connection with the September 2010 and May 2009 financings.

The \$3.0 million recorded was due to the decline in fair value of warrant liability for the year ended 2010. Such decline 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. On December 31, 2010, we changed the way we estimated volatility when determining the fair value of the warrants using the Black-Scholes model. For more information, see “Note 3 — Fair Value Measurements” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

The warrants issued in May 2009 were subject to certain adjustments if we issued or sold shares below the original exercise price. A September 2010 equity financing triggered such adjustment provisions and, as a result, the aggregate number of shares underlying such unexercised warrants increased by 135,600 to 2,953,344 as of December 31, 2010 and the per share exercise price decreased from \$3.92 to \$3.74. Pursuant

to the terms of the warrant agreement, the terms of the warrants issued in May 2009 will not be further adjusted for any future transactions.

The \$6.2 million loss on the change in fair value of warrant liability for the year ended 2009 was attributable to the warrants issued in connection with the May 2009 financing.

***Income tax benefit (provision)***

	Years Ended December 31,		
	2011	2010	2009
	(In millions)		
Income tax benefit (provision).....	\$ —	\$ 0.20	\$ (0.2)

In 2010, we recorded a tax benefit for the recovery of taxes paid in the previous year. The provision for income tax in 2009 relates to alternative minimum tax incurred in connection with the December 2008 transactions with Merck KGaA and the final process manufacturing transfer payment received during 2009. While we have incurred substantial losses in historical periods (except for 2008), 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, 2011, our principal sources of liquidity consisted of cash and cash equivalents of \$11.6 million, short-term investments of \$52.3 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, corporate debt securities, commercial paper and certificates of deposit insured by the Federal Deposit Insurance Corporation with maturities not exceeding 12 months. Our long-term investments are invested in debt securities of U.S government agencies with maturities exceeding 12 months. 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 \$11.6 million as of December 31, 2011 compared to \$5.5 million as of December 31, 2010, an increase of \$6.1 million, or 110.9%. The increase was primarily attributable to net proceeds of \$43.1 million from the sale of our common stock pursuant to an underwritten public offering, net proceeds of approximately \$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 General Electric Capital Corporation, and approximately \$1.9 million received from warrant exercises. Such increase was partially offset by net purchase of investments of \$31.4 million and net cash used in operations of \$21.0 million.

As of December 31, 2011, our working capital was \$60.1 million compared to \$28.2 million as of December 31, 2010, an increase of \$31.9 million, or 113.1%. The increase in working capital was primarily attributable to an increase in short-term investments of \$28.9 million and cash and cash equivalents of \$6.1 million. Such increase was offset by a \$1.7 million increase in current portion of notes payable, a \$0.8 million increase in accrued liabilities and a decrease in government grants receivable of \$0.5 million.

In February 2011, we entered into a loan agreement with GE Capital, pursuant to which the lenders extended to us an initial term loan with an aggregate principal amount of \$5.0 million. The proceeds of the initial term loan, after payment of lender fees and expenses, were approximately \$4.8 million. The net proceeds are being used for general corporate purposes, including research and product development, such as funding pre-clinical studies and clinical trials and otherwise moving product candidates towards commercialization, or the possible acquisition or licensing of new product candidates or technology which could result in other product candidates. See “Note 6 — Notes Payable” to the consolidated financial statements for additional information regarding the loan agreement.

On May 4, 2011, we closed an underwritten public offering of 11,500,000 shares of our common stock at a price to the public of \$4.00 per share, resulting in net cash proceeds of approximately \$43.1 million.

In July and August of 2011, warrants with respect to 402,101 underlying shares of our common stock were exercised, resulting in gross cash proceeds of approximately \$1.9 million.

On October 4, 2011, we sold an aggregate of 639,071 shares of our common stock pursuant to our committed equity line financing facility, at a per share purchase price of approximately \$6.43 resulting in net cash 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 our common stock on The NASDAQ Global Market during a 10-day pricing period, net a discount of 5% per share.

On November 10, 2011, we sold an aggregate of 805,508 shares of our common stock pursuant to our committed equity line financing facility, at a per share purchase price of approximately \$6.21 resulting in net cash proceeds of \$4.9 million. The per share purchase price was established under the financing facility by reference to the volume weighted average prices of our common stock on The NASDAQ Global Market during a 10-day pricing period, net of a discount of 5% per share.

### ***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 and earnings recognition.

Net cash used in operating activities totaled \$21.0 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 the greater activity in the development of PX-866 and ONT-10, which was partially offset by a decrease in general and administrative expenses.

Net cash used in operating activities totaled \$17.7 million in 2010, compared to \$9.1 million in 2009. The increase in net cash used in operating activities compared to 2009 was primarily due to an increase in research and development and general and administrative expenses.

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

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.

We had cash outflows of \$9.4 million from investing activities during the year ended December 31, 2010, a decrease of \$6.2 million from the \$15.6 million outflow during the year ended December 31, 2009. This change was attributable principally to net purchases of short-term investments of \$9.1 million in 2010 compared to net purchases in the prior year of \$14.2 million and lower expenditures on capital assets of \$1.1 million.

### *Cash Flows from Financing Activities*

Cash provided by financing activities during 2011 was \$58.7 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 General Electric Capital Corporation, and approximately \$1.9 million received from warrant exercises. This was partially offset by \$0.2 million cash paid in connection with the vesting of RSUs and 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.

During the year ended December 31, 2009, we generated \$24.6 million of net cash from financings completed in May and August 2009, each of 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, debt financing, the provision of goods and services, and acquisition of technology access rights, among others. The following table presents contractual obligations arising from these arrangements as of December 31, 2011:

	Total	Payments Due by Period			
		Less than 1 Year	1 – 3 Years	4 – 5 Years	After 5 Years
			(In thousands)		
Operating leases.....	\$ 4,194	\$ 577	\$ 1,186	\$ 1,209	\$ 1,222
Notes payable .....	4,924	1,818	3,106	—	—
Interest commitment on notes payable.....	720	434	286	—	—
Total.....	<u>\$ 9,838</u>	<u>\$ 2,829</u>	<u>\$ 4,578</u>	<u>\$ 1,209</u>	<u>\$ 1,222</u>

In May 2008, we entered into a sublease for an office and laboratory facility in Seattle, Washington totaling approximately 17,000 square feet where we have consolidated our operations. The sublease expired on December 17, 2011. The sublease provided for a base monthly rent of \$33,324 increasing to \$36,354. In May 2008, we also entered into a lease directly with the landlord of such facility which has a seven year term beginning at the expiration of the sublease. 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 September 2015 for certain office equipment.

In connection with the acquisition of ProlX, we assumed two loan agreements under which approximately \$199,000 was outstanding at December 31, 2010. We are required to repay such loans if we commercialize or sell the product that was the subject of such agreements. In February 2011, we provided notice to the counterparty to such agreements that we do not intend to commercialize such product. As a result, the agreements were terminated in March 2011 and we do not expect to be required to repay the loans.

In connection with the acquisition of ProlX, we may become obligated to issue additional shares of our common stock to the former stockholders of ProlX 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 ProlX product. We may 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 ProlX 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, 2011, 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, FASB issued new guidance on testing goodwill for impairment. The new guidance simplifies how an entity tests goodwill for impairment. It allows an entity 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 new guidance will be effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted. We have not adopted this standard or determined the impact of this standard on our results of operations, cash flows and financial position.

In June 2011, FASB and the International Accounting Standards Board, or IASB, updated the guidance on presentation of items within other comprehensive income. In this update, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. For both options, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. This update eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders'

equity. This update does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments in this update should be applied retrospectively. For public entities, the amendments are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We have not adopted this standard; however, the adoption of this standard is only expected to impact the presentation of our financial statements, and not our results of operations or financial position.

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 to be applied prospectively. For public entities, the amendments are effective during interim and annual periods beginning after December 15, 2011. Early application by public entities is not permitted. The adoption of this standard is only expected to impact the presentation of our financial statements, and not our results of operations or financial position.

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

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

As of December 31, 2011 and 2010, approximately \$74,420 and \$68,809 respectively, of our cash and cash equivalents were denominated in Canadian dollars. As a result, 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 \$66.4 million and \$28.9 million as of December 31, 2011 and 2010, 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 100 basis points decline in interest rates, occurring January 1, 2011 and sustained throughout the period ended December 31, 2011, would have resulted in a decline in investment income of approximately \$0.5 million 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. Based on this evaluation, our chief executive officer and chief financial officer have concluded that, as of the end of the period covered by this report, 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 (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

### **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, 2011.

Based on our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2011. The effectiveness of our internal control over financial reporting as of December 31, 2011 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report thereto, appearing in Part II Item 8 in this Annual Report on Form 10-K.

### **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**

There have been no changes in our internal control over financial reporting during 2011 that have materially affected, or are reasonably likely to materially affect, 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, 2011, 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, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board

(United States), the 2011 consolidated financial statements of Oncothyreon Inc. and our report dated March 9, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington  
March 9, 2012

**ITEM 9B. Other Information**

None.

## PART III

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

#### Executive Officers and Key Employees

The names, ages as of March 9, 2012 and positions of each of our executive officers and key employees in 2011 are set forth below.

Name	Age	Position
<i>Executive Officers</i>		
ROBERT KIRKMAN, M.D. ....	63	President, Chief Executive Officer and Director
JULIA M. EASTLAND .....	47	Chief Financial Officer, Secretary and Vice President, Corporate Development
GARY CHRISTIANSON.....	57	Chief Operating Officer
DIANA HAUSMAN, M.D.....	48	Chief Medical Officer and Vice President, Clinical Development
<i>Key Employees</i>		
SCOTT PETERSON, Ph.D. ....	50	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. 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 9, 2012:

### ***Directors Continuing in Office Until the 2012 Annual Meeting of Stockholders***

*Christopher Henney*, Ph.D., age 71, 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 66, 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.

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

*Richard Jackson*, Ph.D., age 72, 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 63, 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 53, 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. Mr. Spiegelman is 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 the chief financial officer of Rapidscan Pharma Solutions, Inc., a start-up company that has licensed the rights 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, Cyclacel Pharmaceuticals, Inc., a development-stage biopharmaceuticals company, Omeros Corporation, a clinical-stage biopharmaceutical company, Anthera Pharmaceuticals, Inc., a development-stage biopharmaceutical company, and several private biopharmaceutical companies. 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 53, 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 previously served as a director of Array BioPharma Inc., a biopharmaceutical company, and Aerovance, Inc., a privately-held biopharmaceutical company, and was a director of 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.

### **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 2011, our directors, executive officers, and ten percent stockholders complied with all Section 16(a) filing requirements applicable to them.

## **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 2011 annual meeting of Oncothyreon stockholders filed with the SEC on April 26, 2011.

## **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. 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). For 2011, our named executive officers include our executive officers and Dr. Henney, who assumed

Dr. Kirkman's responsibilities and acted as our principal executive officer from September 12, 2011 through December 1, 2011. For purposes of this compensation discussion and analysis, references to our chief executive officer will be a reference to Dr. Kirkman, unless otherwise specified.

### *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 2011, 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 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.

### *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. Robert Kirkman, our chief executive officer, was on medical leave from September 12, 2011 to December 1, 2011. During this period, the chairman of our board of directors, Dr. Henney, assumed Dr. Kirkman’s responsibilities. The board of directors determined that during such period the directors other than Drs. Kirkman and Henney would take any action that would otherwise have been in the purview of the compensation committee.

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 2011 compensation plan but did rely on the survey data described below.

### ***Competitive Market Review for 2011***

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 2011, we benchmarked our compensation levels using U.S. professional salary surveys. These include:

- Radford Global Life Sciences Salary Survey 2011; and
- WorldatWork Salary Survey 2011

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 2011***

In analyzing our executive compensation program for 2011, 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 2011, our peer group consisted of:

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

### *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 (other than Dr. Henney) 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. For service as a non-employee director, Dr. Henney receives cash fees as set forth in the section captioned "— Fiscal Year 2011 Director Compensation."

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 and to \$398,000 for 2011. On January 4, 2012, the compensation committee increased Dr. Kirkman's base salary to \$410,000 for 2012.

For a discussion of the base salaries of our other executive officers, see "— Employment Agreements and Offer Letters" included elsewhere in this Annual Report on Form 10-K.

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

We pay performance-based bonuses to our named executive officers (other than Dr. Henney) 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. Dr. Henney does not receive any variable cash compensation for his services as a director.

Under the performance review policy, our named executive officers (other than Dr. Henney) 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 (other than Dr. Henney), 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 (other than Dr. Henney) 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 (other than Dr. Henney), 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. Reflective of the decreasing level of influence within our company as a whole, with respect to our director-level and senior director-level employees, at least 60% of the performance objectives must be linked to corporate objectives and with respect to non-executive management and senior non-executive management employees, at least 40% of the performance objectives must be linked to corporate objectives. In each case the remaining performance objectives will be linked to personalized individual performance goals based on the nature of the individual's role within our company. We designed the performance review policy in this manner based on our belief that more senior personnel are in a greater position to influence the achievement of corporate objectives, and therefore, a greater number of their performance goals should be tied to corporate rather than personalized individual 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, while the chief executive officer bears such responsibility for other employees. 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 will typically pay bonuses to employees shortly after the end of each year and 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 vice president, clinical development, 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 (other than Dr. Henney) for 2011 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>Regulatory (6)</b>	<b>Business Development (7)</b>
Robert Kirkman.....	30%	25%	10%	10%	5%	5%	15%

Named Executive Officer	Cash Position (1)	Market Capitalization /Investor Perception (2)	Clinical Assessment (3)	Pre-Clinical Assessment (4)	Technical Operations (5)	Regulatory (6)	Business Development (7)
Julie Eastland .....	30	25	10	10	5	5	15
Gary Christianson	5	5	10	10	50	15	5
Diana Hausman	5	5	50	10	5	15	10
Scott Peterson.....	5	5	10	50	5	15	10

- (1) As of December 31, 2011, have sufficient cash and short-term investments to fund our operations at least through December 31, 2012, as determined in the discretion of our board of directors.
- (2) Improved investor perception and increased market capitalization.
- (3) Timely completion of two Phase 1/2 trials in PX-866 and timely enrollment of patients in Phase 1 study in ONT-10.
- (4) Timely completion of evaluations of PX-866, ONT-10 and other pre-clinical drug candidates.
- (5) Timely completion of supply, formulation and manufacturing goals.
- (6) Timely filing of IND applications for ONT-10 and completion of pre-IND application meeting for other pre-clinical drug candidates.
- (7) In-license or acquisition of a drug development candidate.

The target and actual bonus amounts for 2011 for our named executive officers (other than Dr. Henney) were as follows, based on achievement against the corporate performance goals (as discussed above):

Named Executive Officer	Base Salary (\$)	Annual Target as Percentage of Base Salary	Target Bonus (\$)	Target Goals Achieved	2011 Incentive Bonus Actually Paid (\$)
Robert Kirkman .....	\$ 398,000	50%	\$ 199,000	96.5%(1)	\$ 192,035
Julia Eastland.....	252,500	30	75,750	96.5(2)	73,098(2)
Gary Christianson .....	283,250	35	99,137	87.5(3)	86,745
Diana Hausman.....	307,750	30	92,325	86.5(4)	79,861
Scott Peterson .....	200,000	30	60,000	96.5(5)	57,900

- (1) Dr. Kirkman's achievement level of 96.5% was based on achievement of the goals involving cash position, market capitalization and investor perception, pre-clinical assessment and business development, and partial achievement of the goals involving clinical assessment and technical operations.
- (2) Ms. Eastland's achievement level of 96.5% was based on achievement of the goals involving cash position, market capitalization, investor perception, pre-clinical assessment and business development, and partial achievement of the goals involving clinical assessment and technical operations.
- (3) Mr. Christianson's achievement level of 87.5% was based on achievement of the goals involving cash position, market capitalization and investor perception, pre-clinical assessment and business development, and partial achievement of the goals involving clinical assessment and technical operations.
- (4) Dr. Hausman's achievement level of 86.5% was based on achievement of the goals involving cash position, market capitalization and investor perception, pre-clinical assessment and business development, and partial achievement of the goals involving clinical assessment and technical operations.
- (5) Dr. Peterson's achievement level of 96.5% was based on achievement of the goals involving cash position, market capitalization and investor perception, pre-clinical assessment and business development, and partial achievement of the goals involving clinical assessment and technical operations.

In January 2012, the compensation committee approved target percentages for 2012. Dr. Kirkman, Ms. Eastland, Mr. Christianson, Dr. Hausman and Dr. Peterson are eligible to receive in 2012 incentive bonuses under our performance review policy of up to 50%, 30%, 35%, 30%, 30%, respectively, of their base salary. The 2012 performance goals for our executive officers are related to various corporate objectives, including objectives related to our financial condition, stock price performance, 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 (other than Dr. Henney) 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. Dr. Henney, as a non-employee director, receives equity awards in the form of restricted share units under our restricted share unit

The size and terms of any initial option grants to new employees, including named executive officers (other than Dr. Henney), 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 (other than Dr. Henney), our board of directors relied in part on survey data and peer group comparisons. In accordance with the offer letter of August 29, 2006, Dr. Kirkman, our chief executive officer, was granted an option to purchase 450,000 shares of our common stock at a price of Cdn.\$7.38 per share. On May 3, 2007, Dr. Kirkman received an option to purchase 137,537 shares of our common stock at an exercise price per share of Cdn.\$8.04, in connection with the terms of his offer letter, under which he was eligible to receive an additional option award to purchase a number of shares equal to 3% of any shares issued during his first year of employment with us. Such grant has vested, or will vest, in four equal annual installments of 34,384 shares on May 3, 2008, 2009, 2010, and 2011. Consistent with the provisions of our share option plan as in effect at the time of grant, the option was priced at the closing price of our shares of common stock on the Toronto Stock Exchange on the day immediately prior to the date of board approval. The exercise prices of all outstanding options granted to Dr. Kirkman prior to April 2008 were based on the Toronto Stock Exchange trading price and were priced in Canadian dollars. Beginning in April 2008, the exercise price of option grants were based on The NASDAQ Global Market trading price and were priced in U.S. dollars. On June 4, 2008, Dr. Kirkman received an additional option to purchase 45,000 shares of our common stock at an exercise price per share of \$3.43. This grant has vested, or will vest, in four equal annual installments of 11,250 shares on June 4, 2009, 2010, 2011 and 2012. On March 11, 2009, Dr. Kirkman also received an additional option to purchase 100,000 shares of our common stock at an exercise price per share of \$1.10. This grant has vested, or will vest, in four equal annual installments of 25,000 shares on March 11, 2010, 2011, 2012 and 2013. On December 3, 2009, Dr. Kirkman received an additional option to purchase 200,000 shares of our common stock at an exercise price per share of \$4.71. This grant has vested, or will vest, in four equal annual installments of 50,000 shares on December 3, 2010, 2011, 2012 and 2013. Also, on December 1, 2010, Dr. Kirkman received an additional option to purchase 100,000 shares of our common stock at an exercise price per share of \$3.32. This grant will vest as to 25,000 shares on December 1, 2011, with the balance vesting in monthly increments for 36 months following December 1, 2011, such that the option will be fully exercisable on December 1, 2014. On December 1, 2011, Dr. Kirkman received an additional option to purchase 100,000 shares of our common stock at an exercise price per share of \$6.92.

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 and December 2011, 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, or employee, 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.

As noted above, consistent with the terms of the share option plan and subject to the policy against pricing options during regularly scheduled closed quarterly trading windows, we have historically priced option grants based on the closing sales price of our shares of common stock trading on the Toronto Stock Exchange. On April 3, 2008 our board of directors amended our share option plan to provide that each option 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.

During 2011, we granted, in the aggregate, the following options to our executive officers as follows:

Named Executive Officer	Options (#)
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).

Dr. Henney receives equity awards in the form of restricted share units as set forth in the section captioned “— Fiscal Year 2011 Director Compensation.”

### ***Benefits***

We provide the following benefits to our named executive officers (other than Dr. Henney), 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 (other than Dr. Henney) 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, 2011, 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 2011, Richard Jackson, Christopher Henney and W. Vickery Stoughton served on our compensation committee. During 2011, 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. Robert Kirkman, our chief executive officer, was on medical leave from September 12, 2011 to December 1, 2011. During this period, the chairman of our board of directors, Dr. Henney, assumed Dr. Kirkman’s responsibilities. The board of directors determined that during such period the directors other than Drs. Kirkman and Henney would take any action that would otherwise have been in the purview of the compensation committee. 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 — 2011, 2010, and 2009

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 2009, 2010 and 2011. We refer to these officers in this Annual Report on Form 10-K as the “named executive officers.” Dr. Kirkman, our chief executive officer, was on medical leave from September 12, 2011 to December 1, 2011. During this period, the chairman of our board of directors, Dr. Henney, assumed Dr. Kirkman’s responsibilities and acted as our principal executive officer. Dr. Henney has never been appointed as an officer of our company and we have never had an employment relationship with him. The compensation that Dr. Henney has received from us is further described in the section captioned “— Fiscal Year 2011 Director Compensation.”

Name and Principal Position	Year	Salary (\$)	Stock Awards (\$)	Option Awards \$(1)	Non-Equity Incentive Plan Compensation \$(2)	All Other Compensation \$(3)	Total (\$)
Robert Kirkman(4).....	2011	\$ 398,000	\$ —	\$ 484,000	\$ 192,035	\$ 11,350	\$ 1,085,385
President, Chief Executive Officer and Director	2010	386,250	—	246,000	135,188	11,923	779,361
	2009	375,000	—	796,412	131,250	11,586	1,314,248
Christopher Henney(5).....	2011	—	203,000	—	—	—	203,000
Acting principal executive officer; Chairman of the Board of Directors	2010	—	30,000	—	—	—	30,000
	2009	—	56,513	—	—	—	56,513
Julia Eastland(6).....	2011	252,500	—	242,000	73,098	6,517	574,115
Chief Financial Officer, Secretary and Vice President, Corporate Development	2010	79,647	—	220,600	25,000	106	325,353
Gary Christianson(7).....	2011	283,250	—	242,000	86,745	8,703	620,698
Chief Operating Officer	2010	275,000	—	123,000	74,883	8,586	481,469
	2009	250,000	—	380,868	70,000	7,836	708,704
Diana Hausman(8).....	2011	307,750	—	242,000	79,861	9,438	639,049
Vice President, Clinical Development	2010	298,700	—	123,000	67,476	9,297	498,473
	2009	96,667	—	289,222	29,000	3,012	417,501
Scott Peterson(9).....	2011	200,000	—	242,000	57,900	6,205	506,105
Vice President, Research and Development	2010	180,250	—	123,000	37,312	5,743	346,305
	2009	72,917	—	287,250	18,229	2,109	380,505

- (1) These amounts represent the aggregate grant date fair value of option awards for fiscal years 2009, 2010 and 2011. These amounts do not represent the actual amounts paid to or realized by the named executive officer for these awards during fiscal years 2009, 2010 or 2011. 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 — Stock-Based Compensation” and “Note 8 — Stock-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 2009, 2010 and 2011, 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 each of 2009 and 2010 and \$205 for 2011.
- (5) Dr. Henney has never been appointed as an officer of our company and we have never had an employment relationship with him. He is included in this table as a result of his assuming Dr. Kirkman’s responsibilities during Dr. Kirkman’s medical leave. Amounts represent the aggregate grant date fair value of RSUs granted in 2011, 2010 and 2009. As of December 31, 2011, Dr. Henney held 32,965 RSUs. 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. The fair value of stock awards for 2011 includes 25,000 RSUs granted to Dr. Henney on December 1, 2011 in recognition of Dr. Henney taking on additional responsibilities during our chief executive officer’s medical leave of absence. Such RSUs were fully vested and the closing price of our common stock on The NASDAQ Global Market on December 1, 2011 was \$6.92. The compensation that Dr. Henney has received from us is further described in the section captioned “— Fiscal Year 2011 Director Compensation.”

- (6) 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 and \$205 for 2011.
- (7) Amounts listed in “All Other Compensation” include life insurance premiums of \$336 for each of 2009 and 2010 and \$205 for 2011.
- (8) Dr. Hausman’s employment with us began on September 1, 2009. Amounts listed in “All Other Compensation” include life insurance premiums of \$112, \$336 and \$205 for 2009, 2010 and 2011, respectively.
- (9) Dr. Peterson’s employment with us began on August 1, 2009. Amounts listed in “All Other Compensation” include life insurance premiums of \$140, \$336 and \$205 for 2009, 2010 and 2011, respectively.

### Grants of Plan-Based Awards

The following table sets forth each grant of an award made to a named executive officer (other than Dr. Henney) during 2011 under any of our incentive plans or equity plans.

Name	Grant Date (1)	Estimated Future Payouts Under Non- Equity Incentive Plan Awards Target \$(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 1, 2011	\$ 199,000	100,000	\$ 6.92	\$ 484,000
Julia Eastland(6) .....	December 1, 2011	75,750	50,000	6.92	242,000
Gary Christianson(7) .....	December 1, 2011	99,138	50,000	6.92	242,000
Diana Hausman(8) .....	December 1, 2011	92,325	50,000	6.92	242,000
Scott Peterson(9).....	December 1, 2011	60,000	50,000	6.92	242,000

- (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.
- (2) Performance bonuses were earned in 2011. The actual amounts paid to each of the named executive officers for 2011 are set forth in the individual footnotes below.
- (3) There was no set “Threshold” or “Maximum” performance bonus amounts established with respect to our 2011 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 2011. These amounts do not represent the actual amounts paid to or realized by the named executive officer for these awards during fiscal year 2011. 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 — Stock-Based Compensation” and “Note 8 — Stock-Based Compensation” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.
- (5) On January 4, 2012, the compensation committee approved a performance bonus of \$192,035 under the performance review policy.
- (6) On January 4, 2012, the compensation committee approved a performance bonus of \$73,098 under the performance review policy.
- (7) On January 4, 2012, the compensation committee approved a performance bonus of \$86,745 under the performance review policy.
- (8) On January 4, 2012, the compensation committee approved a performance bonus of \$79,861 under the performance review policy.
- (9) On January 4, 2012, the compensation committee approved a performance bonus of \$57,900 under the performance review policy.

The following table sets forth each grant of an award made to Dr. Henney during 2011 under any of our incentive plans or equity plans.

Name	Grant Date	All Other Stock Awards:	
		Number of Shares of Stock or Units: (#)	Grant Date Fair Value of Stock Awards (\$)(1)
Christopher S. Henney .....	June 9, 2011	4,538	\$ 30,000
	December 1, 2011	25,000(2)	173,000

- (1) Dollar amounts represent the aggregate grant date fair value of RSUs granted in 2011, 2010 and 2009. Each RSU may be converted into one share of our common stock at the end of the grant period, which is two years for each of the RSUs granted on or after June 12, 2009.
- (2) This award was granted to Dr. Henney on December 1, 2011 in recognition of Dr. Henney taking on additional responsibilities during our chief executive officer's medical leave of absence. The compensation that Dr. Henney has received from us is further described in the section captioned "— Fiscal Year 2011 Director Compensation."

### Outstanding Equity Awards at 2011 Fiscal Year-End

The following table sets forth the equity awards outstanding at December 31, 2011 for each of the named executive officers (other than Dr. Henney's RSU awards). 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
	33,750	11,250(4)	\$ 3.43	June 4, 2016
	50,000	50,000(5)	\$ 1.10	March 11, 2017
	100,000	100,000(6)	\$ 4.71	December 3, 2017
	25,000	75,000(7)	\$ 3.32	December 1, 2018
Christopher Henney .....	—	100,000(12)	\$ 6.92	December 1, 2019
	2,666	—(13)	CDn. \$ 15.00	March 11, 2013
	416	—(14)	CDn. \$ 15.00	May 4, 2013
	520	—(15)	CDn. \$ 12.00	July 29, 2013
Julia Eastland .....	50,000	—(16)	CDn. \$ 7.56	September 7, 2014
	12,500	27,500(8)	\$ 3.31	November 10, 2018
	12,500	37,500(7)	\$ 3.32	December 1, 2018
Gary Christianson .....	—	50,000(12)	\$ 6.92	December 1, 2019
	16,666	—(9)	CDn. \$ 6.72	June 29, 2015
	11,250	3,750(4)	\$ 3.43	June 4, 2016
	15,000	15,000(5)	\$ 1.10	March 11, 2017
	50,000	50,000(6)	\$ 4.71	December 3, 2017
	12,500	37,500(7)	\$ 3.32	December 1, 2018
Diana Hausman .....	—	50,000(12)	\$ 6.92	December 1, 2019
	15,000	15,000(10)	\$ 4.96	October 1, 2017
	25,000	25,000(6)	\$ 4.71	December 3, 2017
	12,500	37,500(7)	\$ 3.32	December 1, 2018
Scott Peterson .....	—	50,000(12)	\$ 6.92	December 1, 2019
	12,500	12,500(11)	\$ 6.56	August 1, 2017
	25,000	25,000(6)	\$ 4.71	December 3, 2017
	12,500	37,500(7)	\$ 3.32	December 1, 2018
	—	50,000(12)	\$ 6.92	December 1, 2019

- (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 vests on August 29, 2009, and vests at a rate of 1/3 annually on the anniversary of grant.
- (3) This stock option fully vests on May 3, 2011, and vests at a rate of 1/4 annually on the anniversary of grant.
- (4) This stock option fully vests on June 4, 2012, and vests at a rate of 1/4 annually on the anniversary of grant.
- (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 vests on June 29, 2011, and vests at a rate of 1/4 annually on the anniversary of grant.
- (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 vested on March 11, 2009.
- (14) This stock option fully vested on November 4, 2005.
- (15) This stock option fully vested on January 29, 2006.
- (16) This stock option fully vested on September 7, 2010.

The following table sets forth the RSU awards outstanding at December 31, 2011 for Dr. Henney.

Name	Stock Awards			
	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (#)
Christopher Henney .....	32,965	\$ 249,875	—	—

### Option Exercises and Stock Vested

None of our named executive officers exercised stock options during 2011. We have not granted any stock awards to date.

### 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% per cent 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 to \$386,250 for 2010 and to \$398,000 for 2011. On January 4, 2012, the compensation committee increased Dr. Kirkman’s salary to \$410,000 for 2012. 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 4, 2012, Dr. Kirkman received a performance bonus of \$192,035. 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. On January 4, 2012, the compensation committee increased Ms. Eastland’s salary to \$260,000. 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 4, 2012, Ms. Eastland received a performance bonus of \$73,098.

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 \$250,000 for 2009, \$275,000 for 2010 and \$283,250 for 2011, respectively. In January 2012, Mr. Christianson's base salary was increased to \$292,000 for 2012. 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 4, 2012, Mr. Christianson received a performance bonus of \$86,745. 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 and on January 4, 2012, Dr. Hausman's base salary was increased to \$335,000. 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 4, 2012, Dr. Hausman received a performance bonus of \$79,861.

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 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 and on January 4, 2012, Mr. Peterson's base salary was increased to \$220,000 for 2012. 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 4, 2012, Dr. Peterson received a performance bonus of \$57,900.

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, 2011 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 (other than Dr. Henney) are entitled to, please see "— Employment Agreements and Offer Letters" included elsewhere in this Annual Report on Form 10-K.

Name	Change of Control			Termination Other Than for Cause <sup>(3)</sup>		
	Equity Acceleration (1)	Salary (2)	Insurance Benefits	Equity Acceleration (4)	Salary (5)	Insurance Benefits
Robert L. Kirkman.....	\$ 1,043,187	\$ 1,194,000	\$ —	\$ —	\$ 597,000	\$ —

- (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, 2011, assuming a stock price of \$7.58 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 30, 2011.
- (2) The amount shown in this column is a lump sum payment equal to two times Dr. Kirkman's base salary for 2011 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 2011 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.

***Christopher Henney***

Name	Change of Control			Termination Other Than for Cause		
	Equity Acceleration (1)	Salary	Insurance Benefits	Equity Acceleration	Salary	Insurance Benefits
Christopher Henney .....	\$ 249,875(2)	\$ —	\$ —	\$ —	\$ —	\$ —

- (1) Pursuant to the terms of our RSU plan, in the event of the occurrence of a change of control, all unvested RSUs shall immediately vest and the holder of the RSUs shall be entitled to receive an amount in full settlement of a RSU covered by a Grant, which amount shall be either (a) one share for each RSU, or (b) upon the election by the RSU holder, a cash payment, provided that the RSU holder is continuously a member of our board of directors from the date of the RSU grant to the date of the change of control. If any shares of our stock are sold as part of the transaction constituting the change of control, the amount of the cash payment described above would be equal to the weighted average of the prices paid for the shares by the acquiror, provided that if any portion of the consideration paid for such shares by the acquiror is paid in property other than cash, our board of directors shall determine that fair market value of such property as of the date of the change of control for purposes of determining the amount of the cash payment. If no shares are sold as part of the transaction constituting the change of control, the amount of the cash payment shall equal the arithmetic average of the closing prices for the shares on the Nasdaq Global Market, the Nasdaq Global Select Market or the Nasdaq Capital Market, as applicable, for the five trading days immediately preceding the date of the change of control.
- (2) Based on closing stock price on December 30, 2011 of \$7.58 and acceleration of 989 shares under RSU granted on December 10, 2007, 19,352 shares under RSU granted on March 11, 2009, 8,086 shares under RSU granted on June 3, 2010 and 4,538 shares under RSU granted on June 9, 2011.

***Julia Eastland***

Name	Change of Control			Termination Other Than for Cause(3)		
	Equity Acceleration (1)	Salary (2)	Insurance Benefits	Equity Acceleration (4)	Salary (5)	Insurance Benefits
Julia Eastland.....	\$ 310,175	\$ 328,250	\$ —	\$ —	\$ 246,188	\$ —

- (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, 2011, assuming a stock price of \$7.58 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 30, 2011.
- (2) The amount shown in this column is a lump sum payment equal to Ms. Eastland's base salary for 2011 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 2011 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 .....	\$ 449,012	\$ 382,387	\$ —	\$ —	\$ 286,790	\$ 15,511

- (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, 2011, assuming a stock price of \$7.58 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 30, 2011.
- (2) The amount shown in this column is a lump sum payment equal to Mr. Christianson's base salary for 2011 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 2011 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 .....	\$ 303,800	\$ 400,075	\$ —	\$ —	\$ 200,037	\$ —

- (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, 2011, assuming a stock price of \$7.58 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 30, 2011.
- (2) The amount shown in this column is a lump sum payment equal to Dr. Hausman's base salary for 2011 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 2011 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 .....	\$ 277,250	\$ 260,000	\$ —

- (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, 2011, assuming a stock price of \$7.58 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 30, 2011.
- (2) The amount shown in this column is a lump sum payment equal to Dr. Peterson's base salary for 2011 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

### **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 4,361,310 shares of our common stock for issuance pursuant to our share option plan as of December 31, 2011. As of December 31, 2011, options to purchase 2,441,725 shares of our common stock were outstanding and 1,919,585 shares of our common stock were available for future grant under 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 January 1 to December 31, 2011, options to purchase 426,250 shares of common stock were granted under our share option plan at a weighted average exercise price of \$6.78 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, 2011, grants covering 143,495 shares of our common stock were outstanding, 200,922 shares of our common stock were available for future grant under our restricted share unit plan and 122,249 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 and on June 9, 2011 each board member was awarded 4,538 RSUs for fiscal year 2011. 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 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 2011 Director Compensation

The following table sets forth compensation information for our non-employee directors for the year ended December 31, 2011. The table excludes Dr. Kirkman who did not receive any compensation from us in his role as director in the year ended December 31, 2011. All compensation numbers are expressed in U.S. dollars.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (1)(2)(3)	Total (\$)
Christopher Henney(4) .....	\$ 105,000	\$ 203,000	\$ 308,000
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 2011.
- (2) As of December 31, 2011, 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, 32,965 RSUs); Dr. Jackson (4,016 options, 32,965 RSUs); Mr. Stoughton (8,700 options, 32,965 RSUs); Mr. Spiegelman (zero options, 31,976 RSUs); Dr. Williams (zero options, 12,624 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.
- (4) Includes 25,000 RSUs granted to Dr. Henney on December 1, 2011 in recognition of Dr. Henney taking on additional responsibilities during our chief executive officer's medical leave of absence. Such RSUs were fully vested and the closing price of our common stock on The NASDAQ Global Market on December 1, 2011 was \$6.92.

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

#### Equity Compensation Plan Information as of December 31, 2011

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

Plan Category	(A) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(B) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	(C) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A))(1)
Equity compensation plans approved by security holders:			
Share option plan (\$Cdn.)(2).....	769,683	\$ 8.07	—
Share option plan (\$U.S.)(2).....	1,672,042	\$ 4.50	1,919,585
RSU plan.....	143,495	N.A.	200,922
Equity compensation plans not approved by security holders.....	—	N.A.	—
Total.....	2,585,220	N.A.	2,120,507

- (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.

### 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 29, 2012 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 29, 2012.

Name and Address of Beneficial Owner (1)	Common Stock Beneficially Owned	
	Number of Shares(2)	Percent of Class(3)
5% Stockholders:		
Ayer Capital Management, LP(4).....	4,644,062	10.65%
Viking Global Investors LP(5).....	3,112,250	7.14
Steven T. Newby(6).....	2,550,528	5.85
Antipodean Domestic Partners LP (7).....	2,302,000	5.28
Directors and Executive Officers:		
Christopher Henney(8).....	146,524	*
Richard Jackson(9).....	19,855	*
W. Vickery Stoughton(10).....	23,705	*
Daniel Spiegelman(11).....	6,715	*
Douglas Williams(12).....	4,639	*
Robert Kirkman(13).....	837,953	1.89
Gary Christianson(14).....	122,727	*

<u>Name and Address of Beneficial Owner (1)</u>	<u>Common Stock Beneficially Owned</u>	
	<u>Number of Shares(2)</u>	<u>Percent of Class(3)</u>
Julia Eastland(15).....	40,584	*
Diana Hausman(16).....	56,667	*
Scott Peterson(17).....	64,425	*
All directors and executive officers as a group (10 persons)(18).....	1,323,794	2.96

\* 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 29, 2012 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 43,613,107 shares of common stock issued and outstanding as of February 29, 2012.
- (4) Based on information of beneficial ownership as of April 29, 2011, included in a Schedule 13G/A filed with the SEC on May 10, 2011. The address of the Ayer Capital Management, LP is 230 California St., Suite 600, San Francisco, CA 94111.
- (5) Based on information of beneficial ownership as of December 31, 2011, included in a Schedule 13G filed with the SEC on February 14, 2012. Includes shares of common stock beneficially owned by Viking Global Investors LP and various affiliated entities and individuals. The address of Viking Global Investors LP is 55 Railroad Avenue, Greenwich, CT 06830.
- (6) Based on information of beneficial ownership as of January 30, 2012, included in a Schedule 13G/A filed with the SEC on February 3, 2012. The address of Steven T. Newby is 12716 Split Creek Court, North Potomac, MD 20878.
- (7) Based on information of beneficial ownership as of July 21, 2011, included in a Schedule 13G filed with the SEC on August 1, 2011. The address of Antipodean Domestic Partners, LP is 499 Park Avenue, New York, NY 10022.
- (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 29, 2012. 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 29, 2012.
- (9) Includes 3,183 shares of common stock that Dr. Jackson has the right to acquire under outstanding options exercisable within 60 days after February 29, 2012. 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 29, 2012.
- (10) Includes 7,867 shares of common stock that Mr. Stoughton has the right to acquire under outstanding options exercisable within 60 days after February 29, 2012. 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 29, 2012.
- (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 29, 2012.
- (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 29, 2012.
- (13) Includes 829,620 shares of common stock that Dr. Kirkman has the right to acquire under outstanding options exercisable within 60 days after February 29, 2012.
- (14) Includes 117,083 shares of common stock that Mr. Christianson has the right to acquire under outstanding options exercisable within 60 days after February 29, 2012.
- (15) Includes 32,500 shares of common stock that Ms. Eastland has the right to acquire under outstanding options exercisable within 60 days after February 29, 2012.
- (16) Includes 56,667 shares of common stock that Dr. Hausman has the right to acquire under outstanding options exercisable within 60 days after February 29, 2012.

- (17) Includes 54,167 shares of common stock that Dr. Peterson has the right to acquire under outstanding options exercisable within 60 days after February 29, 2012.
- (18) Includes 1,154,689 shares of common stock that can be acquired under outstanding options exercisable within 60 days after February 29, 2012.

## **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 2011.

#### *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. One non-executive employee is indebted to us for approximately \$127,000 (excluding accrued and unpaid interest). As of December 31, 2010, an allowance for the remaining

balance on the loan was recorded. During 2011, the Company wrote off the notes receivable balance of \$153,720. For more information, see “Note 4 — Notes Receivable, Employees”.

None of our directors, executive officers, or associates of any of them, is, or, at any time since the beginning of the most recently completed financial year has been, indebted to us or any of our subsidiaries, 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, or pursuant to any stock purchase program or any other program.

### **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**

In November 2010, we transitioned services from Deloitte & Touche LLP, the independent registered public accounting firm previously engaged to audit our consolidated financial statements and engaged Ernst & Young LLP as our registered independent public accounting firm.

#### **Fees Billed to Us by Ernst & Young LLP during 2011**

##### *Audit Fees*

Fees and related expenses for the 2011 audit by Ernst & Young LLP of our annual financial statements, its review of the financial statements included in our 2011 quarterly reports and other services that are provided in connection with statutory and regulatory filings totaled \$363,750, of which \$195,000 was billed to us in 2011. Fees and related expenses for the 2010 integrated audit by Ernst & Young LLP totaled \$257,000.

##### *Audit-Related Fees*

For the years 2011 and 2010, Ernst & Young LLP billed us \$130,904 and zero, respectively, for its services related to financings, acquisitions, consultations on accounting issues, and other audit-related matters.

##### *Tax Fees*

None

### *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			Filed Herewith
		Form	Exhibit No.	Filing Date	
2.1(a)	Agreement and Plan of Reorganization among ProLX 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(1).....				
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	
4.5	Registration Rights Agreement, dated July 6, 2010 between Oncothyreon Inc. and Small Cap Biotech Value, Ltd. ....	8-K	4.1	July 7, 2010	
4.6	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. ....				X
10.2*	Form of Stock Option Agreement under the Amended and Restated Share Option Plan.....				X

Exhibit No.	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit No.	Filing Date	
10.3*	Amended and Restated Restricted Share Unit Plan. ....				X
10.4*	Form of Restricted Share Unit Agreement under the Amended and Restated Restricted Share Unit Plan. ....				X
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	
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	Loan and Security Agreement between Oncothyreon Inc. and General Electric Capital Corporation dated February 8, 2011. ....	8-K	10.1	February 9, 2011	
10.14(a)	Amendment to Loan and Security Agreement between Oncothyreon Inc. and General Electric Capital Corporation dated February 3, 2011. ....				X
10.15	Promissory Note issued by Oncothyreon Inc. to General Electric Capital Corporation dated February 8, 2011. ....	8-K	10.2	February 9, 2011	
10.16	Common Stock Purchase Agreement, dated July 6, 2010 between Oncothyreon Inc. and Small Cap Biotech Value, Ltd. ....	8-K	10.1	July 7, 2010	
10.17	Securities Purchase Agreement, dated September 23, 2010, by and among Oncothyreon Inc. and the signatories thereto. ....	8-K	10.1	September 27, 2010	
10.17(a)	Amendment No. 1 to the Securities Purchase Agreement, dated September 28, 2010. ....	8-K	10.1	September 30, 2010	
10.18†	License Agreement between Biomira Inc. and the Dana-Farber Cancer Institute, Inc., dated November 22, 1996. ....	S-4	10.6	September 12, 2007	
10.19†	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	
10.20	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	
10.21†	License Agreement between the Governors of the	S-4/A	10.14	September 27, 2007	

Exhibit No.	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit No.	Filing Date	
10.22†	University of Alberta and Biomira Inc., dated December 1, 2001.....				
10.23†	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	
10.23(a)	Exclusive License Agreement between the University of Arizona and ProLX Pharmaceuticals Corporation, dated July 29, 2004. ....	S-4	10.18	September 12, 2007	
10.24†	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	
10.25†	Adjuvant License Agreement between Biomira International Inc. and Corixa Corporation, dated October 20, 2004. ....	S-4/A	10.19	September 27, 2007	
10.26†	Adjuvant Supply Agreement between Biomira International Inc. and Corixa Corporation, dated October 20, 2004. ....	S-4/A	10.20	September 27, 2007	
10.26(a)	Exclusive Patent License Agreement between the University of Arizona and ProLX Pharmaceuticals Corporation, dated September 15, 2005.....	S-4	10.21	September 12, 2007	
10.26(b)	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	
10.27†	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	
10.28	Letter Agreement between the University of Arizona and Biomira Inc., dated October 6, 2006.....	S-4	10.28	September 12, 2007	
10.29†	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	
10.30	Amended and Restated License Agreement between Biomira Management, Inc. and Merck KGaA, dated December 18, 2008.....	10-Q	10.1	May 15, 2009	
10.31	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	
21.1	Tax Indemnity Agreement by and between Biomira International Inc. and Merck KGaA dated May 3, 2001....	10-K	10.42	May 6, 2010	
23.1	Subsidiaries of Oncothyreon Inc. ....				X
23.2	Consent of Deloitte & Touche LLP, independent registered public accounting firm. ....				X
24.1	Consent of Ernst & Young LLP, independent registered public accounting firm. ....				X
31.1	Power of Attorney (included on signature page). ....				
31.2	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
32.1	Certification of Julie 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
	Certification of Robert L. Kirkman, M.D., President and				X

Exhibit No.	Exhibit Description	Incorporated by Reference		
		Form	Exhibit No.	Filing Date
	Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(2).....			
32.2	Certification of Julie 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(2). ....			
101.INS	XBRL Instance Document(2).....			
101.SCH	XBRL Taxonomy Extension Schema Document(2).....			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document(2).....			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document(2).....			
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document(2).....			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document(2).....			

(1) Incorporated by reference from Annex A to the Company's free writing prospectus, dated as of May 19, 2009, and filed on May 20, 2009

(2) Furnished herewith.

\* 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 9, 2012.

ONCOTHYREON INC.

By: /s/Robert L. Kirkman  
Robert L. Kirkman  
President, CEO and Director

## 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>
<u>/s/Robert L. Kirkman</u> Robert L. Kirkman	President, Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2012
<u>/s/Julia M. Eastland</u> Julia M. Eastland	Chief Financial Officer, Secretary and Vice President of Corporate Development (Principal Financial and Accounting Officer)	March 9, 2012
<u>/s/Christopher S. Henney</u> Christopher S. Henney	Chairman and Director	March 9, 2012
<u>/s/Richard L. Jackson</u> Richard L. Jackson	Director	March 9, 2012
<u>/s/Daniel K. Spiegelman</u> Daniel K. Spiegelman	Director	March 9, 2012
<u>/s/W. Vickery Stoughton</u> W. Vickery Stoughton	Director	March 9, 2012
<u>/s/Douglas Williams</u> Douglas Williams	Director	March 9, 2012

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS  
ONCOTHYREON INC.**

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**REPORT OF ERNST & YOUNG LLP, 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, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2011. 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, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2011, 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, 2011, 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 9, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP  
Seattle, Washington

March 9, 2012

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

To the Board of Directors and Stockholders of  
Oncothyreon Inc.  
Seattle, Washington

We have audited the accompanying consolidated statements of operations, stockholders' equity and cash flows of Oncothyreon Inc. and subsidiaries (the "Company") for the year ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements 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 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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated results of operations and cash flows of Oncothyreon Inc. and subsidiaries for the year ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP  
Seattle, Washington

**ONCOTHYREON INC.**

**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share and per share amounts)

	As of December 31,	
	2011	2010
<b>ASSETS</b>		
Current:		
Cash and cash equivalents .....	\$ 11,609	\$ 5,514
Short-term investments .....	52,267	23,363
Accounts and other receivables .....	321	131
Government grant receivable .....	—	489
Prepaid and other current assets .....	610	583
	64,807	30,080
Long-term investments .....	2,531	—
Property and equipment, net .....	1,643	1,958
Other assets .....	253	290
Goodwill .....	2,117	2,117
Total assets .....	\$ 71,351	\$ 34,445
<b>LIABILITIES</b>		
Current:		
Accounts payable .....	\$ 459	\$ 624
Accrued liabilities .....	1,287	533
Accrued compensation and related liabilities .....	858	686
Current portion of notes payable .....	1,749	—
Current portion of restricted share unit liability .....	329	—
Current portion of deferred revenue .....	—	8
	4,682	1,861
Notes Payable .....	3,059	199
Non-current portion of deferred revenue .....	—	127
Deferred rent .....	617	388
Restricted share unit liability .....	759	—
Warrant liability .....	28,771	12,983
Class UA preferred stock, 12,500 shares authorized, 12,500 shares issued and outstanding .....	30	30
	37,918	15,588
Commitments and contingencies .....		
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding .....	—	—
Common stock, \$0.0001 par value, 100,000,000 shares authorized, 43,613,107 and 30,088,628 shares issued and outstanding .....	353,851	353,850
Additional paid-in capital .....	74,537	17,328
Accumulated deficit .....	(389,911)	(347,255)
Accumulated other comprehensive loss .....	(5,044)	(5,066)
	33,433	18,857
Total liabilities and stockholders' equity .....	\$ 71,351	\$ 34,445

*See accompanying notes to the consolidated financial statements.*

**ONCOTHYREON INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(In thousands, except share and per share amounts)**

	Years Ended December 31,		
	2011	2010	2009
Revenues			
Licensing revenue from collaborative and license agreements .....	\$ 145	\$ 18	\$ 2,051
Licensing, royalties, and other revenue .....	<u>—</u>	<u>—</u>	<u>27</u>
Total revenues .....	145	18	2,078
Operating Expenses			
Research and development, net .....	17,915	11,601	6,215
General and administrative .....	<u>6,929</u>	<u>7,901</u>	<u>6,724</u>
Total operating expenses .....	<u>24,844</u>	<u>19,502</u>	<u>12,939</u>
Loss from operations .....	(24,699)	(19,484)	(10,861)
Other income (expense)			
Investment and other income (expense), net .....	305	636	(8)
Interest expense .....	(631)	—	—
Change in fair value of warrant liability .....	<u>(17,631)</u>	<u>3,030</u>	<u>(6,150)</u>
Total other income (expense), net .....	(17,957)	3,666	(6,158)
Loss before income taxes .....	(42,656)	(15,818)	(17,019)
Income tax benefit (provision) .....	<u>—</u>	<u>200</u>	<u>(200)</u>
Net loss .....	<u>\$ (42,656)</u>	<u>\$ (15,618)</u>	<u>\$ (17,219)</u>
Loss per share — basic and diluted .....	<u>\$ (1.12)</u>	<u>\$ (0.58)</u>	<u>\$ (0.76)</u>
Shares used to compute basic and diluted loss per share .....	<u>38,197,666</u>	<u>26,888,588</u>	<u>22,739,138</u>

*See accompanying notes to the consolidated financial statements.*

**ONCOTHYREON INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**(In thousands, except share amounts)**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Shareholders' Equity
	Number	Value				
Balance as of December 31, 2008.....	<u>19,492,432</u>	<u>\$ 325,043</u>	<u>\$ 15,094</u>	<u>\$ (314,418)</u>	<u>\$ (5,066)</u>	<u>\$ 20,653</u>
Net loss .....	—	—	—	(17,219)	—	(17,219)
Comprehensive loss .....	—	—	—	—	—	(17,219)
Common stock issued, net of						
offering costs of \$0.4 million .....	6,159,495	20,013	—	—	—	20,013
Warrant exercises .....	91,558	668	—	—	—	668
Warrants expiration .....	37	—	—	—	—	37
Restricted stock units converted .....	9,920	75	(75)	—	—	—
Restricted stock units granted .....	—	—	257	—	—	257
Share-based employee						
compensation expense .....	—	—	1,009	—	—	1,009
Balance as of December 31, 2009.....	<u>25,753,405</u>	<u>345,836</u>	<u>16,285</u>	<u>(331,637)</u>	<u>(5,066)</u>	<u>25,418</u>
Net loss .....	—	—	—	(15,618)	—	(15,618)
Comprehensive loss .....	—	—	—	—	—	(15,618)
Common stock issued, net of						
offering costs of \$1.2 million .....	4,302,791	7,849	—	—	—	7,849
Employee stock purchase plan .....	20,434	58	—	—	—	58
Restricted stock units converted .....	9,498	80	(80)	—	—	—
Restricted stock units granted .....	—	—	150	—	—	150
Share-based employee						
compensation expense .....	—	—	973	—	—	973
Stock option exercise .....	2,500	—	—	—	—	—
Warrants expiration .....	—	27	—	—	—	27
Balance as of December 31, 2010.....	<u>30,088,628</u>	<u>353,850</u>	<u>17,328</u>	<u>(347,255)</u>	<u>(5,066)</u>	<u>18,857</u>
Net Loss	—	—	—	(42,656)	—	(42,656)
Unrealized gain on available-for- sale securities	—	—	—	—	22	22
Comprehensive loss .....	—	—	—	—	—	(42,634)
Common stock issued, net of						
offering costs of \$3.1 million .....	12,944,579	1	52,031	—	—	52,032
Employee stock purchase plan .....	71,969	—	207	—	—	207
Restricted stock units granted .....	—	—	323	—	—	323
Restricted stock units, cash settled						
on conversion .....	—	—	(189)	—	—	(189)
Share-based employee						
compensation expense .....	—	—	1,204	—	—	1,204
Stock option exercise .....	12,708	—	48	—	—	48
Warrants issued .....	—	—	114	—	—	114
Warrants exercise .....	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)
Balance as of December 31, 2011.....	<u>43,613,107</u>	<u>\$ 353,851</u>	<u>\$ 74,537</u>	<u>\$ (389,911)</u>	<u>\$ (5,044)</u>	<u>\$ 33,433</u>

*See accompanying notes to the consolidated financial statements.*

**ONCOTHYREON INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year Ended December 31,		
	2011	2010	2009
Cash flows from operating activities:			
Net loss .....	\$ (42,656)	\$ (15,618)	\$ (17,219)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	457	462	269
Amortization of discount and deferred financing costs on notes payable .....	149	—	—
Share-based equity facility structuring fee .....	—	200	—
Stock-based compensation expense .....	2,342	1,123	1,266
Provision for notes receivable, employees .....	—	154	—
Change in fair value of warrant liability .....	17,631	(3,030)	6,150
Recognition of deferred revenue .....	(145)	(22)	(15)
Derecognition of debt .....	(199)	—	—
Other .....	13	6	7
Changes in assets and liabilities:			
Accounts and other receivables .....	(203)	(58)	1,782
Government grants receivables .....	489	(489)	40
Prepaid and other current assets .....	(31)	(434)	151
Other long term assets .....	161	148	—
Accounts payables .....	(165)	(2)	147
Accrued liabilities .....	754	(120)	(997)
Accrued compensation and related liabilities .....	172	(118)	(803)
Deferred rent .....	229	93	110
Net cash used in operating activities .....	<u>(21,002)</u>	<u>(17,705)</u>	<u>(9,112)</u>
Cash flows from investing activities:			
Purchases of investments .....	(88,118)	(29,331)	(16,127)
Redemption of investments .....	56,705	20,212	1,883
Purchases of property and equipment .....	(142)	(324)	(1,433)
Payments received on notes receivable from employees .....	—	—	34
Net cash used in investing activities .....	<u>(31,555)</u>	<u>(9,443)</u>	<u>(15,643)</u>
Cash flows from financing activities:			
Proceeds from issuance of common stock and warrants, net of issuance costs .....	52,239	13,688	24,563
Proceeds from stock option exercised .....	48	—	—
Proceeds from warrants exercised .....	1,901	—	—
Proceeds from debt financing, net of issuance cost .....	4,804	—	—
Cash settled on conversion of restricted share units .....	(189)	—	—
Principal payment on notes payable .....	(151)	—	—
Net cash provided by financing activities .....	<u>58,652</u>	<u>13,688</u>	<u>24,563</u>
Increase (decrease) in cash and cash equivalents .....	6,095	(13,460)	(192)
Cash and cash equivalents, beginning of year .....	5,514	18,974	19,166
Cash and cash equivalents, end of year .....	<u>\$ 11,609</u>	<u>\$ 5,514</u>	<u>\$ 18,974</u>
Supplemental disclosure of cash flows information:			
Interest paid .....	<u>\$ 437</u>	<u>\$ —</u>	<u>\$ —</u>
Income taxes paid .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 200</u>

*See accompanying notes to the consolidated financial statements.*

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements Years ended December 31, 2011, 2010 and 2009

#### 1. DESCRIPTION OF BUSINESS

Oncothyreon Inc. (the “Company” or “Oncothyreon”) is a clinical-stage biopharmaceutical company incorporated in the State of Delaware on September 7, 2007. Oncothyreon is focused primarily on the development of therapeutic products for the treatment of cancer. Oncothyreon’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. Oncothyreon’s operations are not subject to any seasonality or cyclical 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*

In 2011, the Company reclassified depreciation and amortization expense such that these amounts are no longer presented as a separate line on the statements of operations; instead, these expenses are allocated to research and development, net and general and administrative expenses based on the respective head count. The prior years’ depreciation and amortization expenses were reclassified for consistency with current period presentation. These reclassifications had no effect on reported operating expenses, loss from operations, or net loss.

Depreciation and amortization expense for the years ended December 31, 2011, 2010 and 2009 was \$0.46 million, \$0.46 million and \$0.26 million, respectively. The amounts allocated to research and development, net expenses were \$0.35 million, \$0.36 million and \$0.13 million; and the amounts allocated to general and administrative expenses were \$0.11 million, \$0.10 million and \$0.13 million for the years ended December 31, 2011, 2010 and 2009, respectively.

##### *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, 2011, cash and cash equivalents was comprised of \$4.8 million in cash, \$3.9 million in certificates of deposit and \$2.9 million in money market funds. As of December 31, 2010, cash and cash equivalents was comprised of \$4.3 million in cash and \$1.2 million in certificates of deposit. The carrying value of cash equivalents approximates their fair value.

### *Investments*

Investments are classified as available-for-sale securities and are carried at market value with unrealized temporary holding gains and losses, where applicable, excluded from net loss and reported in other comprehensive loss and also as a net amount in accumulated other comprehensive loss until realized. Available-for-sale securities are written down to fair value through income 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 from purchase date of 12 months. The Company's long-term investments are investment with maturities exceeding 12 months but less than five years. 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.

The amortized cost, unrealized gains or losses and estimated fair value of the Company's cash, cash equivalents and investments for the periods presented are summarized below (in thousands):

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</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>
As of December 31, 2010:				
Cash.....	\$ 1,509	\$ —	\$ —	\$ 1,509
Money market funds.....	4,005	—	—	4,005
Certificates of deposits.....	23,363	—	—	23,363
Total.....	<u>\$ 28,877</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 28,877</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 7 — 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 carried at cost and 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.

#### ***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 accrued 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, 2011, the Company had not applied these provisions to any of our revenue arrangements as the Company had not entered into any new, or materially modified any of its existing, revenue arrangements in 2011.

The Company has 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 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.

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.

*Licensing, royalties, and other revenue.* Licensing, royalties, and other revenue consists of revenue from sales of compounds and processes from patented technologies to third parties and royalties received pursuant to collaborative agreements and license agreements. Royalties based on reported sales, if any, of licensed products are recognized based on the terms of the applicable agreement when and if reported sales are reliably measurable and collectability is reasonably assured.

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.

#### ***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. Prior to 2010, the Company credited funding received from government research and development grants against research and development expenses since the grants were received in the same period as expenditures were incurred. In 2010, the Company was awarded a federal grant for \$0.5 million under the U.S. Government's Qualifying Therapeutic Discovery Project ("QTDP") 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 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.

### ***Foreign exchange***

The Company's consolidated financial statements are reported in U.S. dollars.

Effective January 1, 2008, the Company changed its functional currency to the U.S. dollar from the Canadian dollar in order to more accurately represent the currency of the economic environment in which it operates as a result of the Company's redomicile into the United States effective December 10, 2007 (See "Note 1 — Description of Business") and increasing U.S. dollar denominated revenues and expenditures. For periods subsequent to January 1, 2008, the Company's foreign subsidiaries are considered to be integrated foreign operations and, accordingly, have the same functional currency as the parent, the U.S. dollar.

Accumulated other comprehensive loss consists of cumulative translation adjustments related to the consolidation of the Company's investments in foreign subsidiaries arising in periods prior to the change in functional currency. Should the Company 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 Company does not utilize derivative instruments. At December 31, 2011, the Company had a minimal amount of Canadian dollar denominated cash and cash equivalents.

### ***Earnings 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 dividing net income or loss by the weighted-average number of shares of the common stock outstanding and other dilutive securities outstanding during the period. The potential dilutive shares of the Company's common stock resulting from the assumed exercise of outstanding stock options, restricted shares units, warrants and shares under the Company's 2010 Employee Stock Purchase Plan are determined under the treasury stock method. Basic net loss per share equaled the diluted loss per share for the years ended December 31, 2011, 2010 and 2009, and 8,507,309, 9,111,864 and 5,861,841 shares, respectively, were excluded from the calculations of diluted net loss per share, since the effect of these shares, potentially issuable upon the exercise or conversion, was anti-dilutive.

### ***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 12 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 loss*

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income or loss includes unrealized gains and losses on its available-for-sale short-term and long-term investments. In addition to the unrealized gains and losses on investments, accumulated other comprehensive income (loss) consists of foreign currency translation adjustments which arose from the conversion of the Canadian dollar functional currency consolidated financial statements to the U.S. dollar reporting currency consolidated financial statements prior to January 1, 2008. As of December 31, 2011, our accumulated other comprehensive income (loss) consist primarily of foreign currency translation adjustment. The cumulative translation adjustment balance as of December 31, 2011, 2010 and 2009 was approximately \$5,066 million each respectively.

### *Stock-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. Stock-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.

The Company sponsors a Restricted Share Unit (“RSU”) Plan for non-employee directors 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 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, or until settlement of the award, and any changes in valuation are recorded as compensation expense for the period. The Company uses 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.

### *Segment information*

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

### *Recent accounting pronouncements*

In September 2011, FASB issued new guidance on testing goodwill for impairment. The new guidance simplifies how an entity tests goodwill for impairment. It allows an entity 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 new guidance will be effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted. The Company has not adopted this standard or determined the impact of this standard on the Company's results of operations, cash flows and financial position.

In June 2011, FASB and the International Accounting Standards Board ("IASB") updated the guidance on presentation of items within other comprehensive income. In this update, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. For both options, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. This update eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. This update does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments in this update should be applied retrospectively. For public entities, the amendments are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company has not adopted this standard; however, the adoption of this standard will only impact the presentation of the Company's financial statements, and not the results of operations or financial position of the Company.

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 to be applied prospectively. For public entities, the amendments are effective during interim and annual periods beginning after December 15, 2011. Early application by public entities is not permitted. The adoption of this standard is only expected to impact the presentation of the Company's financial statements, and not the results of operations or financial position of the Company.

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

The Company measures at fair value certain financial assets and liabilities 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 which reflect the Company's

market assumptions when measuring fair value. 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
- 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 consisted of the following as of December 31, 2011 and 2010 (in thousands):

	December 31, 2011				December 31, 2010			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Financial Assets:								
Money market funds	\$ 2,869	\$ —	\$ —	\$ 2,869	\$ 4,005	\$ —	\$ —	\$ 4,005
Certificates of deposits	—	10,633	—	10,633	—	23,363	—	23,363
Debt securities of U.S. government agencies .....	—	16,380	—	16,380	—	—	—	—
Corporate debt securities and commercial paper.....	—	31,684	—	31,684	—	—	—	—
	<u>\$ 2,869</u>	<u>\$ 58,697</u>	<u>\$ —</u>	<u>\$ 61,566</u>	<u>\$ 4,005</u>	<u>\$ 23,363</u>	<u>\$ —</u>	<u>\$ 27,368</u>
Financial Liability: .....								
Restricted Share Units .....	\$ 1,088	\$ —	\$ —	\$ 1,088	\$ —	\$ —	\$ —	\$ —
Warrants .....	—	—	28,771	28,771	—	—	12,983	12,983

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. These investments are included in Level 2 and consist of 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 2011. The change in fair value of warrants classified in Level 3, in the amount of \$17.6 million, is recorded as other expense in the condensed consolidated statements of operations for the year ended December 31, 2011.

The estimated fair value of warrants accounted for as liabilities was determined on the issuance date and warrants are subsequently marked to market at each financial reporting date. The change in fair value of the warrants is recorded in the statement of operations as a gain (loss) estimated using the Black-Scholes option-pricing model with the following inputs:

	<u>As of December 31, 2011</u>	
	<u>May 2009 Warrants</u>	<u>September 2010 Warrants</u>
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

	<u>As of December 31, 2010</u>	
	<u>May 2009 Warrants</u>	<u>September 2010 Warrants</u>
Exercise price .....	\$ 3.74	\$ 4.24
Market value of stock at end of period .....	\$ 3.26	\$ 3.26
Expected dividend rate .....	0.0%	0.0%
Expected volatility .....	102.7%	92.2%
Risk-free interest rate.....	1.2%	1.9%
Expected life (in years).....	3.40	4.75

The table below shows the change in fair value of the warrant liability during the year ended December 31, 2011. The change includes warrants that were valued on their exercise dates and reclassified from liability to equity upon issuance of common shares.

**(in thousands)**

Warrant liability as of January 1, 2011 .....	\$ 12,983
Change in fair value for the twelve months ended December 31, 2011 .....	17,631
Reclassified to equity upon exercise for the twelve months ended December 31, 2011 .....	<u>(1,843)</u>
Balance as of December 31, 2011 .....	<u>\$ 28,771</u>

On December 31, 2010, the Company changed the way it estimates volatility when determining the fair value of the warrants using the Black-Scholes model. Prior to December 31, 2010, the volatility was calculated using the Company's historical stock price, and discounting it by 15% to give effect to estimated lowered volatility expected by warrant holders. Before estimating the fair value of the warrants on December 31, 2010, the Company commissioned a study on volatility, and determined that the most appropriate volatility to use as of December 31, 2010, and for the foreseeable future, is the unadjusted volatility calculated using the Company's historical stock price.

#### **4. NOTES RECEIVABLE, EMPLOYEES**

Pursuant to the acquisition of ProlX, the Company advanced cash of \$0.3 million to certain employees of ProlX and a former director of ProlX. The principal amount of the loans, together with interest accrued at the rate of 5.0% per annum to the date of payment, was due and payable on April 28, 2009. The former director repaid his loan in 2008 and one former employee repaid \$38,635 of interest and principal during 2009 and \$39,200 was forgiven in 2010 subject to meeting certain conditions outlined in a subsequent consulting agreement. The original due date for the remaining loan was extended to April 28, 2011. Interest income of \$7,000 and \$9,000 related to these loans has been recorded in the consolidated statements of operations in 2010 and 2009, respectively.

Notes receivable due from employees is reviewed whenever circumstances indicate that the carrying amount of the receivable may not be recoverable. For the year ended December 31, 2010, the Company intended to forgive the remaining loan in 2011 and therefore recorded an allowance of \$153,720 for the remaining balance. During 2011, the Company wrote off the notes receivable balance of \$153,720.

## 5. 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, 2011 and 2010:

	2011		
	Cost	Accumulated Depreciation and Amortization (in thousands)	Net Carrying Value
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>
	2010		
	Cost	Accumulated Depreciation and Amortization (in thousands)	Net Carrying Value
Leasehold improvements.....	\$ 1,510	\$ 227	\$ 1,283
Scientific equipment.....	1,321	702	619
Office equipment.....	27	8	19
Computer software and equipment.....	300	263	37
	<u>\$ 3,158</u>	<u>\$ 1,200</u>	<u>\$ 1,958</u>

Depreciation and leasehold improvement amortization expense for the years ended December 31, 2011, 2010 and 2009 was \$0.5 million, \$0.5 million and \$0.3 million, respectively.

## 6. NOTES PAYABLE

### *Notes payable assumed in connection with the acquisition of ProlX*

In connection with the acquisition of ProlX, the Company assumed two loan agreements under which approximately \$199,000 was outstanding at December 31, 2010. The Company is required to repay such loans if it commercializes or sells the product that was the subject of such agreement. In February 2011, the Company provided notice to the counterparty to such agreements that the Company does not intend to commercialize such product. As a result, the agreements were terminated March 2011 and the Company does not expect to incur any repayment obligations of such loans; therefore, the note payable was derecognized in March 2011 and \$199,000 was recognized as other income.

*Notes payable — General Electric Capital Corporation*

On February 8, 2011, the Company entered into a Loan and Security Agreement with General Electric Capital Corporation (“GECC”, and together with the other financial institutions that may become parties to the Loan and Security Agreement, the “Lenders”), pursuant to which the Lenders agreed to make a term loan in an aggregate principal amount of \$5.0 million (the “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 accrues interest at a fixed rate of 10.64% per annum and is payable over a 42-month period. The Company is required to make monthly payments of interest only, through November 1, 2011, and is required to repay the principal amount of the Term Loan over a period of 32 consecutive equal monthly installments of principal of \$151,515 plus accrued interest, commencing on December 1, 2011. At maturity of the Term Loan, the Company is also required to make a final payment equal to 1.5% (\$75,000) of the Term Loan, which has been treated as a discount to the loan. The Company may incur additional fees if it elects to prepay the Term Loan. 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.

The Company allocated the aggregate proceeds of the Term Loan between the warrant and the debt obligations based on their relative fair values. The fair value of the warrant issued to the affiliate of GECC was calculated utilizing the Black-Scholes option-pricing model. The Company is amortizing the relative fair value of the warrants of \$114,447 together with the final payment of \$75,000 as a discount over the term of the loan through maturity date using the effective interest method, resulting in a total effective interest rate of 14.89%. As of December 31, 2011, the unamortized Term Loan discount was \$116,080. If the maturity of the debt is accelerated due to an event of default, then the amortization would also be accelerated.

The loan agreement with GECC contains certain restrictive covenants that limit or restrict the Company’s ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, or repurchase stock. The loan agreement also requires that the Company have 12 months of unrestricted cash and cash equivalents (as calculated in the loan agreement) as of each December 31 during the term of the loan agreement. As security for its obligations under the Loan agreement, the Company granted the Lenders a lien on substantially all of its assets, excluding intellectual property. The Company was in compliance with its financial and non-financial covenants as of December 31, 2011.

Deferred financing costs of \$196,039 were capitalized as other assets and are being amortized to interest expense over the term of the Term Loan. As of December 31, 2011, the unamortized Term Loan deferred financing costs were \$120,119.

As of December 31, 2011, the future contractual principal payments on the Term Loan including the final payment fee are as follows (in thousands):

2012 .....	\$	1,818
2013 .....		1,818
2014 .....		1,288
Total.....	\$	<u>4,924</u>

A reconciliation of the face value of the Term Loan to the carrying value of the Term Loan as of December 31, 2011 is as follows (in thousands):

Total Term Loan, including final payment fee (face value) .....	\$ 4,924
Less: Term Loan discount balance .....	(116)
Total Term Loan carrying value .....	<u>4,808</u>
Less: current portion of notes payable .....	<u>(1,749)</u>
Long-term notes payable .....	<u>\$ 3,059</u>

Interest expense for the year ended December 31, 2011, all of which related to the Term Loan, was \$631,132. No interest expense was incurred for the years ended December 31, 2010 and 2009. 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 \$149,287 for the year ended December 31, 2011.

## 7. SHARE CAPITAL

### *Class UA preferred stock*

As of December 31, 2011 and 2010, 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 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, 2011 and 2010, 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.

### ***Common stock***

As of December 31, 2011, 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 \$4,360 and \$3,000 of which represents par value of common stock as of December 31, 2011 and 2010 respectively. Additional paid-in capital primarily relates to amounts for share-based compensation (see "Note 8 — Stock-based Compensation").

### ***Equity Financings and Warrants***

On May 26, 2009, the Company closed the sale of 3,878,993 shares of its common stock and warrants to purchase an additional 2,909,244 shares of common stock for gross proceeds of approximately \$11.1 million. The purchase price per unit, consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock, was \$2.85. The exercise price of the warrants is \$3.92 per share. The warrants are exercisable at any time on or prior to May 26, 2014. Upon exercise, holders of the warrants are required to deliver the aggregate exercise price with respect to the number of underlying shares; provided that if a registration statement is not available with respect to the issuance of such shares upon exercise, under certain

circumstances, holders may exercise warrants on a “net” basis. If holders exercise warrants on a “net” basis, the Company would not receive any cash in respect of the shares issued upon exercise. At the election of the warrant holder, upon certain transactions, including a merger, tender offer or sale of substantially all of the assets of the Company, the holder may receive cash in exchange for the warrant, in an amount determined by application of the Black-Scholes option valuation model.

The warrants issued in May 2009 were subject to certain adjustments if the Company issued or sold shares below the original exercise price. A September 2010 equity financing, discussed below, triggered such adjustment provisions and, as a result, the aggregate number of shares underlying such unexercised warrants increased by 135,600 to 2,953,344 as of December 31, 2010 and the per share exercise price decreased from \$3.92 to \$3.74. Pursuant to the terms of the warrant agreement, the terms of the warrants issued in May 2009 will not be further adjusted for any future transactions. During 2011, 262,101 of the May 2009 warrants were exercised. As of December 31, 2011, there were 2,691,241 outstanding warrants from the May 2009 financing.

On August 7, 2009, the Company closed the sale of 2,280,502 shares of its common stock and warrants to purchase an additional 684,150 shares of common stock for gross proceeds of approximately \$15.0 million. The purchase price per unit, consisting of one share of common stock and a warrant to purchase 0.30 shares of common stock, was \$6.58. The exercise price of the warrants is \$6.58 per share. The warrants were exercisable at any time on or prior to August 7, 2011. During 2011, 140,000 of the August 2009 warrants were exercised and 544,150 warrants expired.

On September 28, 2010, the Company closed the sale of 4,242,870 units, with each unit consisting of one share of Company common stock and a warrant to purchase 0.75 shares of common stock, at \$3.50 per unit for proceeds of approximately \$13.6 million, net of \$1.2 million in issuance costs associated with the offering. A total of 3,182,147 shares of common stock are issuable upon the exercise of such warrants. The exercise price of the warrants is \$4.24 per share. These warrants are exercisable at any time on or after the six-month anniversary of the closing through and including the five year anniversary of the earlier of (i) the date on which the shares of common stock underlying the warrants may be freely resold pursuant to a resale registration statement and (ii) the date on which the shares of common stock underlying the warrants may be sold under Rule 144, promulgated under the Securities Act of 1933, as amended, without any restriction or limitation and without the requirement to be in compliance with Rule 144(c)(1). Upon exercise, holders of the warrants are required to deliver an executed exercise notice, the aggregate exercise price with respect to the number of underlying shares as to which the warrant is being exercised and, if the warrant is exercised in full, the original warrant. If, on the date the exercise notice is delivered to the Company, there is not an effective registration statement registering, or no current prospectus available for the resale by the holder of the shares underlying the warrant, then the holder may exercise the warrants on a “net” basis. If a holder exercises the warrant on a “net” basis, the Company would not receive any cash in respect of the shares issued upon exercise. By delivery to the Company of a written request before the 30th day after the consummation of certain transactions, including a merger, tender offer or sale of substantially all of the assets of the Company, a holder may receive cash in exchange for the warrant, in an amount determined by application of the Black-Scholes option valuation model to the unexercised portion of the warrant on the date of such transaction. As of December 31, 2011, there were 3,182,147 outstanding warrants from the September 2010 financing.

The warrants issued in May 2009 and September 2010 have been classified as liabilities, as opposed to equity, due to the potential cash settlement upon the occurrence of certain transactions as noted above.

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. For additional information regarding the Company's term loan with GECC, see "Note 6 — Notes Payable" of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

A summary of outstanding warrants as of December 31, 2011 and 2010 and changes during the years then ended is presented below (in thousands).

	<u>2011</u>	<u>2010</u>
	<u>Shares</u>	<u>Shares</u>
	<u>Underlying</u>	<u>Underlying</u>
	<u>Warrants</u>	<u>Warrants</u>
Balance, beginning of year .....	6,819,641	3,838,918
Equity placements.....	—	3,317,747
Warrants issued with term loan .....	48,701	—
Exercise of warrants .....	(402,103)	—
Expiration of warrants .....	(544,150)	(337,024)
Balance, end of year .....	<u>5,922,089</u>	<u>6,819,641</u>

The following table summarizes information regarding warrants outstanding at December 31, 2011:

<u>Exercise Price</u>	<u>Shares</u> <u>Underlying</u> <u>Outstanding</u> <u>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	September 28, 2015
	<u>5,922,089</u>	
		<b>For the Years Ended</b> <b>December 31,</b>
		<u>2011</u> <u>2010</u>
Shares underlying warrants outstanding classified as liabilities .....	5,873,388	6,135,491
Shares underlying warrants outstanding classified as equity .....	48,701	684,150

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.

***Conversion of restricted share units***

Restricted share units of 121,393, 9,498 and 9,920 with a weighted average fair value of \$7.47, \$8.46 and \$7.56 were converted into 121,393, 9,498 and 9,920 shares of common stock during 2011, 2010 and 2009 respectively. Pursuant to an October 2011 amendment to the Company's RSU plan, the Company withheld 28,271 shares of the 121,393 RSUs, representing 25% of the shares of our common stock otherwise deliverable in connection with the vesting of the RSUs, and the Company delivered to each non-employee director an amount in cash equal to the fair market value of the shares on the vesting date in order to facilitate satisfaction of the non-employee directors' income tax obligation with respect to the vested RSUs. See "Note 8 Stock-Based Compensation" of the audited financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

***Loss per share***

The following is a reconciliation of the numerators and denominators of basic and diluted loss per share computations:

	<u>2011</u>	<u>2010</u>	<u>2009</u>
	<u>(in thousands, except share amounts)</u>		
Numerator:			
Net loss .....	\$ (42,656)	\$ (15,618)	\$ (17,219)
Denominator:			
Weighted average shares outstanding used to compute loss per share— basic .....	38,197,666	26,888,588	22,739,138
Effect of dilutive securities .....	<u>—</u>	<u>—</u>	<u>—</u>
Weighted average shares outstanding and dilutive securities used to compute loss per share — diluted .....	<u>38,197,666</u>	<u>26,888,588</u>	<u>22,739,138</u>

Shares potentially issuable upon the exercise or conversion of director and employee stock options of 2,441,725, 2,075,025 and 1,836,657; non-employee director restricted share units of 143,495, 217,198 and 186,266; and warrants of 5,922,089, 6,819,641 and 3,838,918 have been excluded from the calculation of diluted loss per share in the years ended December 31, 2011, 2010 and 2009 respectively because their effect was anti-dilutive.

For all periods presented, shares contingently issuable in connection with the May 2, 2001 Merck KGaA agreement (discussed below), 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.

In May 2001, under the terms of a common stock purchase agreement, the Company issued to Merck KGaA 318,702 shares of Company common stock for proceeds of \$15.0 million net of issuance costs of

\$9,000. Upon the first submission of a biologics license application, or BLA for Stimuvax, 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.

## 8. STOCK-BASED COMPENSATION

### *Stock option plan*

The Company sponsors a stock option plan (the “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. In general, 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. The current maximum number of shares of common stock reserved for issuance under the Option Plan is 4,361,310. As of December 31, 2011, 1,919,585 shares of common stock remain available for future grant under the Option Plan.

A summary of the status of the Option Plan as of December 31, 2011, 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.

	2011	
Stock Options	Weighted Average Exercise Price	
Outstanding, beginning of year \$CDN .....	815,275	\$ 8.24
Outstanding, beginning of year \$US.....	1,259,750	3.71
Granted \$US .....	426,250	6.78
Exercised \$US .....	(12,708)	3.12
Forfeited \$US .....	(1,250)	3.08
Expired \$CDN .....	(45,592)	11.17
Balance, end of the year \$CDN .....	769,683	8.07
Balance, end of the year \$US .....	1,672,042	4.50
Options exercisable, end of year \$CDN .....	768,558	8.07
Options exercisable, end of year \$US.....	540,323	\$ 3.78

As of December 31, 2011, there were 1,601,104 U.S. dollar denominated options vested and expected to vest with a weighted-average exercise price of \$4.48, a weighted-average remaining contractual term of 6.50 years and an aggregate intrinsic value of \$5.0 million. For the same period, there were 769,683 Canadian dollar denominated options vested and expected to vest with a weighted-average exercise price of

CDN \$8.07, a weighted-average remaining contractual term of 2.64 years and an aggregate intrinsic value of zero.

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, 2011. The aggregate intrinsic value at December 31, 2011 for options outstanding was \$5.2 million and for options exercisable was \$2.1 million. 12,708 options were exercised in 2011 with aggregate intrinsic value of \$0.03 million. The aggregate intrinsic value of options exercised under the Option Plan was immaterial during 2010 and 2009.

There were 12,708, 2,500 and 250 stock options exercised in 2011, 2010 and 2009, respectively. As of December 31, 2011, there were 1,066,696 exercisable, in-the-money options based on the Company's closing share price of \$7.58 on The NASDAQ Global Market.

The following tables summarize information on stock options outstanding and exercisable at December 31, 2011. The range of exercise prices and weighted average exercise prices are listed in their respective dollar denominations.

Range of Exercise Prices (\$CDN per share)	Stock Options Outstanding			Stock Options Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
\$4.60 — 7.50 .....	471,665	2.71	\$ 7.33	470,540	2.70	\$ 7.34
7.51 — 10.00 .....	234,173	3.05	8.09	234,173	3.05	8.09
10.01 — 16.02 .....	<u>63,845</u>	0.60	13.44	<u>63,845</u>	0.60	13.44
	<u>769,683</u>	2.64	\$ 8.07	<u>768,558</u>	2.63	\$ 8.07
<b>Range of Exercise Prices (\$USD per share)</b>						
\$1.10 — 3.00 .....	164,500	5.20	\$ 1.11	82,250	5.20	\$ 1.11
3.01 — 4.00 .....	531,042	6.51	3.36	179,073	6.05	3.39
4.01 — 5.00 .....	534,500	5.92	4.73	265,250	5.91	4.73
5.01 — 6.56 .....	<u>442,000</u>	7.76	6.85	<u>13,750</u>	5.62	6.45
	<u>1,672,042</u>	6.52	\$ 4.50	<u>540,323</u>	5.84	\$ 3.78

A summary of the status of non-vested stock options as of December 31, 2011 and changes during 2011 is presented below:

	Number of Non-Vested Options	Weighted Average Grant Date Fair Value \$
Balance at December 31, 2010 \$CDN .....	45,508	\$ 6.16
Balance at December 31, 2010 \$US .....	1,030,250	2.78
Granted \$US .....	426,250	4.76
Vested \$CDN .....	(44,383)	6.22
Vested \$US .....	(323,531)	2.83
Forfeited \$US .....	(1,250)	2.18
Expired \$CDN .....	—	—
Expired \$USD .....	—	—
Balance at December 31, 2011 \$CDN .....	1,125	3.84

	<b>Number of Non-Vested Options</b>	<b>Weighted Average Grant Date Fair Value \$</b>
Balance at December 31, 2011 \$US .....	1,131,719	\$ 3.52

Stock based compensation expense related to the stock option plan of \$1.1 million, \$0.9 million and \$1.0 million was recognized in 2011, 2010 and 2009, respectively. Total compensation cost related to non-vested stock options not yet recognized was \$3.1 million as of December 31, 2011, which will be recognized over the next 37 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:

	<b>2011</b>	<b>2010</b>	<b>2009</b>
Weighted average grant-date fair value per stock option \$US .....	\$ 4.76	\$ 2.49	\$ 3.03
Expected dividend rate .....	—	—	—
Expected volatility .....	<b>82.63%</b>	89.11%	92.46%
Risk-free interest rate.....	<b>1.29%</b>	2.00%	2.47%
Expected life of options in years .....	<b>6.0</b>	6.0	6.0

The expected life of options in years is determined utilizing the “simplified” method, which calculates the expected life as the average of the vesting term and the contractual term of the option. 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 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.

Stock-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 Restricted Share Unit Plan (the “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, 2011, 200,922 shares of common stock remain available for future grant under the RSU Plan.

Pursuant to an October 2011 amendment to the RSU Plan, the Company is required to settle 25% of the shares of common stock of the Company 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 the satisfaction of the non-employee directors’ U.S. federal 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, or

until settlement of the award, and any changes in valuation are recorded as compensation expense for the period.

The company recognized approximately \$0.8 million in expense related to the remeasurement of the awards for the year ended December 31, 2011. As of December 31, 2011, the liability related to the unsettled awards was approximately \$1.1 million.

A summary of the status of the Company's RSU Plan as of December 31, 2011, and changes during such year is presented below:

	<u>Restricted Share Units</u>	<u>Weighted Average Fair Value per Unit</u>
Outstanding, beginning of year.....	217,198	\$ 3.81
Granted.....	47,690	6.77
Converted.....	<u>(121,393)</u>	7.47
Outstanding, end of year.....	<u>143,495</u>	7.58

Stock based compensation expense of \$1.1 million, \$0.1 million and \$0.3 were recognized on the RSU Plan in 2011, 2010 and 2009 respectively, representing the fair value of restricted share units granted. During the year ended December 31, 2011, the Company's RSU compensation expense of \$1.1 million included \$0.7 million related to the revaluation of outstanding RSUs.

RSUs are converted into common stock upon vesting. Pursuant to the October 2011 amendment to the RSU plan described above, the Company is required to settle 25% of the shares of common stock of the Company 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 in order to facilitate the satisfaction of the non-employee directors' U.S. federal income tax obligation with respect to the vested RSUs.

### ***Employee Stock Purchase Plan***

The Company adopted an Employee Stock Purchase Plan ("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. For the year ended December 31, 2011 and 2010, expense related to this plan was \$153,000 and \$54,000, respectively. Under the ESPP, 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. During 2010, the Company issued 20,434 shares to employees at a purchase price of \$2.82 per share. There are 807,597 shares reserved for future purchases as of December 31, 2011.

## 9. 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, Stimuvax 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 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 Stimuvax 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 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 Stimuvax 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 Stimuvax, 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 Stimuvax 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 Stimuvax.

### ***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 Stimuvax, (2) participation in a joint steering committee, (3) participation in a manufacturing/CMC Project team, (4) delivery of any improvements of Stimuvax 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 Stimuvax in the United States and, subject to certain conditions, to act as a secondary manufacturer of Stimuvax. The Company’s right to commercialize Stimuvax 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 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 Stimuvax 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 Stimuvax in the United States. In February 2007, the Company announced that the first patient had been enrolled in the global Phase 3 Stimuvax 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 Stimuvax, 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 Stimuvax, (2) participation in a joint steering committee, (3) participation in a manufacturing/CMC Project team, (4) delivery of any improvements of Stimuvax 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 Stimuvax in Canada. For accounting purposes, the license grant to develop Stimuvax in Canada was effective as of 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 Stimuvax. 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 Stimuvax, 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 Stimuvax 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 Stimuvax, 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 Stimuvax, a \$3.0 million payment tied to the transfer of certain Stimuvax manufacturing technology and a \$2.0 million payment tied to the receipt of the first manufacturing run at commercial scale of Stimuvax (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 Stimuvax. After execution of the 2007 supply agreement, the Company reported revenue and associated clinical trial material costs related to the supply of Stimuvax 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 Stimuvax 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 Stimuvax 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 Stimuvax, 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 Stimuvax-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 Stimuvax were removed and continuing involvement by the Company in the development and manufacturing of Stimuvax ceased (although the Company continues to be entitled to certain information rights with respect to clinical testing, development and manufacture of Stimuvax).

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 Stimuvax 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 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.

The table below presents the roll-forward of the deferred revenue balances resulting from the payments received from Merck KGaA (in thousands):

	<u>2008</u>
Deferred revenue balance, beginning of year .....	\$ 18,067
Additional revenues deferred in the year: .....	
Licensing revenue from collaborative and license agreements.....	3,000
Contract manufacturing .....	4,060
Less revenue recognized in the year: .....	
Licensing revenue from collaborative and license agreements.....	(25,009)
Effect of changes in foreign exchange rates .....	(118)
Deferred revenue — long term .....	<u>\$ —</u>
Manufacturing process transfer payment received and recognized currently.....	<u>—</u>

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, Stimuvax, placebo and raw materials, and Merck KGaA agreed to assume certain liabilities related to the manufacturing of Stimuvax 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.

As result of the December 2008 transactions, 43 persons who had previously been employed by the Company in its Edmonton facility were transferred to Merck KGaA.

### ***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 (“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 (“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.

## 10. INVESTMENT AND OTHER INCOME (EXPENSE), NET

Net investment and other income (expense) includes the following components for the periods indicated:

	Years Ended December 31,		
	2011	2010	2009
	(In thousands)		
Government grant .....	\$ —	\$ 489	\$ —
Investment income (loss), net .....	115	177	82
Net foreign exchange loss .....	(9)	(27)	(83)
Loss on sale of equipment .....	—	(6)	(7)
Other revenue .....	199	3	—
Total investment and other income (expense), net .....	<u>\$ 305</u>	<u>\$ 636</u>	<u>\$ (8)</u>

## 11. INCOME TAX

The income tax benefit (provision) consists of the following for year ended December 31, 2011, 2010 and 2009:

	Years Ended December 31,		
	2011	2010	2009
	(In thousands)		
Federal:			
Current .....	\$ —	\$ 200	\$ (200)
Deferred .....	—	—	—
Income tax benefit (provision) .....	<u>\$ —</u>	<u>\$ 200</u>	<u>\$ (200)</u>

There is no income tax benefit or provision for the year ended December 31, 2011.

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.

In 2009, the Company recorded a current federal tax provision of \$0.2 million for the year ended December 31, 2009, which consists of federal alternative minimum tax due to limitations on net operating loss usage.

The benefit (provision) for income taxes is different from applying the statutory federal income tax rate as follows:

	<u>2011</u>	<u>2010</u>	<u>2009</u>
Tax benefit at statutory rate .....	35.0%	35.0%	35.0%
Change in fair value of warrant liability .....	(14.6)	6.8	(12.7)
Deferred tax adjustment.....	1.0	15.0	0.0
Other .....	(1.6)	4.0	(0.8)
Change in valuation allowance .....	(16.4)	(50.2)	(22.9)
Expiration of loss carryforwards and credits .....	(3.4)	(9.2)	0.0
Income tax benefit (provision).....	<u>0.0%</u>	<u>1.4%</u>	<u>(1.4)%</u>

The Company's net deferred tax assets consist of the following items at the end of the year:

	<u>2011</u>	<u>2010</u>
	(In thousands)	
Net deferred tax assets		
Stock based compensation.....	\$ 1,783	\$ 1,056
Intangible assets.....	1,275	1,409
Other .....	259	258
Tax benefits from losses carried forward and tax credits .....	139,251	134,820
Net deferred income tax asset before allowance.....	142,568	137,543
Less valuation allowance.....	<u>(142,568)</u>	<u>(137,543)</u>
	<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 \$5.0 million and \$13.0 million during the years ended December 31, 2011 and 2010, respectively.

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 12 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.

The Company has recorded the following uncertain tax positions as of December 31, 2011 (in thousands):

Balance at December 31, 2010 .....	\$ —
Decrease related to prior year tax positions.....	—

Increase related to prior year tax positions .....	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 .....	—
Balance at December 31, 2011 .....	<u>\$ 729</u>

### *United States*

The Company has accumulated net operating losses of \$103 million and \$82.5 million for United States federal tax purposes at December 31, 2011 and 2010 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 2012 through 2030. The Company has federal research and development tax credit carry forwards of \$0.7 million that will expire in fiscal years 2012 through 2022, if not utilized.

### *Canada*

The Company has unclaimed Canada federal investment tax credits of \$20.6 million and \$20.6 million (CAD) at December 31, 2011 and 2010, respectively that expire in fiscal years 2018 through 2029. The Company has scientific research & experimental development expenditures of \$137.9 million and \$137.9 million for Canada federal purposes and \$60.1 million and \$60.1 million for provincial purposes at December 31, 2011 and 2010 respectively. These expenditures may be utilized in any period and may be carried forward indefinitely. The Company also has Canada federal capital losses of \$186.4 million and \$186.4 million and provincial capital losses of \$186.5 million and \$186.5 million at December 31, 2011 and 2010 respectively that can be carried forward indefinitely to offset future capital gains. The Company has accumulated net operating losses of \$6.5 million and \$6.2 million at December 31, 2011 and 2010 for Canada federal tax purposes and \$4.2 million and \$3.9 million at December 31, 2011 and 2010 for provincial purposes which expire between 2027 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. The Company is subject to examination for years after 2007. However, carryforward attributes that were generated prior to 2007 may still be adjusted by a taxing authority upon examination if the attributes have been or will be used in a future period.

## **12. CONTINGENCIES, COMMITMENTS, AND GUARANTEES**

### *Royalties*

In connection with the issuance of the Class UA preferred stock (See “Note 7 — 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.

Pursuant to various license agreements, the Company is obligated to pay royalties based both on the achievement of certain milestones and a percentage of revenues derived from the licensed technology.

***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 \$0.1 million in each of the years ended December 31, 2011, 2010 and 2009, respectively. There were no changes to the plan during the year ended December 31, 2011.

***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>		
012.....	\$	577
2013.....		587
2014.....		596
2015.....		604
Thereafter .....		<u>1,830</u>
		<u>\$ 4,194</u>

Rental expense for operating leases in the amount of \$0.5 million, \$0.6 million and \$0.7 million have been recorded in the consolidated statements of operations in 2011, 2010 and 2009 respectively. In May 2008, the Company entered into a sublease agreement to lease office and laboratory space for its headquarters in Seattle, Washington totaling approximately 17,000 square feet. The sublease expired on December 17, 2011. The sublease provided for a monthly base rent of \$33,000 increasing to \$36,000. In May 2008, the Company also entered into a lease agreement directly with the landlord beginning on December 18, 2011 for a period of 84 months to December 18, 2017. The lease provides for a monthly base rent of \$48,000 increasing to \$52,000 in 2017. The Company has also entered into operating lease obligations through September 2015 for certain office equipment, which are included in the table above.

***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 license agreement.

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, 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.

### 13. SUBSEQUENT EVENTS

On February 3, 2012, the Company entered into a Sales Agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”) to sell shares of the Company’s common stock, having aggregate gross 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. 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 to date.

In connection with the entry into the Sales Agreement, the Company determined that it would terminate its committed equity line financing facility (discussed in “Note 7 — Share capital.”). Termination of the equity line financing facility was effective as of February 3, 2012.

In connection with the entry into the Sales Agreement and the termination of the equity line financing facility, the Company amended the terms of its Loan and Security Agreement with GECC (discussed in “Note 6 — Notes payable”) to substitute references to the equity line financing facility with references to the “at the market” equity offering program.

In connection with the Company’s agreement with Merck KGaA, which is discussed further in “Note 9 — Collaborative and License Agreements”, on March 6, 2012, Merck Serono, a division of Merck KGaA of Darmstadt, Germany, informed the Company that the Independent Data Monitoring Committee (the “DMC”) for the Phase 3 START trial of Stimuvax in NSCLC met and the DMC recommendation is to continue the study. Final results from the study are expected in 2013.

### 14. CONDENSED QUARTERLY FINANCIAL DATA (unaudited)

The following table contains selected unaudited statement of operations information for each quarter of 2011 and 2010. 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 (in thousands, except per share data):

	Three Months Ended,			
	March 31	June 30	September 30	December 31
<b>2011</b>				
Revenues.....	\$ 145	\$ —	\$ —	\$ —
Operating expenses .....	6,017	5,826	6,443	6,558
Net income (loss).....	(7,116)	(33,973)	9,937	(11,504)(1)

	Three Months Ended,			
	March 31	June 30	September 30	December 31
<b>Net income (loss) per share — basic .....</b>	<b>(0.24)</b>	<b>(0.91)</b>	<b>0.24</b>	<b>(0.27)</b>
<b>Net income (loss) per share — diluted .....</b>	<b>(0.24)</b>	<b>(0.91)</b>	<b>0.22</b>	<b>(0.27)</b>
2010 .....				
Revenues .....	\$ 5	\$ 4	\$ 4	\$ 5
Operating expenses .....	5,438	4,722	4,345	4,997
Net loss .....	(772)	(4,340)	(4,352)	(6,154)(2)
Net loss per share — basic and diluted .....	(0.03)	(0.17)	(0.17)	(0.20)

- (1) Net 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).
- (2) Net loss for the three months ended March 31, June 30, September 30 and December 31, 2010 includes change in fair value of warrants income (expense) of approximately \$4.6 million, \$0.4 million, \$(0.3) million and \$(1.7) million respectively (see Note 3).

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