



ANNUAL REPORT

**2015**

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

(Mark One)

**Form 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2015**

**OR**

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

**TO**

**Commission file number: 001-33882**

**ONCOTHYREON INC.**

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

**Delaware**

*(State or other jurisdiction of incorporation or organization)*

**26-0868560**

*(I.R.S. Employer Identification Number)*

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

*(Address of principal executive offices)*

**98121**

*(Zip Code)*

**Registrant's telephone number, including area code:**

**(206) 801-2100**

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

**Title of Each Class**

**Name of Exchange on Which Registered**

Common Stock, \$0.0001 par value

The NASDAQ Stock Market LLC  
(The NASDAQ Global Market)

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

**None**

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

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

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

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the Registrant, based on the closing sale price of the Registrant's common stock on the last day of its most recently completed second fiscal quarter, as reported on the NASDAQ Global Market, was approximately \$317 million. Shares of common stock held by each executive officer and director and by each person who owns 10% 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 94,961,859 shares of the Registrant's common stock, \$0.0001 par value, outstanding on March 14, 2016.

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**DOCUMENTS INCORPORATED BY REFERENCE**

**None.**

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**ONCOTHYREON INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2015**  
**TABLE OF CONTENTS**

		<b>Page</b>
<b>PART I</b>		
Item 1.	Business .....	1
Item 1A.	Risk Factors .....	16
Item 1B.	Unresolved Staff Comments .....	33
Item 2.	Properties .....	33
Item 3.	Legal Proceedings .....	33
Item 4.	Mine Safety Disclosures .....	33
<b>PART II</b>		
Item 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities .....	34
Item 6.	Selected Financial Data .....	36
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations .....	37
Item 7A.	Quantitative and Qualitative Disclosure About Market Risk .....	48
Item 8.	Financial Statements and Supplementary Data .....	48
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure .....	49
Item 9A.	Controls and Procedures .....	49
Item 9B.	Other Information .....	51
<b>PART III</b>		
Item 10.	Directors, Executive Officers and Corporate Governance .....	52
Item 11.	Executive Compensation .....	56
Item 12.	Security Ownership of Certain Beneficial Owners and Management .....	81
Item 13.	Certain Relationships and Related Transactions and Director Independence .....	83
Item 14.	Principal Accountant Fees and Services .....	85
<b>PART IV</b>		
Item 15.	Exhibits and Financial Statement Schedules .....	87
	Signatures .....	92

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## PART I

### ITEM 1. **Business**

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

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

*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 discover, develop and commercialize novel compounds that have the potential to improve the lives and outcomes of cancer patients. Our lead clinical-stage product candidate is ONT-380, an orally active and selective small-molecule HER2 inhibitor. We are also developing preclinical product candidates in oncology using our Chk1 kinase inhibitor and our protocell technology.

ONT-380 is a selective small molecule inhibitor of HER2, also known as ErbB2, a receptor tyrosine kinase that is over-expressed in breast cancer and other cancers, such as gastric and ovarian cancer. We are developing ONT-380 for the treatment of HER2-positive (HER2+) metastatic breast cancer. Over-expression of HER2 in breast cancer historically has been associated with increased mortality in early stage disease, decreased time to relapse, and increased incidence of metastases. The introduction of HER2-targeted therapies, including antibody based therapies as well as the small molecule tyrosine kinase inhibitor lapatinib, has led to improvement in the outcomes of patients with HER2+ cancer. Unlike lapatinib, a dual HER2/EGFR inhibitor approved for treatment of Her2+ breast cancer, ONT-380 selectively inhibits HER2. This specificity may lead to improved tolerability due to decreased rates of toxicities associated with EGFR inhibition, including skin toxicity and Grade 3 (severe) diarrhea, particularly in combination with chemotherapy such as capecitabine. ONT-380 has also demonstrated activity in animal models of HER2+ brain tumors suggesting that it may be a potential new treatment for patients with HER2+ breast cancer and brain metastases. We have an exclusive license agreement with Array BioPharma Inc. (Array) to develop, manufacture and commercialize ONT-380. We are currently conducting two Phase 1b trials of ONT-380, one in combination with Kadcyła® (ado-trastuzumab emtansine or TDM-1) and another in combination with Xeloda® (capecitabine) and/or Herceptin® (trastuzumab). Interim data from these trials indicated tolerability and preliminary clinical activity, including in the central nervous system, in a heavily pretreated patient population.

We recently completed the evaluation of two dosing cohorts in our Phase 1b trial of ONT-10, a therapeutic vaccine targeting the Mucin 1 peptide antigen (MUC1), in combination with the anti-CD27 T-cell agonist antibody varlilumab in collaboration with Celldex. Preliminary data from these two cohorts did not demonstrate sufficient activity to

move forward with the program. Based on these results, we do not plan to conduct any further trials with ONT-10 and have ended our collaboration with Celldex.

We are increasingly focused on expanding our pipeline of product candidates through both internal research and collaborative efforts. To support our internal efforts, in August 2014 we acquired Alpine Biosciences, Inc., of Seattle, Washington (Alpine), a privately held biotechnology company developing protocells, a novel nanoparticle platform technology designed to enable the targeted delivery of therapeutic agents, including nucleic acids, proteins, peptides or small molecules. We intend to utilize the protocell technology to develop new product candidates for the treatment of cancer, either on our own or with partners. We are also collaborating with Sentinel Oncology Ltd., of Cambridge, United Kingdom (Sentinel) to develop novel small molecule Chk1 kinase inhibitors. In addition, we are collaborating with Adimab LLC of Lebanon, New Hampshire to discover novel antibodies against undisclosed immunotherapy targets in oncology.

We have not developed a therapeutic product to the commercial stage. As a result, our revenue has been limited to date and our ability to generate revenue in future periods, if at all, will depend substantially on the progress of ongoing and potential future clinical trials for ONT-380 and any future product candidates, our success in obtaining regulatory approval for ONT-380 and any future product candidates and our ability to establish commercial markets for these drugs.

In January 2016, our previous chief executive officer retired, and Dr. Christopher Henney, the Chairman of our board of directors, was appointed as our Interim Chief Executive Officer. We are currently conducting a search for a new chief executive officer.

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 current good manufacturing practice (cGMP) material. We expect expenditures associated with these activities to increase in future years as we continue the development of ONT-380 and as we advance the development of our preclinical pipeline.

We were incorporated in 1985 in Canada under the name Biomira Inc. (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 our 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 the investor relations section of our 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 Securities and Exchange Commission (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 periodic reports, proxy statements, and other information that we file or furnish electronically with them at [www.sec.gov](http://www.sec.gov).

## **Our Strategy**

Our strategy is primarily focused on the development of therapeutic products for the treatment of cancer. Our lead product candidate is ONT-380, which is currently in Phase 2 clinical development. Our preclinical and discovery research technologies include the protocell nanotechnology platform, our novel small molecule Chk1 kinase inhibitor program licensed from Sentinel and the Adimab antibody discovery program. We intend to supplement our product pipeline through both internal discovery research activities as well as by in-licensing product candidates. We believe the development of multiple products increases our opportunity for success, diversifies risk, creates development synergies and allows us to establish strategic partnerships. Our pipeline is the foundation on which we intend to build a valuable oncology franchise. Key elements of our strategy are to:

*Advance our clinical stage product candidates.* Our primary focus is advancing our clinical-stage product candidate, ONT-380. To that end, we maintain internal expertise in our research and development, regulatory, clinical and manufacturing groups. We also have relationships with key scientific advisors, research organizations and contract manufacturers to supplement our internal efforts.

*Increase our product pipeline through discovery research and preclinical development.* We seek to develop new product candidates through internal discovery research. We intend to use our protocell technology to develop product candidates in oncology. To support these efforts we have expanded our internal research capabilities and maintain expertise in pre-clinical and clinical development, as well as product manufacturing. We also supplement our internal efforts with collaborations to expand the range of potential product opportunities. For example, in 2013 we initiated a collaboration with Sentinel to perform chemistry and analytical services for the development of novel Chk1 kinase inhibitors. In addition, in 2014 we initiated a collaboration with Adimab for the discovery of novel antibodies against undisclosed immunotherapy targets in oncology.

*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, pharmaceutical companies and academic institutions. For example, in late 2014 we completed an exclusive license agreement with Array for the development, manufacture and commercialization of ONT-380, replacing a prior collaboration agreement. In addition, in August 2014 we acquired Alpine for its protocell technology platform. We plan to continue supplementing our internal development programs through strategic acquisition or in-licensing transactions.

*Support our internal activities with strategic collaborations and out-licensing.* We believe that the protocell platform has the potential to create product candidates for our own pipeline as well as result in the generation of products or technologies that could be licensed to partners. We may also enter into collaborations, acquisitions or license arrangements at appropriate stages in our research and development process to advance the development or potential commercialization of programs in our pipeline. Such relationships can supplement our own internal expertise in areas such as discovery research, clinical trials and manufacturing, as well as provide us with access to licensees' marketing, sales and distribution capabilities.

## Product Candidates Overview

<u>Product Candidate</u>	<u>Technology</u>	<u>Most Advanced Indication</u>	<u>Development Stage</u>
ONT-380	Small Molecule	Breast cancer	Phase 2
Chk1	Small Molecule	To be determined	Preclinical

In the table above, under the heading “Development Stage,” “Phase 2” indicates clinical testing of efficacy, safety, dosage tolerance, pharmacokinetics and pharmacodynamics. “Pre-clinical” indicates undergoing toxicology and pharmacology studies intended to support subsequent clinical development.

## Clinical-Stage Product Candidates

### **ONT-380**

ONT-380 (previously known as ARRY-380) is an orally active, reversible and selective small-molecule HER2 inhibitor. HER2, also known as ErbB2, is a receptor tyrosine kinase that is over-expressed in HER2+ metastatic breast cancer, including patients with brain metastases.

*Breast cancer.* Breast cancer is the most common form of cancer in women worldwide, and the second leading cause of cancer-related death in women in North America. The American Cancer Society estimated that in 2015 more than 230,000 women in the U.S. would develop breast cancer and more than 40,000 would die from the disease. Approximately 15 – 20% of breast cancers overexpress HER2.

The treatment of breast cancer differs by stage and includes surgery and radiation for most earlier stage patients. The addition of HER2 targeted agents, including antibody-based therapies and a small molecule, has led to significant improvements in progression-free and overall survival, both in the adjuvant setting and for patients with metastatic HER2+ disease. There are currently four approved agents for the treatment of HER2+ breast cancer, Herceptin (trastuzumab), Perjeta (pertuzumab), Kadcyla (ado-trastuzumab emantasine, TDM1) and Tykerb (lapatinib). The size of the worldwide market for these types of agents in 2015 exceeded \$9.0 billion.

The prevention and treatment of metastatic disease in the central nervous system (CNS), including brain metastases, remains a significant unmet medical need for patients with HER2+ breast cancer. The incidence of first relapse occurring in the brain is increasing in patients who have progressed following Herceptin containing adjuvant regimens, and approximately 30 – 50% of patients with HER2+ metastatic disease will develop brain metastases during the course of their disease.

*Prior results and status.* In multiple HER2 – positive preclinical tumor models, ONT-380 was well tolerated and inhibited tumor growth as a single agent, and in combination with other drugs, including Herceptin® or Taxotere® (docetaxel). ONT-380 has also demonstrated superior activity, based on overall survival, compared to Tykerb® and to the investigational drug, neratinib, in an intracranial HER2+ breast cancer xenograft model.

A Phase 1 trial of ONT-380, with both dose-escalation and cohort expansion components, was completed by Array in 50 patients, 43 of whom had HER2+ metastatic breast cancer. All HER2+ breast cancer patients had progressed on a Herceptin-containing regimen as well as other chemotherapeutic agents. In addition, over 80% had been treated with Tykerb, with many progressing on therapy. In this study, ONT-380 demonstrated an acceptable safety profile; treatment-related adverse events were primarily Grade 1. Because ONT-380 is selective for HER2 and does not inhibit the epidermal growth factor receptor (EGFR), there was a low incidence and severity of treatment-related diarrhea, rash and fatigue. Additionally, there were no treatment-related cardiac events or Grade 4 treatment-related adverse events reported. Twenty-two HER2+ breast cancer patients with measurable disease were treated with ONT-380 at doses greater than or equal to 600 mg

BID. In this heavily pretreated patient population, there was a clinical benefit rate (partial response [n = 3] plus stable disease for at least 6 months [n = 3]) of 27%.

In February 2014 we initiated two Phase 1b trials of ONT-380. The trials are closed to enrollment although patients remain on treatment. The following is a summary of these studies:

*Phase 1b Trial of ONT380 in combination with Xeloda® (capecitabine) and/or Herceptin® (trastuzumab):*

The first trial evaluated ONT-380 in combination with Xeloda® (capecitabine) and/or Herceptin® (trastuzumab) in patients who have been previously treated with Herceptin and Kadcyła® (ado-trastuzumab emtansine or TDM-1) for HER2+ metastatic breast cancer. Patients may also have been previously treated with Perjeta or Tykerb. The primary objective of this study was to determine the maximum-tolerated and/or recommended Phase 2 dose (MTD/RP2D) of ONT-380 in combination with the approved dose of either Xeloda or Herceptin or both. Secondary objectives included an evaluation of the safety and preliminary anti-tumor activity of the combinations. The study included expansion cohorts at the MTD/RP2D of ONT-380 in combination with both Xeloda and Herceptin and with Herceptin alone in patients with and without brain metastases.

Interim safety and efficacy data from this trial were presented in December 2014 at the San Antonio Breast Cancer Symposium (SABCS) for 21 patients, and June 2015 at the American Society of Clinical Oncology (ASCO) annual meeting for 32 patients. Updated efficacy data were presented in December 2015 at SABCS for 41 patients. The data from these abstracts are summarized below.

In a heavily pretreated population, durable (> 6 months) systemic and CNS responses as well as disease stabilization were seen across all three treatment combinations, including patients previously treated with Perjeta and/or Tykerb as well as Herceptin and Kadcyła. As reported at SABCS in 2015, in seven patients treated with ONT-380 and Xeloda, the objective response rate (ORR) was 83%, with a CNS response in one of one patients with assessable brain metastases and at least one follow-up scan. In 16 patients treated with ONT-380 and Herceptin, the ORR was 29%, with a CNS response in one of seven patients with assessable brain metastases and at least one follow-up scan. In 18 patients treated with ONT-380 and Xeloda and Herceptin, the ORR was 39%, with CNS response in two of four patients with assessable brain metastases and at least one follow-up scan.

ONT-380 in combination with either Xeloda, Herceptin or Xeloda and Herceptin has been generally well tolerated. As reported at ASCO in 2015, the majority of adverse events were Grade 1 or 2. The most common adverse events overall were diarrhea, nausea, constipation, fatigue, palmar-plantar erythrodysesthesia syndrome (PPE) and vomiting, with no Grade 3 diarrhea at the RP2D of ONT-380. Reversible Grade 3 elevations in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) were seen in 6% of patients.

Plans for an international, multi-center Phase 2, randomized, placebo-controlled study of ONT-380 vs placebo in combination with Xeloda and Herceptin were announced in December 2015. This study will enroll patients with unresectable locally advanced or metastatic HER2+ breast cancer that has progressed after prior treatment with Herceptin, a taxane, Perjeta, and Kadcyła. Patients with stable treated brain metastases, asymptomatic untreated brain metastases, or asymptomatic brain metastases that have progressed after prior local treatment are eligible, as are patients without a history of brain metastases. The primary endpoint of the trial is bi-compartmental progression free survival, both CNS and non-CNS, as assessed by independent review using both RECIST 1.1 and Response Assessment in Neuro-Oncology – Brain Metastases (RANO-BM) criteria. Secondary

endpoints include time to CNS progression, ORR, clinical benefit rates (CBR) for both CNS and non-CNS metastatic disease and overall survival. This study opened to enrollment in January 2016.

*Phase 1b Trial of ONT380 in combination with Kadcyra (ado-trastuzumab emtansine or TDM-1):*

The second Phase 1b trial studied ONT-380 in combination with Kadcyra in patients with metastatic HER2+ breast cancer who had progressed following prior treatment with Herceptin and a taxane. This trial was a dose-escalation study of ONT-380 in combination with the approved dose of Kadcyra, with expansion cohorts in patients with and without brain metastases. The primary objective was to determine the MTD/RP2D of ONT-380 in combination with the approved dose of Kadcyra. Secondary objectives included an evaluation of the safety and preliminary anti-tumor activity of the combination.

Interim safety and efficacy data were presented for this trial in December 2014 at SABCS for 17 patients and updated data were presented at SABCS in December 2015 for 57 patients, including 50 treated at maximum tolerated dose (MTD) of ONT-380. Efficacy data for patients with brain metastases including some patients from this trial were also presented in June 2015 at ASCO.

As reported at SABCS 2015, patients treated at the MTD of ONT-380 with Kadcyra had previously been treated with trastuzumab, and in addition, 46% with prior pertuzumab, and 20% with prior lapatinib. Overall, sixty percent of patients had a history of brain metastases and 42% had brain metastases that were either untreated or had progressed after prior local treatment. In this high risk population durable (> 6 months) systemic and CNS responses as well as disease stabilization were seen. The ORR was 41% ( $\frac{14}{34}$ ) in patients with measurable disease and at least one follow-up scan, and CNS response rate was 33% ( $\frac{4}{12}$ ).

The combination of ONT-380 and Kadcyra was clinically well tolerated. In 50 patients treated at the MTD of ONT-380, the majority of adverse events were low grade in severity, Grade 1 or 2 and included nausea, fatigue, diarrhea, vomiting, thrombocytopenia, and asymptomatic elevated liver enzymes. Grade 3 diarrhea occurred in only two patients (4%), with no mandatory use of anti-diarrheal medications. While asymptomatic elevations in ALT/AST were seen in most patients, the majority were Grade 1 or 2 in severity requiring no change in dosing. Asymptomatic Grade 3 elevations were reported in 18% of patients ( $\frac{9}{50}$ ) and Grade 4 elevation in 2% ( $\frac{1}{50}$ ). Except in the setting of progressive liver metastases, all Grade 3 or greater elevations of ALT/AST were reversible with dose interruption and dose reduction of ONT-380 and Kadcyra. Two of fifty patients (4%), experienced asymptomatic decreases in left ventricular ejection fraction, reported as Grade 1 heart failure. Both of these patients had a prior history of treatment with Herceptin and Perjeta. Treatment with both ONT-380 and Kadcyra was discontinued in one of these patients, and treatment with Kadcyra alone was discontinued in a second patient who went on to recover normal cardiac function.

The Dana-Farber Cancer Institute, Boston, Massachusetts, is also currently conducting an investigator-sponsored trial of ONT-380 in combination with Herceptin patients with brain metastases from HER2+ breast cancer.

## **Pre-clinical Product Candidates**

### ***Checkpoint kinase 1 inhibitors***

Checkpoint kinase 1 (Chk1) is a protein kinase that is activated in response to DNA damage and DNA replication stress. Together with other cellular factors, Chk1 provides a coordinated “checkpoint” to arrest the cell division cycle in response to damaged DNA. The induction of this cell cycle checkpoint enables cells to repair DNA lesions and ensures the fidelity of the cell division process. Cancer cells commonly have mutations that reduce

or eliminate the activity of DNA damage response factors that function in parallel with Chk1. These mutations make tumor cells more reliant on the activity of Chk1 to provide cell cycle checkpoint control, which may make them more sensitive to Chk1 inhibitors and produce a synergistic tumor killing effect when combined with DNA targeted chemotherapy drugs.

In pre-clinical studies, Chk1 inhibitors have been shown to inhibit tumor growth as single agents and can substantially increase the effectiveness of anti-cancer drugs that induce DNA damage or target DNA replication. We are developing a series of potent, selective, and orally active Chk1 inhibitors in collaboration with Sentinel. We have identified lead molecules, and currently expect to initiate IND-enabling studies in 2017, which will trigger a \$1.0 million milestone payment to Sentinel. Pursuant to the terms of our agreement with Sentinel, we are responsible for clinical development, manufacture and commercialization.

## **Discovery Research**

### ***Protocells***

Protocells are nanoparticles designed to enable the targeted delivery of a variety of therapeutic agents, including nucleic acids, proteins, peptides or small molecules. We intend to use the protocell technology to develop product candidates for the treatment of cancer, either alone or with partners.

Each protocell consists of a very small silica nano-particle surrounded by a lipid bilayer. The silica nano-particle is synthesized with many small pores and tunnels, creating a large surface area to which the cargo to be delivered is adsorbed. Furthermore, the surface of the silica nano-particle can be chemically modified to optimize the adsorption and release of specific cargos. We are currently focusing our activities with protocells on the targeted delivery of mRNA or RNAi to T cells to activate the immune system against tumors. Future research may also include the application of this technology to directly target tumors to deliver nucleic acids or other drug payloads.

We believe that the potential of the protocell technology may ultimately allow us to create multiple product candidates, not all of which we may be able to develop ourselves. We intend to seek partners to develop these additional product candidates, if any, while retaining the rights to the technology platform for ourselves.

### ***Immunotherapy***

We are collaborating with Adimab for the discovery of novel antibodies against undisclosed immunotherapy targets in oncology. We are utilizing our internal expertise in immunotherapy to screen antibodies identified by Adimab against one or more targets which we have selected. The program is at an early discovery phase.

## **License Agreements**

*Array BioPharma Inc.* In December 2014 we entered into a license agreement with Array. Pursuant to the license agreement, Array has granted us an exclusive license to develop, manufacture and commercialize ONT-380. The license agreement replaced a development and commercialization agreement under which we and Array were previously jointly developing ONT-380. As part of the agreement, we paid Array \$20 million as an upfront fee. In addition, we will pay Array a portion of any payments received from sublicensing ONT-380 rights. If we are acquired within three years of the effective date of the license agreement, Array will be eligible for up to \$280 million in commercial milestone payments. Array is also entitled to receive up to a double-digit royalty based on net sales of ONT-380.

*STC.UNM.* In August 2014, we acquired Alpine and by way of assignment became a party to an exclusive license agreement to protocell technology with STC.UNM, a New Mexico nonprofit corporation affiliated with the University of New Mexico. Under the terms of the license, we have the right to conduct research, clinical development and commercialize all

inventions and products that are developed from the platform technology in certain fields of use as described in the license. Under the license, STC.UNM is eligible to receive success-based milestone payments up to \$5 million of which \$1.2 million has been accrued and recorded in research and development expenses for the year ended December 31, 2015. Royalty obligations under the license agreement include a double-digit royalty on commercial sublicensing income and a low single-digit royalty based on net sales.

*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 two product candidates, including tecemotide (formerly known as L-BLP25 or Stimuvax), a MUC1-based liposomal cancer vaccine. This collaboration agreement was subsequently revised and ultimately replaced in 2008 with a license agreement.

## **Collaborations**

*Sentinel Oncology Ltd.* In 2014 we entered into a research collaboration agreement with Sentinel for the discovery of novel Chk1 inhibitors. Under the agreement we make payments to Sentinel to support their chemistry research. We are responsible for pre-clinical and clinical development, manufacture and commercialization of any resulting compounds. Sentinel is eligible to receive success-based development and commercial milestone payments up to approximately \$90 million based on development and commercialization events, including the initiation of cGMP toxicology studies, the initiation of certain clinical trials, regulatory approval and first commercial sale. We plan to start cGMP toxicology studies in 2017, which will trigger a \$1.0 million milestone payment to Sentinel. Sentinel is also entitled to a single-digit royalty based on net sales.

*Celldex Therapeutics, Inc.* We have been collaborating with Celldex on a combined clinical trial of ONT-10 and varlilumab, a fully human monoclonal antibody that targets CD27. Interim data from these two cohorts did not demonstrate sufficient activity to move forward with the program. Based on these results, we do not plan to conduct any further trials with ONT-10 and in February 2016, we concluded our collaboration with Celldex. No payments were made or are due under this agreement.

*Adimab LLC.* In 2014 we initiated a collaboration with Adimab for the discovery of novel antibodies against undisclosed immunotherapy targets in oncology. Oncothyreon will have sole responsibility for the manufacture, development and commercialization of any antibody products which result. The collaboration is currently at an early discovery stage. Adimab is entitled to research funding, success-based development milestone payments up to \$17 million and a low single digit royalty based on net sales.

## **Acquisitions**

On August 8, 2014, we entered into an Agreement and Plan of Reorganization (Merger Agreement) with Alpine, a privately held biotechnology company developing protocells, a nanoparticle comprising a silica nanoparticle surrounded by a lipid bilayer. Protocells are nanoparticles designed to enable the targeted delivery of nucleic acids, proteins, peptides or small molecules to specific cell types, including T cells or tumor cells. Pursuant to the terms of the Merger Agreement, on August 8, 2014, through a merger sub, we consummated the acquisition of Alpine. In connection with the closing of the acquisition, we issued 9,245,344 shares of our common stock in exchange for all of the outstanding capital stock of Alpine (Merger Consideration). The issued shares represented ten percent of our capital stock on a fully-diluted basis immediately following the acquisition and reflected adjustments made pursuant to the Merger Agreement. The shares are subject to certain resale restrictions. An amount of stock equal to 12.5% of the Merger Consideration was placed in escrow as security for the indemnification obligations of Alpine's stockholders. In February 2016, 50% of the shares held in escrow were released to the Alpine stockholders. We intend to utilize the protocell technology to develop new product candidates for the treatment of cancer either on our own or with partners.

## 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, 2015, we owned approximately 7 U.S. patents and patent applications, and held exclusive or partially exclusive licenses to approximately 37 U.S. patents and patent applications as well as the corresponding foreign patents and patent applications.

Our patents and patent applications are directed to composition and use of our product candidate as well as to our protocell technology and 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 collaborators.

Patent protection afforded by the patents and patent applications covering our clinical product candidates will expire over the following time frames:

<u>Product Candidate</u>	<u>Expiration of U.S. Patent Protection</u>	<u>Expiration of Foreign Patent Protection</u>
ONT-380 . . . . .	2023 – 2032	2024 – 2035
Chk1 Inhibitors . .	2032	N/A

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 generated by the individual in the course of rendering services to us.

## Manufacturing

We currently outsource the manufacturing of drug substances and drug products for ONT-380. This arrangement allows us to use contract manufacturers that already have extensive cGMP manufacturing experience. We have a staff with experience in the management of contract manufacturing and the development of efficient commercial manufacturing processes for our products. We currently intend to outsource the supply of all our commercial products.

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 significant 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.

*ONT-380.* ONT-380 is an inhibitor of the receptor tyrosine kinase HER2, also known as ErbB2. There are multiple marketed products which target HER2, including the antibodies trastuzumab (Herceptin®) and pertuzumab (Perjeta®) and the antibody toxin conjugate ado-trastuzumab emtansine (Kadcyla®), all from Roche/Genentech. In addition, GlaxoSmithKline markets the dual HER1/HER2 oral kinase inhibitor lapatinib (Tykerb®) for the treatment of metastatic breast cancer, Puma Biotechnology is developing the HER1/HER2/HER4 inhibitor neratinib in Phase 3, Merrimack is developing MM-302, a HER2-targeted liposomal doxorubicin in Phase 2, and MacroGenics is developing Margetuximab, a HER2 targeted, Fc-optimized antibody in Phase 3.

*Checkpoint Kinase 1 Inhibitors.* There are currently no marketed drugs which specifically target Chk1. Genentech is conducting a Phase 1 trial of an oral Chk1 inhibitor in patients with refractory solid tumors or lymphoma. Eli Lilly and Company is developing an intravenous Chk1 inhibitor in several clinical settings, the most advanced of which is Phase 2.

## **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 Food and Drug Administration (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 (NDA) route for approval, a new biologic will follow the biologics



license application (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 (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 (SPA), which is an agreement between an applicant and the FDA on the design and size of clinical trials that is intended to form the basis of an NDA or BLA.

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

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

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

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

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

The FDA also has established priority and standard review classifications for original NDAs and efficacy supplements. Priority review applies to the time frame for FDA review of completed marketing applications and is separate from and independent of the Fast Track and accelerated approval mechanisms. The classification system, which does not preclude

the FDA from doing work on other projects, provides a way of prioritizing NDAs upon receipt and throughout the application review process.

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

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

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

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

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

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

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

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

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

### ***Reimbursement***

Sales of biopharmaceutical products depend in significant part on the availability of third party reimbursement, including Medicare. Each third party payer 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 payers. 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, 2015, 2014 and 2013, we expended approximately \$23.5 million, \$41.9 million and \$33.2 million, respectively, on research and development activities. Our research and development expenses included a \$10.0 million upfront license payment to Array in 2013 upon initiation of our ONT-380 collaboration, and a \$20.0 million upfront license payment to Array in 2014 in connection with our exclusive license of ONT-380.

## **Employees**

As of December 31, 2015, we had 53 employees, 41 of whom are engaged in development activities, 12 in finance and administration, and 11 of whom hold Ph.D. and/or M.D. degrees. A number of our management and professional employees have had prior experience with other pharmaceutical or medical products companies.

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

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

## **Financial Information**

We manage our operations and allocate resources as a single reporting segment. Financial information regarding our operations, including net loss, for the years ended December 31, 2015, 2014 and 2013, our total assets, liabilities and stockholders' equity as of December 31, 2015 and 2014, is included in our audited financial statements located elsewhere in this Annual Report on Form 10-K.

## **Item 1A. Risk Factors**

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

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

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

The successful development of pharmaceutical products is highly uncertain. Products that appear promising in research and development may be delayed or fail to reach later stages of development. For example, preliminary data from our Phase 1b trial of ONT-10 in combination with the T-cell agonist antibody varlilumab did not demonstrate sufficient activity to move forward with the program. We, therefore, decided not to continue this trial, and in February 2016 we terminated our collaboration agreement with Celldex. Additionally, the ongoing or future trials for ONT-380 may fail to demonstrate that this product candidate is sufficiently safe and effective to warrant further development.

Furthermore, decisions regarding the further development of product candidates must be made with limited and incomplete data, which makes it difficult to accurately predict whether the allocation of limited resources and the expenditure of additional capital on specific product candidates will result in desired outcomes. Preclinical and clinical data can be interpreted in different ways, and negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent the development of a product candidate, which could harm our business, financial condition or the trading price of our securities. There can be no assurance as to whether or when we will receive regulatory approvals for any of our product candidates, including ONT-380.

#### ***There is no assurance that ONT-380 will be safe, effective or receive regulatory approval.***

ONT-380 is an early stage clinical development candidate and the risks associated with its development are significant. Promising pre-clinical data in animal models and early clinical data may not be predictive of later clinical trial results. Additional clinical data may fail to establish that ONT-380 is effective in treating breast cancer or central nervous system disease or may indicate safety profile concerns not indicated by early clinical data. In December 2014, we announced that interim data from our ongoing Phase 1b trials indicated preliminary clinical activity and tolerability in a heavily pretreated patient population. Updates to some of these data were announced in May 2015 and December 2015 and provided further preliminary evidence of clinical activity and tolerability, including in the central nervous system. However, these trials are not yet complete, and even if final Phase 1 data are encouraging, further trials will be necessary to establish safety and efficacy.

If the results of the current Phase 1 ONT-380 trials, or of future ONT-380 trials, including our Phase 2 trial, do not indicate a favorable safety and efficacy profile for ONT-380, or otherwise fail to support the continued development of ONT-380, a substantial decline in the price of our common stock could result. There can be no assurance as to whether we will be able to successfully develop and commercialize ONT-380.

#### ***Our pipeline as a whole is subject to the inherent risks of early stage pharmaceutical development and our business is highly dependent on the success of ONT-380.***

As a function of their development stage, preclinical programs and product candidates in early clinical development are inherently subject to a high degree of risk. Research programs to identify new product candidates require substantial technical, financial and

human resources. Because our current product pipeline is comprised of technologies in research stage, pre-clinical development and a product candidate in Phase 1 and 2 clinical trials, our business is heavily subject to the risks of early stage pharmaceutical development.

If we are not able to advance our research and preclinical programs or ONT-380 fails, our pipeline of products in development could be reduced or eliminated. This would cause our stock price to decline and would have a material adverse effect on our business, including but not limited to our ability to raise capital to rebuild our pipeline and develop future product candidates.

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

We have expended and continue to expend substantial funds in connection with our product development activities and clinical trials and regulatory approvals. The very limited funds generated currently from our operations will be insufficient to enable us to bring all of our products currently under development to commercialization. Accordingly, we need to raise additional funds from the sale of our securities, partnering arrangements or other financing transactions in order to finance the commercialization of our product candidates. We cannot be certain that additional financing will be available when and as needed or, if available, that it will be available on acceptable terms. If financing is available, it may be on terms that adversely affect the interests of our existing stockholders or restrict our ability to conduct our operations. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. 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;
- our capacity to enter into collaborative or licensing agreements with respect to our protocell technology;
- 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 could have a material adverse effect on our business and financial condition.

***We may not be successful in our efforts to use our protocell platform to develop a pipeline of product candidates or create partnership opportunities.***

We intend to use our protocell platform to discover and develop our own product candidates. Our protocell technology platform is at an early stage of development and has

not yet, and may never, lead to the development of product candidates or valuable intellectual property. Even if we are successful in developing new product candidates, such product candidates may not successfully advance through clinical development, as a result of their harmful side-effects, limited efficacy or other characteristics that make it unlikely such product candidates will receive regulatory approval or achieve commercial success.

We also intend to enter into strategic partnerships with respect to our protocell platform, including business development transactions that license certain rights to our protocell platform to third parties and research collaborations. We may not be successful in entering into any capital-generating transactions with respect to this technology. Establishing strategic partnerships is difficult and time-consuming. Potential partners may reject partnerships based upon their assessment of our technology or product offerings or our financial, regulatory or intellectual property position. If we fail to establish a sufficient number of partners on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further research and development efforts. Even if we establish new partnerships, these relationships may never result in the successful development or commercialization of any product candidates.

***We are currently conducting a search for a new chief executive officer. If we are unable to timely find a suitable permanent chief executive officer or integrate such person into our operations, our business may be harmed.***

In January 2016, our previous chief executive officer retired, and Dr. Christopher Henney, the Chairman of our board of directors, was appointed as our Interim Chief Executive Officer. We are currently conducting a search for a new chief executive officer, but there can be no assurance that a permanent replacement will be found on a timely basis, or at all. In such a case, our inability to find a suitable permanent replacement may have a detrimental impact on our company and impede the progress of our research and development objectives, as well as our ability to raise additional capital as needed.

Additionally, any changes in our business and development strategy that may result from hiring a new chief executive officer or the recent appointment of new directors to our board, may have a disruptive impact on our ability to implement our business and development strategy and could have a material adverse effect on our business. Any changes in business and development strategies can create uncertainty, may negatively impact our ability to execute our business strategy quickly and effectively and may ultimately be unsuccessful. In addition, management transition periods can be difficult as the new management gains detailed knowledge of research and development operations, and friction or further management changes or disruptions could result from changes in strategy and management style. Until we integrate a new chief executive officer, we may be unable to successfully manage our research and development efforts, and our business could suffer as a result.

***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. 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, 2015, our accumulated deficit was approximately \$514.6 million. Our losses have resulted primarily from expenses incurred in research and development of our product candidates. We may make significant capital commitments to fund the development of our product candidates. If these development efforts are unsuccessful, the development costs would be incurred without any future revenue, which could have a material adverse effect on our financial condition. We do not know when or if we will complete our product development efforts, receive regulatory approval for any of our product candidates, or successfully



commercialize any approved products. As a result, it is difficult to predict the extent of any future losses or the time required to achieve profitability, if at all. Any failure of our products to complete successful clinical trials and obtain regulatory approval and any failure to become and remain profitable could adversely affect the price of our common stock and our ability to raise capital and continue operations.

***If we fail to identify and acquire new product candidates, we may be unable to grow our pipeline.***

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

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

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

We may encounter delays if we are unable to enroll enough patients to timely initiate or 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 and competition for patients in completing trials. Moreover, when one product candidate is evaluated in multiple clinical trials simultaneously, patient enrollment in ongoing trials can be adversely affected by negative results from completed trials. Our product candidates are focused in oncology, which can be a difficult patient population to recruit. If we fail to enroll patients for clinical trials, our clinical trials may be delayed or suspended, which could delay our ability to generate revenues or raise capital to fund our operations.

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

We are currently conducting two Phase 1b trials and a Phase 2 trial for ONT-380. There can be no assurance that these and future trials will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals. A number of companies in the biotechnology and pharmaceutical industries, including our company, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. For example, in September 2014, we and Merck KGaA announced that Merck KGaA decided to discontinue the clinical development program of tecemotide in NSCLC, including the Phase III INSPIRE and START2 studies.

Further, we 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 can commercialize the product described in the application. Additionally, even if applications are submitted, regulatory approval may not be obtained for any of our product candidates, and regulatory agencies could require additional studies to verify safety or efficacy, which could make further development of our product candidates impracticable. If our product candidates are not shown to be safe and effective in clinical trials, we may not receive regulatory approval, which would have a material adverse effect on our business, financial condition and results of operations.

***We 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 other impediments with respect to development or manufacturing could adversely affect 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 product candidates in a timely manner, or at all.***

We are responsible for the manufacture of ONT-380, which we outsource to third parties. Manufacturing drug products such as ONT-380 is a complex process involving multiple steps and multiple manufacturers. If our third-party manufacturers cease or interrupt production, if our third-party manufacturers and other service providers fail to supply materials, products or services for any reason or experience performance delays, or if materials or products are lost in transit between manufacturers or in the manufacturing process, such interruption could substantially delay progress on our programs or impact clinical trial drug supply, with the potential for additional costs and a material adverse effect on our business, financial condition and results of operations.

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 our product candidates, 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 will need to successfully transfer manufacturing technology to a new manufacturer. Engaging a new manufacturer for a particular product candidate could require us 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 cGMP requirements enforced by the FDA through its facilities inspection program or by foreign regulatory agencies. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised

due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products.

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

We are currently conducting Phase 1 clinical trials and a Phase 2 clinical trial for ONT-380. 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 ability to obtain regulatory approval to commence a clinical trial and conduct a trial in accordance with good clinical practices;
- our 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 intend to sell those product candidates. Accordingly, we 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.

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

We rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to assist in conducting our clinical trials. We have, in the ordinary course of business, entered into agreements with these third parties. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

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

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

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

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

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

Approval of a product candidate may be conditioned upon certain limitations and restrictions as to the drug's use, or upon the conduct of further studies, and may be subject to continuous review. After approval of a product, if any, there will be significant ongoing regulatory compliance obligations, and if we fail to comply with these requirements, we 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 to delay, restrict or discontinue clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. In addition, all statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Any unanticipated delays in clinical studies could delay our ability to generate revenues and harm our financial condition and results of operations.

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

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

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

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

We have in the past and may in the future seek to expand our pipeline and capabilities by acquiring one or more companies or businesses, entering into collaborations or in-licensing one or more product candidates. For example, in December 2014, we entered into a license agreement with Array for exclusive rights to develop and commercialize ONT-380, and in August 2014, we acquired Alpine Biosciences, Inc., a biotechnology company developing protocells. Acquisitions, collaborations and in-licenses, including our ONT-380 license agreement and Alpine acquisition, 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;
- potential adverse consequences if the acquired assets are worth less than we anticipated;
- difficulties in assimilating the operations and technology of the acquired companies;
- potential disputes, including litigation, regarding contingent consideration for the acquired assets;
- the assumption of unknown liabilities of the acquired businesses;
- 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.

Our experience in making acquisitions, entering collaborations and in-licensing product candidates is limited. We cannot assure you that any acquisition, collaboration 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 may depend in part on our ability to manage the growth and technology

integration associated with some of these acquisitions, collaborations and in-licenses. We cannot assure you that we would be able to successfully combine our business with that of acquired businesses, manage collaborations or integrate in-licensed product candidates or that such efforts would be successful. Furthermore, the development or expansion of our business or any acquired business or company or any collaboration or in-licensed product candidate may require a substantial capital investment by us. We may also seek to raise funds by selling shares of our capital stock, which could dilute our current stockholders' ownership interest, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest upon conversion.

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

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

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

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;
- under our license agreement with Array, Array is responsible for the prosecution of patents related to ONT-380, and they may not effectively prosecute and protect those patents;
- 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 later be invalidated or not give us an advantage over competitors with similar products or technology, nor can we assure you that we can obtain, maintain and enforce all ownership and other proprietary rights necessary to develop and commercialize our product candidates.

In addition to the intellectual property and other rights described above, we also rely on unpatented technology, trade secrets, trademarks and confidential information, particularly

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

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

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

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. Much of our technology, including ONT-380, our protocell technology and our Chk1 kinase inhibitors 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 or technology, which they could attempt to assert against us. Further, as we develop our products, third parties may assert that we infringe the patents currently held or licensed by them and it is difficult to provide the outcome of any such action. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations, as a result of claims of patent infringement or violation of other intellectual property rights, which could have a material and adverse effect on our business, financial condition and results of operations.

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

There has been significant litigation in the biotechnology industry over patents and other proprietary rights and if we become involved in any litigation, it could consume a

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

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

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

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payers to contain or reduce the costs of health care through various means. We expect a number of federal, state and foreign proposals to control the cost of drugs through government regulation. We are unsure of the impact recent health care reform legislation may have on our business or what actions federal, state, foreign and private payers may take in response to the recent reforms. Therefore, it is difficult to predict 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.



Domestic and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare, including drugs. In the United States, there have been, and we expect that there will continue to be, federal and state proposals to implement similar governmental control. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affected the pharmaceutical industry.

We anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and downward pressure on the price for any approved product, and could seriously harm our prospects. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

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

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

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

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

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

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address cancer indications for which we are currently developing products or for which we may develop products in the future. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product candidates. We expect any product candidate that we commercialize with our collaborative partners or on our own will compete with existing, market-leading products and products in development.

**ONT-380.** ONT-380 is an inhibitor of the receptor tyrosine kinase HER2, also known as ErbB2. There are multiple marketed products which target HER2, including the antibodies trastuzumab (Herceptin®) and pertuzumab (Perjeta®) and the antibody toxin conjugate ado-trastuzumab emtansine (Kadcyla®), all from Roche/Genentech. In addition, GlaxoSmithKline markets the dual HER1/HER2 oral kinase inhibitor lapatinib (Tykerb®) for the treatment of metastatic breast cancer, Puma Biotechnology is developing the HER1/HER2/HER4 inhibitor neratinib in Phase 3, Merrimack is developing MM-302, a HER2-targeted liposomal doxorubicin in Phase 2 and MacroGenics is developing Margetuximab, a HER2 targeted, Fc-optimized antibody in Phase 3.

**Checkpoint Kinase 1 Inhibitors.** There are currently no marketed drugs which specifically target Chk1. Genentech is conducting a Phase 1 trial of an oral Chk1 inhibitor in patients with refractory solid tumors or lymphoma. Eli Lilly and Company is developing an intravenous Chk1 inhibitor in several clinical settings, the most advanced of which is Phase 2.

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. We may not be able to enter into such arrangements 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 will 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, including a new Chief Executive Officer, 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 and recent leadership changes, 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 complex environmental legislation that increases both our costs and the risk of noncompliance.***

Our business involves the use of hazardous material, which requires 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 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 for any liability associated with our hazardous

materials activities, and it is possible in the future that our coverage would be insufficient if we incurred a material environmental liability.

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

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

We cannot be certain that the actions we have taken to ensure we have adequate internal controls over financial reporting will be sufficient. In future periods, if the process required by Section 404 of the Sarbanes-Oxley Act reveals any material weaknesses or significant deficiencies, the correction of any such material weaknesses or significant deficiencies could require remedial measures which could be costly and time-consuming. In addition, in such a case, we may be unable to produce accurate financial statements on a timely basis. Any associated accounting restatement could create a significant strain on our internal resources and cause delays in our release of quarterly or annual financial results and the filing of related reports, increase our cost and cause management distraction. Any of the foregoing could cause investors to lose confidence in the reliability of our consolidated financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

***We may face risks related to securities litigation that could result in significant legal expenses and settlement or damage awards.***

We have in the past been, and may in the future become, subject to claims and litigation alleging violations of the securities laws or other related claims, which could harm our business and require us to incur significant costs. We are generally obliged, to the extent permitted by law, to indemnify our current and former directors and officers who are named as defendants in these types of lawsuits. Any future litigation may require significant attention from management and could result in significant legal expenses, settlement costs or damage awards that could have a material impact on our financial position, results of operations, and cash flows.

#### **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. For example, we experienced significant volatility following a release regarding our Phase 1b studies of ONT-380 in

December 2015. 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 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;
- our ability to hire and execute the business strategies of a new chief executive officer;
- technological innovations or new therapeutic products;
- governmental regulations;
- developments in patent or other proprietary rights;
- litigation;
- general market conditions in our industry or in the economy as a whole;
- comments by securities analysts;
- comments made on social media platforms, including blogs, websites, message boards and other forms of Internet-based communications;
- difficulty with the market quickly interpreting and understanding complex data;
- 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; and
- political instability, natural disasters, war and/or events of terrorism.

Additionally, if the closing price of our common stock as reported on the NASDAQ Capital Market falls below \$1.00 for 30 consecutive business days, we will fail to be in compliance with the continued listing requirements of the NASDAQ Capital Market. In such case, if we were unable to regain compliance within the grace period provided by the NASDAQ Stock Market, our shares would become subject to delisting.

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

We expect that we will seek to raise additional capital from time to time in the future. For example, in connection with our February 2015 public offering, we sold an aggregate of 14,699,660 shares of our common stock and 1,333 shares of our Series B convertible preferred stock.

Future financings may involve the issuance of debt, equity and/or securities convertible into or exercisable or exchangeable for our equity securities. These financings may not be available to us on reasonable terms or at all when and as we require funding. If we are able to consummate 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.

***BVF, Inc. owns a significant percentage of our outstanding capital stock and will be able to influence stockholder and management decisions, which may conflict with your interests as a stockholder.***

As of December 31, 2015, BVF Inc. and its affiliates (BVF) collectively held combined voting power over approximately 19.8% of the outstanding shares of our common stock. Additionally, BVF holds shares of our preferred stock convertible into up to 15,333,000 additional shares of our common stock. As a result of its ownership position, BVF may have the ability to significantly influence matters requiring stockholder approval, including, without limitation, the election or removal of directors, mergers, acquisitions, changes of control of our company and sales of all or substantially all of our assets. In addition, pursuant to a letter agreement we entered into with BVF in January 2016, BVF nominated two new members to our board of directors, one of which is the President of BVF and beneficially owns the shares held by BVF. As a result, BVF has significant influence in our management and affairs. This control may delay, deter or prevent acts that may be favored by our other stockholders, as the interests of BVF may not always coincide with the interests of our other stockholders. In addition, this concentration of share ownership may adversely affect the trading price of our shares because it may limit the trading volume and purchase demand for outstanding shares and investors may perceive disadvantages in owning shares in a company with a significant stockholder.

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

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

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

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

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

We have in the past issued, and we may at any time in the future issue, additional shares of authorized preferred stock. For example, in connection with our September 2014 and February 2015 public offerings, we issued 10,000 shares of Series A convertible preferred stock and 1,333 shares of Series B convertible preferred stock, respectively, each share of which is convertible into 1,000 shares of the Company's common stock, subject to certain ownership restrictions. Concurrently but separate from the February 2015 offering, we entered into an exchange agreement with certain affiliates of BVF to exchange 4,000,000 shares of common stock previously purchased by BVF for 4,000 shares of Series B Convertible Preferred Stock. In May 2015, we entered into an exchange agreement with certain affiliates of BVF to exchange 7,500,000 shares of common stock previously purchased by BVF for 7,500 shares of Series C Convertible Preferred Stock. Shares of our Series A, Series B and Series C preferred stock are convertible into common stock on a 1-for-1,000 basis. If the holders of such shares of preferred stock convert their shares into common stock, existing holders of our common stock will experience dilution.

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

In our September 2014 public offering, we sold 11,500,000 shares of our common stock and 10,000 shares of our Series A convertible preferred stock for net proceeds of approximately \$40.2 million. In our February 2015 public offering, we sold 14,699,660 shares of common stock and 1,333 shares of Series B convertible preferred stock for net proceeds of approximately \$22.4 million. We have broad discretion over the use of proceeds from the sale of those shares, and we could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

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

None.

#### **ITEM 2. *Properties***

##### **Description of Property**

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

#### **ITEM 3. *Legal Proceedings***

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

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

Not applicable.

## PART II

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

#### Market Information for Common Stock

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

	<u>High</u>	<u>Low</u>
Fiscal year ended December 31, 2015:		
First Quarter .....	\$ 1.98	\$ 1.48
Second Quarter .....	4.69	1.41
Third Quarter .....	4.02	2.63
Fourth Quarter .....	3.75	2.10
Fiscal year ended December 31, 2014:		
First Quarter .....	\$4.08	\$ 1.73
Second Quarter .....	3.56	2.16
Third Quarter .....	3.60	1.92
Fourth Quarter .....	2.35	1.52

#### 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, 2016, there were 94,961,859 shares of our common stock outstanding held by approximately 652 stockholders of record and approximately 24,100 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."

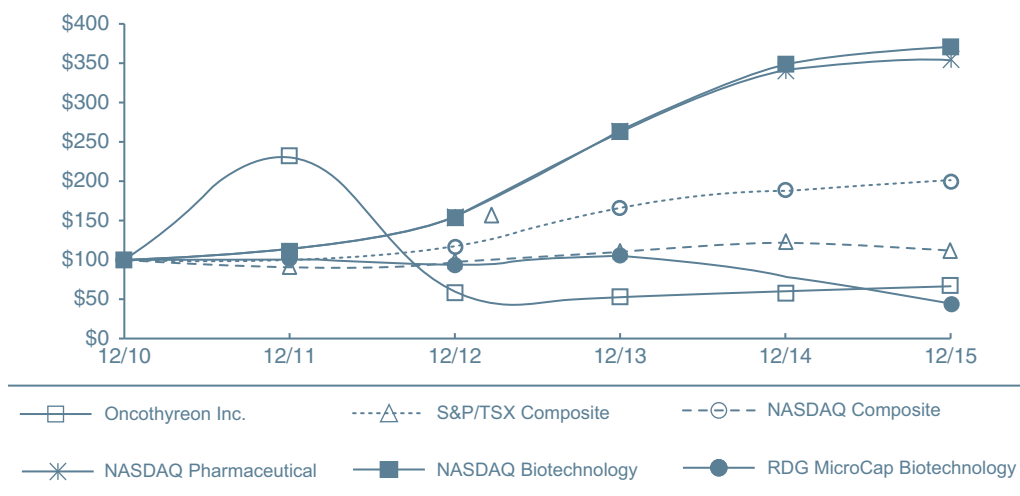
#### Stock Performance Graph

*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 (the Exchange Act) and it shall not be deemed to be incorporated by reference into any of our filings under the Exchange Act or the Securities Act of 1933, as amended, except to the extent we specifically incorporate it by reference into such filing.*



The graph below compares the cumulative total stockholder return of our common stock with that of the NASDAQ Composite Index, NASDAQ Pharmaceutical Index, NASDAQ Biotechnology Index, RDG MicroCap Biotechnology Index and a composite S&P/TSX index from December 31, 2010 through December 31, 2015. 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 12/31/10 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

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**Unregistered Sale of Equity Securities**

During the three months ended December 31, 2015, we did not issue or sell any shares of our common stock or other equity securities pursuant to unregistered transactions in reliance upon exemption from the registration requirements of the Securities Act of 1933, as amended.

**Issuer Purchases of Equity Securities**

We did not make any purchases of our outstanding common stock during the three months ended December 31, 2015.

## ITEM 6. Selected Financial Data

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

	Year Ended December 31,				
	2015	2014	2013	2012	2011
	(Amounts in thousands, except share and per share data.)				
<b>Consolidated Statements of Operations Data:</b>					
Total revenues	\$ —	\$ —	\$ —	\$ —	\$ 145
Total operating expenses	32,789	50,835	41,223	28,499	24,844
Loss from operations	(32,789)	(50,835)	(41,223)	(28,499)	(24,699)
Net loss(1)	<u>\$ (32,581)</u>	<u>\$ (49,963)</u>	<u>\$ (38,759)</u>	<u>\$ (3,415)</u>	<u>\$ (42,656)</u>
Loss per share – basic	<u>\$ (0.34)</u>	<u>\$ (0.64)</u>	<u>\$ (0.62)</u>	<u>\$ (0.06)</u>	<u>\$ (1.12)</u>
Loss per share – diluted	<u>\$ (0.34)</u>	<u>\$ (0.64)</u>	<u>\$ (0.62)</u>	<u>\$ (0.53)</u>	<u>\$ (1.12)</u>
Weighted average number of common shares outstanding – basic	<u>96,617,119</u>	<u>77,619,807</u>	<u>62,387,616</u>	<u>53,728,672</u>	<u>38,197,666</u>
Weighted average number of common shares outstanding – diluted	<u>96,617,119</u>	<u>77,619,807</u>	<u>62,387,616</u>	<u>54,899,955</u>	<u>38,197,666</u>
	As of December 31,				
	2015	2014	2013	2012	2011
	(Amounts in thousands, except share data.)				
<b>Consolidated Balance Sheets Data:</b>					
Cash, cash equivalents and short-term investments	\$ 56,360	\$ 57,671	\$ 60,027	\$ 81,254	\$ 63,876
Total assets(2)	\$ 96,574	\$ 103,103	\$ 77,512	\$ 89,128	\$ 71,539
Total long-term liabilities	\$ 8,044	\$ 7,430	\$ 1,536	\$ 4,041	\$ 33,236
Stockholders’ equity	\$ 83,735	\$ 91,266	\$ 71,550	\$ 82,323	\$ 33,433
Common shares outstanding	94,961,859	91,601,352	70,673,143	57,216,237	43,613,107

- (1) Net loss includes income (expense) from the change in fair market value of warrant liability of \$0.1 million, \$0.8 million, \$2.3 million, \$25.5 million and (\$17.6) million for the years ended December 31, 2015, 2014, 2013, 2012 and 2011, respectively. Please refer to the audited financial statements included elsewhere in this Annual Report on Form 10-K for details on net loss for the years ended December 31, 2015, 2014 and 2013. For additional information on net loss for the years ended December 31, 2012 and 2011, please refer to our Annual Reports on Form 10-K for those years.
- (2) In November 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes”. The standard requires that deferred tax assets and liabilities be classified as noncurrent on the balance sheet rather than being separated into current and noncurrent. We adopted the standard on a retrospective basis beginning with the year ended December 31, 2012, and applied it consistently through the year ended December 31, 2015. The adoption of this standard resulted in the classification of noncurrent deferred tax liabilities of \$0.2 million, \$0.3 million, \$0.2 million and \$0.3 million, respectively, on our consolidated balance sheets as of December 31, 2015, 2014, 2013 and 2012. The netting of noncurrent liabilities with noncurrent assets resulted in the reduction of total assets for the periods presented.

## **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 discover, develop and commercialize novel compounds that have the potential to improve the lives and outcomes of cancer patients. Our lead clinical-stage product candidate is ONT-380, an orally active and selective small-molecule HER2 inhibitor. We are also developing preclinical product candidates in oncology using our Chk1 kinase inhibitor and our protocell technology.

ONT-380 is a selective small molecule inhibitor of HER2, also known as ErbB2, a receptor tyrosine kinase that is over-expressed in breast cancer and other cancers, such as gastric and ovarian cancer. We are developing ONT-380 for the treatment of HER2-positive (HER2+) metastatic breast cancer. Over-expression of HER2 in breast cancer historically has been associated with increased mortality in early stage disease, decreased time to relapse, and increased incidence of metastases. The introduction of HER2-targeted therapies, including antibody based therapies as well as the small molecule tyrosine kinase inhibitor lapatinib, has led to improvement in the outcomes of patients with HER2+ cancer. Unlike lapatinib, a dual HER2/EGFR inhibitor approved for treatment of Her2+ breast cancer, ONT-380 selectively inhibits HER2. This specificity may lead to improved tolerability due to decreased rates of toxicities associated with EGFR inhibition, including skin toxicity and Grade 3 (severe) diarrhea, particularly in combination with chemotherapy such as capecitabine. ONT-380 has also demonstrated activity in animal models of HER2+ brain tumors suggesting that it may be a potential new treatment for patients with HER2+ breast cancer and brain metastases. We have an exclusive license agreement with Array BioPharma Inc. (Array) to develop, manufacture and commercialize ONT-380. We are currently conducting two Phase 1b trials of ONT-380, one in combination with Kadcyla® (ado-trastuzumab emtansine or TDM-1) and another in combination with Xeloda® (capecitabine) and/or Herceptin® (trastuzumab). Interim data from these trials indicated tolerability and preliminary clinical activity, including in the central nervous system, in a heavily pretreated patient population.

We recently completed the evaluation of two dosing cohorts in our Phase 1b trial of ONT-10, a therapeutic vaccine targeting the Mucin 1 peptide antigen (MUC1), in combination with the anti-CD27 T-cell agonist antibody varlilumab in collaboration with Celldex. Preliminary data from these two cohorts did not demonstrate sufficient activity to move forward with the program. Based on these results, we do not plan to conduct any further trials with ONT-10 and have ended our collaboration with Celldex.

We are increasingly focused on expanding our pipeline of product candidates through both internal research and collaborative efforts. To support our internal efforts, in August 2014 we acquired Alpine Biosciences, Inc., of Seattle, Washington (Alpine), a privately held biotechnology company developing protocells, a novel nanoparticle platform technology designed to enable the targeted delivery of therapeutic agents, including nucleic acids, proteins, peptides or small molecules. We intend to utilize the protocell technology to develop new product candidates for the treatment of cancer, either on our own or with partners. We are also collaborating with Sentinel Oncology Ltd., of Cambridge,

United Kingdom (Sentinel) to develop novel small molecule Chk1 kinase inhibitors. In addition, we are collaborating with Adimab LLC of Lebanon, New Hampshire to discover novel antibodies against undisclosed immunotherapy targets in oncology.

We have not developed a therapeutic product to the commercial stage. As a result, our revenue has been limited to date and our ability to generate revenue in future periods, if at all, will depend substantially on the progress of ongoing and potential future clinical trials for ONT-380 and any future product candidates, our success in obtaining regulatory approval for ONT-380 and any future product candidates and our ability to establish commercial markets for these drugs.

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 current good manufacturing practice (cGMP) material. We expect expenditures associated with these activities to increase in future years as we continue the development of ONT-380 and as we advance the development of our preclinical pipeline.

We have incurred substantial losses since our inception. As of December 31, 2015, our accumulated deficit totaled \$514.6 million. We incurred a net loss of \$32.6 million for the year ended December 31, 2015 compared to a net loss of \$50.0 million for the same period in 2014. The decrease in loss for the year ended December 31, 2015 was primarily due to a \$20.0 million upfront payment we paid Array upon entering into an exclusive license agreement in December 2014. See the section captioned “Note 8 – Collaborative and License Agreements” of the audited financial statements included elsewhere in this Annual Report on Form 10-K for additional information. The decrease in loss was partially offset by slightly higher general and administrative expenses and lower non-cash income from the change in the fair value of our warrant liability, which was \$0.1 million for the year ended December 31, 2015 compared to \$0.8 million for the year ended December 31, 2014. The change in the fair value of our warrant liability was due to the expiration of our September 2010 warrants. In future periods, we expect to continue to incur substantial net losses as we expand our research and development activities with respect to our product candidates. To date we have funded our operations principally through the sale of our equity securities, cash received through our prior strategic alliance with Merck KGaA, government grants, debt financings and equipment financings.

## **Key Financial Metrics**

### ***Expenses***

*Research and Development.* Research and development expense 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 primarily include external research and development expenses incurred pursuant to collaboration agreements; agreements with third-party manufacturing and contract research organizations; technology access and licensing fees related to the use of proprietary third-party technologies; and internal expenses associated with employee related costs, including salaries, share-based compensation expense, benefits and related costs; allocated facility overhead which includes depreciation and amortization; and third-party consulting and supplier expenses. We recognize research and development expenses, including those paid to third parties, as they are incurred.

*General and Administrative.* General and administrative expense consists principally of salaries, benefits, share-based compensation expense and related costs for personnel in our executive, business development, finance, accounting, legal, human resource functions and information technology services. 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) consisted of interest and other income on our cash and short-term and long-term investments, debt, foreign exchange gains and losses and other non-operating income (expense). Our investments consist of debt securities of U.S. government agencies and corporate bonds.

*Change in Fair Value of Warrants.* Warrants issued in connection with our securities offerings in May 2009 and September 2010 were classified as a liability due to their potential settlement in cash and other terms, and as such, were recorded at their estimated fair value on the date of the closing of the respective transactions. The warrants issued in connection with our May 2009 securities offering expired in May 2014 and the warrants issued in connection with our September 2010 securities offering expired in October 2015. The warrants are marked to market for each financial reporting period, with changes in estimated fair value recorded as a gain or loss in our consolidated statements of operations. The fair value of the warrants is determined using the Black-Scholes option-pricing model, which requires the use of significant judgment and estimates for the inputs used in the model. For more information, see “Note 3 — Fair Value Measurements” and “Note 6 — Share Capital” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

*Income Tax Benefit (Provision) for Income Tax.* Due to our history of significant losses, we do not recognize the benefit of net operating losses and have established a full valuation allowance against our net deferred tax assets since the realization of these benefits is not reasonably assured.

### **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 U.S. generally accepted accounting principles. 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 SEC 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:

- goodwill impairment;
- indefinite-lived intangible assets — in-process research and development (IPR&D);

- share-based compensation;
- warrant liability; and
- business combinations.

### ***Goodwill Impairment***

Goodwill is not amortized, but is reviewed annually for impairment on October 1 of each year, or more frequently when events or changes in circumstances indicate that the asset may be impaired. As of December 31, 2015, we had one reporting unit and there was an excess of fair value compared to the carrying value. There were no impairment charges recorded for any of the periods presented.

### ***Indefinite-lived Intangible Assets – IPR&D***

Intangible assets with indefinite lives represent the value assigned to IPR&D that, as of the acquisition date, the Company determined that technological feasibility had not been established, and the IPR&D had no alternative future use. The IPR&D will be subject to annual impairment testing until completion or abandonment of the projects. Upon completion of the project, the Company will make a separate determination of useful life of the IPR&D and the related amortization will be recorded as an expense over the estimated useful life. If the IPR&D is abandoned, the carrying value of the asset will be expensed. All research and development costs incurred subsequent to the acquisition of Alpine are expensed as incurred. The Company performs an annual impairment assessment on October 1 of each year for the IPR&D assets, or more frequently if indicators of potential impairment exist, to determine whether it is more likely than not that the carrying value of the assets may not be recoverable. Recoverability of IPR&D is measured by comparing the carrying amount of the asset to the fair value. If the Company determines that an individual asset is impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. As of December 31, 2015, no impairment charges were recorded for any of the periods presented.

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

We maintain a share option plan under which an aggregate of 7,350,500 shares of common stock underlie outstanding options and, as of December 31, 2015, an aggregate of 1,765,777 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, 2015, there were 533,006 shares reserved for future purchases under the ESPP. We maintain a restricted share unit plan. On June 6, 2014, our stockholders approved an increase of 500,000 shares in the number of shares of our common stock reserved for issuance under the RSU Plan. As of December 31, 2015, an aggregate of 228,943 shares of common stock underlying restricted stock units (RSUs) were outstanding and an aggregate of 391,788 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. Pursuant to an October 2011 amendment to the RSU plan, approximately 25% of each RSU represents a contingent right to receive cash upon vesting, and we are required to deliver an amount in cash equal to the fair market value of approximately 25% of the vesting shares on the vesting date to facilitate the satisfaction of the non-employee directors' U.S. federal income tax obligation with respect to the vested RSUs. The outstanding RSU awards are required to be re-measured at each reporting date until settlement of the award, and changes in valuation are recorded as compensation expense for the period. To the extent that the liability recorded in the balance sheet for a modified award is less than the original award value, the difference is recognized in equity.

We use the closing share price of our shares in The NASDAQ Global Market at the reporting or settlement date to determine the fair value of RSUs. We use the Black-Scholes

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

### ***Warrant Liability***

In September 2010, we issued warrants to purchase 3,182,147 shares of our common stock in connection with a registered direct offering of our common stock and warrants. These warrants were classified as liabilities due to potential cash settlement upon the occurrence of certain transactions specified in the warrant agreement. Accordingly, the estimated fair value of the warrants is recorded on our December 31, 2014 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. Warrants to purchase 3,182,147 shares of our common stock from the September 2010 financing expired on October 12, 2015. As of December 31, 2015, no warrants that were classified as liabilities were outstanding.

### ***Business Combination***

In a business combination, we determine if the acquired property and activities meet the definition of a business under current accounting guidance. If the combination meets the definition of a business, we measure the significance of the combination to determine the required reporting and disclosure requirements for the transaction. Business combinations are required to be accounted for under the acquisition method which requires that identifiable assets acquired, liabilities assumed and any noncontrolling interest in the acquiree be recognized and measured as of the acquisition date at fair value. In addition, all consideration transferred must be measured at its acquisition-date fair value.

When necessary, we use a third party valuation expert to determine the fair value of the identifiable assets and liabilities acquired. The estimated fair values of in-process research and development (IPR&D) acquired in a business combination which have not been fully developed are capitalized as indefinite-lived intangible assets and impairment testing is conducted periodically.

## Results of Operations for the years ended December 31, 2015, 2014 and 2013

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

### Overview

	Years Ended December 31,		
	2015	2014	2013
		(In millions)	
Operating expenses .....	\$(32.8)	\$(50.8)	\$(41.2)
Change in fair value of warrant liability .....	\$ 0.1	\$ 0.8	\$ 2.3
Net loss .....	\$(32.6)	\$(50.0)	\$(38.8)

Operating expenses were lower for the year ended December 31, 2015 compared to the year ended December 31, 2014 primarily as a result of a \$20.0 million upfront fee we paid Array upon entering into an exclusive license agreement in December 2014. See “Note 8 – Collaborative and License Agreements” of the audited financial statements included elsewhere in this Annual Report on Form 10-K for additional information. The decrease was partially offset by slight increases in general and administrative expenses.

We incurred a net loss of \$32.6 million for the year ended December 31, 2015 compared to a net loss of \$50.0 million for the year ended December 31, 2014. The decrease in our net loss was primarily due to decreases in operating expenses, partially offset by lower non-cash income from the change in the fair value of our warrant liability, which was \$0.1 million for the year ended December 31, 2015 compared to \$0.8 million for the year ended December 31, 2014.

Income or expense associated with the change in fair value of the warrant liability is the result of the re-measurement of the fair value of the warrant liability at each reporting date. Changes in the fair value of the warrant liability are attributable to increases or decreases in our stock price, volatility and expected life of our liability-classified warrants. In addition, the change in fair value was also due to the expiration of our September 2010 and May 2009 warrants. For more information, see “Note 3 – Fair Value Measurements” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

We incurred a net loss of \$50.0 million for the year ended December 31, 2014 compared to a net loss of \$38.8 million for the year ended December 31, 2013. The increase in our net loss was primarily due to an increase of \$10.0 million in license fees paid to Array. In December 2014, we paid Array \$20.0 million upon entering into an exclusive license agreement, which superseded the collaboration agreement with Array under which we paid Array \$10.0 million in 2013. In addition, the increase in our net loss was also due to lower non-cash income from the change in the fair value of our warrant liability, which was \$0.8 million for the year ended December 31, 2014 compared to \$2.3 million for the year ended December 31, 2013.

Based on our development plans for our product candidates, we will continue to incur operating losses for the foreseeable future.

### Research and Development

	Years Ended December 31,		
	2015	2014	2013
		(In millions)	
Research and development .....	\$23.5	\$41.9	\$33.2

Research and development expenses are related primarily to the development of our discovery research, pre-clinical and clinical stage programs. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis because we are organized and record expense by functional area.



The following table summarizes our research and development expenses by functional area for the years ended December 31, 2015, 2014 and 2013:

	Years Ended December 31,		
	2015	2014	2013
	(In millions)		
<b>External expenses<sup>(1)</sup></b>			
Preclinical research expenses .....	\$ 2.9	\$ 2.2	\$ 1.7
Clinical development expenses .....	6.6	5.5	8.3
Manufacturing expenses .....	0.8	3.1	3.5
License Fees/Milestones .....	0.1	20.1	10.0
<b>Total external expenses</b> .....	<u>10.4</u>	<u>30.9</u>	<u>23.5</u>
All other expenses <sup>(2)</sup> .....	<u>13.1</u>	<u>11.0</u>	<u>9.7</u>
<b>Total research and development</b> .....	<u><u>23.5</u></u>	<u><u>41.9</u></u>	<u><u>33.2</u></u>

(1) *External expenses include costs paid to outside parties for activities associated with our preclinical, clinical and manufacturing efforts as well as costs associated with licensing agreements we have entered into with third parties.*

(2) *All other expenses include personnel costs, stock compensation expenses, facility and equipment costs and other internal costs associated with our research and development activities.*

In the year ended December 31, 2015, research and development expenses decreased by \$18.4 million, or 43.9%, compared to the year ended December 31, 2014, due primarily to the \$20.0 million upfront fee paid to Array in 2014. In addition, the decrease in research and development expenses was due to a decrease in contract manufacturing expenses of \$2.3 million related to clinical materials. The decreases were partially offset by increases in clinical development expenses of \$1.1 million related to contract clinical services associated with the ongoing clinical trials, preclinical research expenses of \$0.7 million related to laboratory supplies and services, and other expenses of \$2.1 million primarily due to increases in headcount.

In the year ended December 31, 2014, research and development expenses increased by \$8.7 million, or 26.2%, compared to the year ended December 31, 2013, due primarily to the net \$10.0 million increase in license fees paid to Array. In addition, the increase in research and development expenses was due to increase in other expenses of \$1.3 million primarily due to increases in headcount. The increase was partially offset by a decrease in clinical development expenses of \$2.8 million related to contract clinical services associated with the ongoing clinical trials.

### **General and Administrative**

	Years Ended December 31,		
	2015	2014	2013
	(In millions)		
General and administrative .....	\$9.3	\$9.0	\$8.0

The \$0.3 million, or 3.3%, increase in general and administrative expense for the year ended December 31, 2015 relative to the year ended December 31, 2014 was principally due to a \$0.2 million increase in director compensation that was primarily related to grants and change in fair value of RSUs on conversion and re-measurement. The change in fair value of RSUs was attributable to the change in the price of our common stock. For more information related to the liability-classified RSUs, see “Note 7 — Share-based Compensation” of the audited financial statements included elsewhere in this Annual Report on Form. In addition, the increase in general and administrative expenses was due to a \$0.2 million increase in professional fees primarily related to legal, patent and regulatory compliance activities.

The \$1.0 million, or 12.5%, increase in general and administrative expense for the year ended December 31, 2014 relative to the year ended December 31, 2013 was principally due to a \$0.5 million increase in professional fees primarily related to our August 2014 acquisition of Alpine. In addition, the increase in general and administrative expenses was due to a \$0.3 million increase in salaries and benefits expense attributable to increased headcount and a \$0.2 million increase in director compensation expense primarily related to grants and the change in fair value of RSUs on conversion.

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

	Years Ended December 31,		
	2015	2014	2013
		(In millions)	
Change in fair value of warrant liability . . . . .	\$0.1	\$0.8	\$2.3

The \$0.1 million, \$0.8 million and \$2.3 million non-cash income recorded during the year ended December 31, 2015, 2014 and 2013, respectively, was due to the change in the estimated fair value of warrant liability during that period. The change in the fair value of the warrant liability was attributable to changes in our stock price, volatility and expected life of our warrants that were classified as liabilities. The change in fair value for the year ended December 31, 2015 and 2014 was due to the expiration of our September 2010 warrants and the expiration of our May 2009 warrants, which expired on October 12, 2015 and May 26, 2014, respectively. We determined 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.

**Liquidity and Capital Resources**

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

As of December 31, 2015, our principal sources of liquidity consisted of cash and cash equivalents of \$27.9 million and short-term investments of \$28.5 million. Our cash and cash equivalents consist of cash, money market funds and securities with an initial maturity of less than 90 days. Our short-term investments are invested in debt securities of U.S government agencies and corporate bonds with maturities not exceeding 12 months from December 31, 2015. Our long-term investments are invested in debt securities of U.S government agencies with maturities exceeding 12 months from December 31, 2015. Our primary source of cash has historically been proceeds from the issuance of equity securities, exercise of warrants, debt, 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 \$27.9 million as of December 31, 2015 compared to \$10.5 million as of December 31, 2014, an increase of \$17.4 million, or 165.7%. The increase was the result of net proceeds of \$22.4 million from our February 2015 financing and net investment redemption of \$24.5 million, partly offset by cash used to fund our operations of \$28.9 million and capital equipment purchases of \$0.8 million.

As of December 31, 2015, our working capital (defined as current assets less current liabilities) was \$53.2 million compared to \$54.5 million as of December 31, 2014, a decrease of \$1.3 million, or 2.4%. The decrease in working capital was primarily attributable to a net decrease in cash, cash equivalents and short-term investments of \$1.3 million and increase in accrued and other liabilities of \$0.9 million, partly offset by an increase in prepaid and other current assets of \$0.5 million and a decrease in accounts payable of \$0.3 million.

On February 11, 2015, we closed concurrent but separate underwritten offerings of 13,500,000 shares of our common stock at a price to the public of \$1.50 per share, for gross proceeds of approximately \$20.3 million and 1,333 shares of our Series B convertible preferred stock at a price to the public of \$1,500 per share, for gross proceeds of

approximately \$2.0 million. Each share of Series B convertible preferred stock is non-voting and convertible into 1,000 shares of the Company's common stock, provided that conversion will be prohibited if, as a result, the holder and its affiliates would beneficially own more than 4.99% of the common stock then outstanding. As part of the common stock offering, we also granted the underwriters a 30-day option to purchase 2,025,000 additional shares of our common stock. On February 18, 2015, we closed a partial exercise of the underwriter's option to purchase 1,199,660 additional shares of our common stock, at a price to the public of \$1.50 per share, less underwriting discounts and commissions, which resulted in net proceeds to us of approximately \$1.7 million. Aggregate gross proceeds from the offerings were approximately \$24.0 million. Aggregate net proceeds from the offerings, after underwriting discounts and commissions and estimated expenses of \$1.6 million, were approximately \$22.4 million.

On September 23, 2014, we closed concurrent but separate underwritten offerings of 10,000,000 shares of our common stock at a price of \$2.00 per share and 10,000 shares of our Series A convertible preferred stock at a price of \$2,000 per share. Each share of Series A convertible preferred stock is non-voting and convertible into 1,000 shares of our common stock at the option of the holder, provided that conversion will be prohibited if, as a result, the holder and its affiliates would beneficially own more than 4.99% of our common stock then outstanding. As part of the common stock offering, the underwriters exercised a 30-day option to purchase 1,500,000 additional shares of our common stock. Aggregate gross proceeds from the offerings were approximately \$43.0 million. Aggregate net proceeds from the offerings, after commissions and estimated expenses of \$2.8 million, were approximately \$40.2 million.

We believe that our currently available cash and cash equivalents and investments will be sufficient to finance our operations for at least the next 12 months. Nevertheless, we expect that we will require additional capital from time to time in the future in order to continue the development of products in our pipeline and to expand our product portfolio. We would expect to seek additional financing from business development activities and the sale and issuance of equity or debt securities.

### ***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 changes in warrant liabilities.

Cash used by operating activities totaled \$28.9 million for the year ended December 31, 2015, compared to \$48.4 million for the year ended December 31, 2014. The decrease was attributable primarily to a decrease of \$20.0 million in license fees. In December 2014, we paid Array \$20.0 million upon entering into an exclusive license agreement. See "Note 8 – Collaborative and License Agreements" of the audited financial statements included elsewhere in this Annual Report on Form 10-K for additional information. The decrease was partially offset by slight increases in general and administrative expenses of \$0.4 million.

Cash used by operating activities totaled \$48.4 million for the year ended December 31, 2014, compared to \$36.3 million for the year ended December 31, 2013. The increase was attributable primarily to an increase in general and administrative expense of \$1.2 million and an increase of \$10.0 million in license fees paid to Array. In December 2014, we paid Array \$20.0 million upon entering into an exclusive license agreement. The exclusive license agreement superseded the collaboration agreement with Array under which we paid Array \$10.0 million in 2013.

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

Cash provided by investing activities was \$23.7 million for the year ended December 31, 2015, compared to \$9.2 million for the year ended December 31, 2014. This change was attributable primarily to redemption of investments, net of purchases, of \$24.5 million for the year ended December 31, 2015 as compared to \$9.5 million for the year ended December 31, 2014, partly offset by an increase in purchases of property and equipment of \$0.4 million during the year ended December 31, 2015 compared to the same period in 2014.

Cash provided by investing activities was \$9.2 million for the year ended December 31, 2014, compared to cash used in investing activities of \$2.7 million for the year ended December 31, 2013. This change was attributable primarily to redemption of investments, net of purchases, of \$9.5 million for the year ended December 31, 2014 as compared to purchases, net of redemptions, of investments of \$2.5 million for the year ended December 31, 2013.

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

Cash provided by financing activities was \$22.6 million during the year ended December 31, 2015, which primarily consisted of net proceeds of approximately \$22.4 million from our February 2015 concurrent but separate underwritten common stock and Series B convertible preferred stock offerings. Net proceeds from our common stock offering were \$20.5 million and net proceeds from our Series B convertible preferred stock offering were \$1.9 million.

Cash provided by financing activities was \$40.4 million during the year ended December 31, 2014, which consisted of net proceeds of approximately \$40.2 million from our September 2014 concurrent but separate underwritten common stock and Series A convertible preferred stock offerings. Net proceeds from our common stock offering were \$21.6 million and net proceeds from our Series A convertible preferred stock offering were \$18.6 million.

Cash provided by financing activities was \$26.1 million during the year ended December 31, 2013, which consisted of net proceeds of \$16.0 million received from the sale of our common stock through our "at the market" equity offering program under the Sales Agreement with Cowen, net proceeds of \$9.9 million received from a registered direct offering completed in June 2013 and cash received of \$0.1 million from ESPP purchases.

### **Contractual Obligations and Contingencies**

In our continuing operations, we have entered into long-term contractual arrangements from time to time for our facilities, the provision of goods and services, and the acquisition of technology access rights, among others. The following table presents contractual obligations arising from these arrangements as of December 31, 2015:

		<b>Payments Due by Period</b>			
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1 – 3 Years</b>	<b>3 – 5 Years</b>	<b>After 5 Years</b>
		<b>(In thousands)</b>			
Operating leases .....	<u>\$1,934</u>	<u>\$652</u>	<u>\$1,282</u>	<u>\$—</u>	<u>\$—</u>

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

In addition to the obligations described above, under certain licensing arrangements for technologies incorporated into our product candidates, we are contractually committed to payments for licensing fees and royalties, as well as contingent payments if certain

milestones (as defined in the agreements) have been achieved. The achievement of milestones is subject to numerous factors, and we cannot predict when or if such milestones will be achieved. For additional detail concerning the financial terms of our licensing arrangements, please refer to “Note 8 – Collaborative and License Agreements” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

As of December 31, 2015, none of the milestones, as defined in the agreements, were achieved and, as such, we are not currently contractually committed to any significant quantifiable payments for royalties or other contingent payments. As of December 31, 2015 we have recorded \$1.2 million in time-based milestones for license fees associated with our agreement with STC.UNM. No other license fees or milestones were achieved or quantifiable.

We also enter into contracts in the ordinary course of our business such as clinical research organization service contracts and manufacturing service contracts. These contracts are fee for service contracts that are terminable at will by us, and do not provide for fixed payments to be made at specific intervals. Payments for these contracts are expensed in the period that the service is incurred.

### **Guarantees and Indemnification**

In the ordinary course of our business, we have entered into agreements with our licensors, vendors, and other persons and entities that include guarantees or indemnity provisions. For example, our agreements with licensors, clinical trial sites, manufacturers and other contract partners contain indemnification provisions and we have entered into indemnification agreements with our officers and directors. Based on information known to us as of the filing date of this report, 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 February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), to improve financial reporting for leasing transactions. The new standard requires lessees to recognize on the balance sheets for a right of use asset and related lease liability. Lessor accounting under the new standard remains similar under current GAAP. The ASU also requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. The effective date for public entities is fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted for all entities. We are currently evaluating any impact this standard may have on our consolidated financial position and results of operations.

In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes, to simplify the presentation of deferred income taxes. The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this update apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update. We adopted the new guidance retrospectively beginning with the year ended December 31, 2012, and applied consistently through the year ended December 31, 2015. The retrospective adoption of this update had no effect on reported operating expenses, loss from operations, net loss, loss per share, financial position or change in cash used in or provided by operating, investing, or financing activities.

In August 2015, FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606) — Deferral of the Effective Date, which defers by one year the effective date of ASU 2014-09, Revenue from Contracts with Customers. For public entities, the standard is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Early adoption is permitted as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. We are currently evaluating any impact this standard may have on our consolidated financial position and results of operations.

In April 2015, FASB issued ASU 2015-05, Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40) Customer's Accounting for Fees Paid in a Cloud Computing Arrangement, to clarify the accounting treatment for cloud computing arrangements. The new standard provides guidance on how customers should evaluate whether a cloud computing arrangement contains a software license that should be accounted for separately. Customers will need to apply the same criteria as vendors to determine whether an arrangement contains a software license or is solely a service contract. This standard is effective for public entities for annual periods, including interim periods within those annual periods, beginning after December 15, 2015. An entity can elect to adopt the standard either prospectively for all arrangements entered into or materially modified after the effective date, or retrospectively. Early adoption is permitted for all entities. We adopted this standard on January 1, 2016. The adoption of this standard had no impact on our consolidated financial position or results of operations.

In November 2014, FASB issued Accounting Standards Update 2014-16, Derivatives and Hedging (Topic 815), Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share is More Akin to Debt or Equity, a consensus of the FASB Emerging Issues Task Force. The standard eliminates diversity in the practice of determining whether the nature of a host contract with a hybrid financial instrument issued in the form of a share is more akin to debt or equity and applies to all reporting entities that are issuers of hybrid financial instruments issued in the form of a share. This standard provides that the determination would be based on a consideration of all economic characteristics and the risk of the entire hybrid financial instrument, including the embedded derivative function. Upon adoption, each issued hybrid share instrument must be evaluated to determine whether it contains embedded features that require bifurcation or no longer require bifurcation under the new standard. Retrospective application and early adoption would both be permitted. The standard is effective for public business entities for fiscal years, and interim periods within those years, beginning after December 15, 2015. We adopted this standard on January 1, 2016. The adoption of this standard had no impact on our consolidated financial position or results of operations.

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

### **Interest Rate Sensitivity**

We had cash, cash equivalents, short-term investments and long-term investment totaling \$56.4 million and \$63.7 million as of December 31, 2015 and 2014, respectively. We do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates since a majority of these assets are of a short term nature. Declines in interest rates, however, would reduce future investment income. A 10 basis point decline in interest rates, occurring January 1, 2015 and sustained throughout the period ended December 31, 2015, would have resulted in a decline in investment income of approximately \$60,000 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 interim chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness, as of the end of the period covered by this report, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. The purpose of this evaluation was to determine whether as of the evaluation date our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the SEC, under the Exchange Act (1) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our interim chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, our interim chief executive officer and chief financial officer have concluded that, as of December 31, 2015, our disclosure controls and procedures were effective.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. We have designed our internal controls to provide reasonable assurance that our financial statements are prepared in accordance with generally accepted accounting principles in the United States (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 (2013 framework) as of December 31, 2015.

Based on our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2015. The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report thereto, appearing below.

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

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of

effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

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

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2015 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, 2015, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (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, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2015 consolidated financial statements of Oncothyreon Inc. and our report dated March 14, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington  
March 14, 2016

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

None.

## PART III

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

#### Executive Officers

The names, ages and positions of each of our executive officers as of March 14, 2016 are set forth below.

<u>Name</u>	<u>Age</u>	<u>Office</u>
<b>Executive Officers</b>		
CHRISTOPHER HENNEY, PH.D .....	75	Interim President & Chief Executive Officer; Chairman of the Board of Directors
JULIA M. EASTLAND .....	51	Chief Financial Officer, Secretary and Vice President, Corporate Development
GARY CHRISTIANSON ....	61	Chief Operating Officer
DIANA HAUSMAN, M.D. ...	52	Chief Medical Officer
SCOTT PETERSON, Ph.D. ..	54	Chief Scientific Officer

*Christopher Henney, Ph.D.* See “Directors, Executive Officers and Corporate Governance – Our Directors” included elsewhere in this Annual Report on Form 10-K for Dr. Henney’s biographical information.

*Julia M. Eastland* has served as our chief financial officer and vice president, corporate development since August 2010 and as our secretary since 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* has served as our chief operating officer since 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 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.

*Diana Hausman, M.D.* has served as our chief medical officer since January 2012. Prior to that, from August 2009 until January 2012, she served as our vice president, clinical development. 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 associate medical director at Berlex Inc., a biopharmaceutical company. From 2001 to 2002, Dr. Hausman worked in drug safety at Immunex Corporation, 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.* has served as our chief scientific officer since June 2012. From June 2009 until June 2012, Dr. Peterson served as our vice president, research and development. From 2007 until 2009 Dr. Peterson served as director and department head, oncology research at Zymogenetics, Inc., a biopharmaceutical company. From 1999 to 2007, Dr. Peterson held a variety of positions at ICOS Corporation, a biopharmaceutical company. Dr. Peterson received his Ph.D. in chemistry (biochemistry) from the University of Colorado, Boulder and holds a B.S. in biology from Washington State University.

## **Our Directors**

The name, age, position(s), term, board committee membership and biographical information for each member of our Board of Directors is set forth below as of March 14, 2016:

### ***Directors Continuing in Office Until the 2016 Annual Meeting of Stockholders***

*Richard Jackson, Ph.D.*, age 76, has been a member of our board of directors since May 2003. Dr. Jackson is a member of our compensation committee and our corporate governance and nominating committee. Dr. Jackson is president of Jackson Associates, LLC, a biotechnology and pharmaceutical consulting company. From September 2006 to August 2014, Dr. Jackson was 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.

*Ted W. Love, M.D.*, age 57, has been a member of our board of directors since September 2013. Dr. Love is the chair of our compensation committee and a member of our audit committee. Since June 2014, Dr. Love has served as chief executive officer of Global Blood Therapeutics, Inc. From February 2010 until August 2012, Dr. Love served as executive vice president and head of research and development and technical operations at Onyx Pharmaceuticals, Inc. From 2001 to January 2009, Dr. Love served as chairman and chief executive officer of Nuvelo, Inc. Dr. Love joined Nuvelo from Theravance, Inc., where he served as senior vice president of development from 1998 to 2001. Previously, he spent six years at Genentech, Inc., where he held a number of senior management positions in medical affairs and product development and served as chairman of Genentech's product development committee. Dr. Love also serves as a member of the board of directors of biopharmaceutical company Amicus Therapeutics, Inc. and from March 2009 to November 2015 served as a member of the board of directors of biopharmaceutical company KaloBios Pharmaceuticals, Inc. Our corporate governance and nominating committee believes that Dr. Love's qualifications for membership on the board of directors include over 15 years of experience in the biotechnology industry. This experience provides our board of directors with significant insights into the strategic and operational issues facing our company. Until April 2012, he served on the California Independent Citizens' Oversight Committee. Dr. Love earned his Bachelor of Science in molecular biology from Haverford College and his M.D. from Yale Medical School.

*Gwen Fyfe, M.D.*, age 64, has been a member of our board of directors since January 2016. From 1997 to 2009, Dr. Fyfe held various positions with Genentech Inc. (now a member of the Roche Group), including Vice President, Oncology Development; Vice President, Avastin Franchise Team, as well as the honorary title of Senior Staff Scientist. Since leaving Genentech in 2009, Dr. Fyfe has been a consultant for venture capital firms and for a variety of biotechnology companies. Dr. Fyfe currently serves as a director of biopharmaceutical companies Infinity Pharmaceuticals, Inc., Array Biopharma, Inc. and Igenica Biotherapeutics, a private company. Dr. Fyfe is also a member of Institute of Medicine panels, National Cancer Institute working groups and grant committees and American Society of Clinical Oncologists oversight committees. Our corporate governance and nominating committee believes that Dr. Fyfe's qualifications for membership on the board of directors include over 20 years of experience in the biotechnology industry. This experience allows Dr. Fyfe to provide our board of directors with extensive industry experience in clinical development for novel oncology therapeutics. Dr. Fyfe received her A.B. and M.D. from Washington University.

***Directors Continuing in Office Until the 2017 Annual Meeting of Stockholders***

*Daniel Spiegelman, M.B.A.*, age 57, has been a member of our board of directors since June 2008. Mr. Spiegelman is the chairman of our audit committee and a member of our corporate governance and nominating committee. Since May 2012, Mr. Spiegelman has been the executive vice president and chief financial officer of Biomarin Pharmaceuticals Inc., a biopharmaceutical company focused on the development and commercialization of therapies for rare diseases. From October 2009 to May 2012, Mr. Spiegelman served as a consultant to provide strategic financial support to a portfolio of public and private life sciences companies. 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 Relypsa, Inc., a biopharmaceutical company and Rapidscan Pharma Solutions, Inc. a private biopharmaceutical company. Our corporate governance and nominating committee believes that Mr. Spiegelman's qualifications for membership on the board of directors include his extensive background in the financial and commercial issues facing growing biotechnology companies. Additionally, as chief financial officer of CV Therapeutics prior to its sale to Gilead Sciences, Mr. Spiegelman was involved in transitioning the company from a research and development focus to a commercial entity with two approved products. This experience allows Mr. Spiegelman to provide our board of directors with significant insights into financial strategy and organizational development. Mr. Spiegelman received his B.A. and M.B.A. from Stanford University.

*Mark Lampert*, age 54, has been a member of our board of directors since January 2016. Mr. Lampert was the founder of, and serves as current President of, BVF Partners L.P., a biotechnology investment firm established in 1993. Previously, Mr. Lampert served as a Vice President at Oppenheimer & Co., founded Biotechnology Royalty Corp. and served as Head of Business Development at CeNeS Pharmaceuticals, Inc. Mr. Lampert has engaged in ventures relating to the biotechnology industry since 1984. Mr. Lampert also serves as a member of the board of directors of Acumen Pharmaceuticals, Inc, Ziarco, Inc., AvMax, Inc. and Mendel Biological Solutions. Our corporate governance and nominating committee believes that Mr. Lampert's qualifications for membership on the board of directors include over 30 years of experience in the biotechnology industry and over 20 years of experience in biotechnology investing. This experience allows Mr. Lampert to provide our board of directors with significant insights into business development strategies. Mr. Lampert received his A.B. from Harvard College and M.B.A. from Harvard Business School.

### ***Directors Continuing in Office Until the 2018 Annual Meeting of Stockholders***

*Christopher Henney*, Ph.D., age 75, 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 has also served as our Interim President and Chief Executive Officer since January 2016. 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 before being sold. 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, chairman of the board of directors of Anthera Pharmaceuticals, Inc., a biopharmaceutical company and as a member of the board of directors of Prothena Corporation plc, a biotechnology 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 and Mymetics Corp. during 2011. 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 and in 2012 was elected to the Hall of Fame of the Association of International Biotechnology CEOs. 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.

*Steven P. James*, age 57, was appointed as a member of our board of directors in February 2015. Mr. James is a member of our audit committee. Mr. James served as President and Chief Executive Officer of Labrys Biologics, Inc., from December 2012 until its acquisition by Teva Pharmaceuticals in July 2014. He was President and Chief Executive Officer of KAI Pharmaceuticals, Inc., from October 2004 until its acquisition by Amgen in July 2012. He was Senior Vice President, Commercial Operations, at Exelixis, Inc., from 2003 until 2004. Previously he held senior business roles at Sunesis Pharmaceuticals, Inc., and Isis Pharmaceuticals, Inc. He began his career in new product planning at Eli Lilly and Company. Mr. James is also a member of the board of directors of Ocera Therapeutics, Inc., and Chrono Therapeutics, both biotechnology companies. Our corporate governance and nominating committee believes that Mr. James' qualifications for membership on the board of directors include his extensive experience in the leadership of development stage biotechnology companies and in business development. Mr. James earned a Bachelor of Arts degree in biology from Brown University and a Masters in Management degree from the Kellogg Graduate School of Management at Northwestern University.

### **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 2015, 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 March 2008, which was last amended in September 2010, 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 2015 annual meeting of Oncothyreon filed with the SEC on April 23, 2015.

### **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 (1) has 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) has authority to engage any independent advisors it deems necessary to carry out its duties, and (4) has appropriate funding to engage any necessary outside advisors. The current members of the audit committee are Daniel Spiegelman (Chairman), Steven P. James and Dr. Ted W. Love. The board of directors has determined that Mr. Spiegelman, the chairman of the audit committee, is an “audit committee financial expert” as that term is defined in Item 407(d)(5) of Regulation S-K promulgated by the SEC and is an “independent director” as that term is defined under the applicable rules and regulations of The NASDAQ Stock Market. 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 in 2015, Dr. Kirkman, Ms. Eastland, Mr. Christianson, Dr. Hausman and Dr. Peterson. Dr. Kirkman served as our President and Chief Executive Officer during 2015 and retired in January 2016.

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

The principal objectives of our compensation policies and programs have 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 we expect that they will continue to reflect, the fact that we are a biopharmaceutical company whose product candidates are in pre-clinical and clinical development 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 on long-term equity incentives relative to cash compensation. 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 also have a performance-based cash bonus program for our executive officers. Payments under this performance-based cash bonus program are based on achievement of pre-established corporate performance goals. All of the performance goals of our executive officers are tied to corporate objectives to reflect the fact that our executive officers make key strategic decisions influencing our company as a whole.

We design and implement compensation programs that combine both cash incentive elements based on annual performance objectives and long-term equity elements. 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. 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.

We believe our executive compensation programs are effectively designed and work well in aligning the interests of our executive officers and stockholders and are instrumental to achieving our company objectives. In determining executive compensation for 2015, our compensation committee considered the stockholder support that the "Say-on-Pay" proposal received at our 2011 and 2014 annual meetings of stockholders. As a result, the compensation committee continued to apply the same effective principles and overall philosophy it has used in previous years in determining executive compensation and will continue to consider stockholder concerns and feedback in the future. With respect to the frequency of future "Say-on-Pay" advisory votes, consistent with the recommendation of our board of directors and the outcome of the stockholder vote regarding the proposal at our 2011 annual meeting of stockholders, we determined to hold an advisory "Say-on-Pay" vote on the compensation of our executive officers every three years. Our next advisory "Say-on-Pay" vote will occur at our 2017 annual meeting of stockholders.

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

During 2015, our compensation committee was comprised of three non-employee members of our board of directors, Dr. Henney, Dr. Jackson and Dr. Love, each of whom was an independent director under the applicable rules and regulations of The NASDAQ Stock Market and a "non-employee director" for purposes of Rule 16b-3 under the Exchange Act

during 2015. In January 2016, in connection with his appointment as our Interim Chief Executive Officer, Dr. Henney resigned from the compensation committee.

Our compensation committee approves and oversees our executive compensation and benefit policies. Our compensation committee acts as the administrator of our equity incentive plans and approves all grants to 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 applicable rules and regulations of The NASDAQ Stock 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 applicable rules and regulations of The NASDAQ Stock 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.

During 2015, our chief executive officer actively supported 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 reported, was responsible for evaluating individual officers' contributions to corporate objectives. Our chief executive officer made 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 met 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 conducted a similar evaluation of the chief executive officer's contribution and performance and made determinations 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 2015 base salary and cash incentive bonuses, but did consider the Radford survey data described below.

In July 2015, the compensation committee engaged the services of Compensia, Inc. (Compensia), a national compensation consulting firm, to advise the compensation committee and the corporate governance and nominating committee regarding the amount and types of compensation that we provide to our executive officers and board members and how our compensation practices compare to the compensation practices of other companies. Specifically, in 2015, Compensia was engaged to (i) develop a peer group for assessing executive and board compensation market practices, (ii) assess our executive officer and director compensation practices, including our short-term incentive and equity usage practices, relative to comparable companies and (iii) advise on 2016 compensation strategies and structure. The compensation committee considered Compensia's analysis



when determining 2015 equity-based incentive compensation. Compensia reports directly to our compensation committee and does not provide any services to us other than the services provided to the compensation committee and to the corporate governance and nominating committee. Our compensation committee believes that Compensia does not have any conflicts of interest in advising the compensation committee under applicable SEC or NASDAQ rules.

### ***Competitive Market Review for 2015***

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 base salary and incentive bonus determinations for 2015, the compensation committee benchmarked our compensation levels using the Radford Global Life Sciences Salary Survey. This survey includes life sciences companies based predominantly in biotechnology markets in the U.S. with which we compete for executive talent.

In evaluating the survey data, we compared our compensation practices and levels with the survey data. This information was used to determine appropriate levels of compensation based on market benchmarks for similarly situated officers.

In making our executive equity-based incentive compensation determinations for 2015, our compensation committee benchmarked the existing long-term incentive value of our equity-based incentive compensation using an analysis prepared by Compensia of the long-term incentive value of equity awards held by executive officers in comparable positions in our peer group. In awarding equity-based incentive compensation, our compensation committee targeted the 50<sup>th</sup> percentile of the peer group, which it believes provides the means to allow a company of our size to attract, compete for and retain the executive talent necessary for us to achieve our goals and also conserve our cash and equity as much as possible.

In developing our compensation peer group, our compensation committee identified publicly-traded clinical-stage biotechnology companies with shares listed on NASDAQ that were comparable to us based on the stage of clinical development, revenue, cash reserves, market capitalization and number of employees. Based on this analysis and the recommendations of Compensia, our compensation committee selected the following companies for our peer group:

Advaxis	Immune Design
Arrowhead Research	Lion Biotechnologies
Bellicum Pharmaceuticals	Mirati Therapeutics
Dicerna Pharmaceuticals	OncoMed Pharmaceuticals
Endocyte	Regulus Therapeutics
Five Prime Therapeutics	Sangamo BioSciences
Geron	Stemline Therapeutics
GTx	Verastem
Idera 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 and the first quarter of the new year. From time to time, the compensation committee may make mid-year changes to executive compensation based on new developments in our business or industry.

In connection with the annual goal setting 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 and board for review in the form of draft corporate objectives. Subsequently, our compensation committee, in consultation with 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 draft objectives prior to the compensation committee's final approval of the objectives.

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

For 2015, our compensation committee's determination of the appropriate use and weight of each element of executive compensation was 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 pre-clinical and clinical-stage product candidates, we seek to place a significant amount of each executive's total potential compensation "at risk" based on performance.

### ***Base Salary***

For 2015, our compensation committee, in its discretion, determined changes in annual base salary for executive officers. Base salary for our executive officers reflected the scope of their respective responsibilities, their relative seniority and experience and competitive market factors, including our compensation committee's review of market compensation for executive officers of U.S. biopharmaceutical companies. Our compensation committee typically aims to set base salary at approximately the 50<sup>th</sup> percentile of base salaries reported in the Radford Global Life Sciences Salary Survey for comparable positions at companies of comparable size. Salary adjustments for 2015 were based on a comparison of 2014 base salary to the 50<sup>th</sup> percentile reported in the Radford Global Life Sciences Salary Survey, individual performance and changes in job duties. The compensation committee determined based on these factors that it was appropriate to increase 2015 base salaries for each of Dr. Kirkman, Mr. Christianson and Dr. Hausman by 3% in order to keep salaries for those officers aligned approximately with the 50<sup>th</sup> percentile of the comparable salaries reported in the Radford Global Life Sciences Salary Survey. The compensation committee

determined to increase Ms. Eastland's base salary by 8.5% to reflect her exemplary performance and in order to more closely align her salary with approximately the 50<sup>th</sup> percentile of the comparable salaries reported in the Radford Global Life Sciences Salary Survey. The compensation committee determined to increase Dr. Peterson's base salary by 16.5% to reflect an increase in his job responsibilities, his exemplary performance and in order to more closely align his salary with approximately the 50<sup>th</sup> percentile of the comparable salaries reported in the Radford Global Life Sciences Salary Survey. Effective January 1, 2015, Dr. Kirkman's base salary was increased to \$448,050, Ms. Eastland's base salary to \$300,000, Mr. Christianson's base salary to \$319,300, Dr. Hausman's base salary to \$366,165 and Dr. Peterson's base salary to \$315,000.

#### ***Variable Cash Compensation – Incentive Bonuses***

We pay performance-based bonuses to our executive officers pursuant to our performance review policy, which we believe enhances each executive's incentive to contribute to corporate objectives and aligns their interests with those of our stockholders. Under the performance review policy, our executive officers are eligible to receive bonuses based on achievement of pre-established corporate performance goals. The weighting among the goals is individualized based on the nature of the executive's role within the company. As further described in the paragraphs below, each goal is assigned a percentage for each executive based on the importance to us that the goal be achieved by that executive and the extent to which the goal falls within the executive's area of operational control. 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 reduced or no incentive compensation and 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, the compensation committee retains discretion to increase or decrease variable cash incentive compensation to our officers as it determines appropriate, based on actual achievement against the goals.

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

The 2015 performance goals approved by the compensation committee in January 2015 for each executive officer are set forth in the table below. With input from the board, the compensation committee selected these particular corporate objectives based on its judgment that they represented areas in which each of the executive officers have significant operational control and on which the board and compensation committee

believed each of the executive officers should focus to move our strategic plan forward and enhance stockholder value. As is reflected in the table below, the weighting of specific performance goals varies among executive officers based on each executive officer's role and position within the company. For example, because Dr. Hausman holds a position as our chief medical officer, the compensation committee felt it was appropriate to more heavily weight her bonus on achievement of certain clinical development milestones. Mr. Christianson and Dr. Peterson's goals are more heavily weighted to the achievement of technical operations and pre-clinical assessment goals, respectively, to align their goals with their respective roles as our chief operating officer and chief scientific officer. Dr. Kirkman and Ms. Eastland's goals are more heavily weighted toward the achievement of goals relating to cash position, investor perception and business development. Since the compensation committee believes that our performance is also determined by the performance of executive management acting collaboratively as a team, no corporate goal was assigned a weight of less than 5% for any of our executive officers.

<b>Named Executive Officer</b>	<b>Cash Position (1)</b>	<b>Investor Perception (2)</b>	<b>Clinical Assessment (3)</b>	<b>Pre-Clinical Assessment (4)</b>	<b>Technical Operations (5)</b>	<b>Protocell (6)</b>	<b>Regulatory (7)</b>	<b>Business Development (8)</b>
Robert Kirkman .....	25%	20%	10%	10%	10%	10%	5%	10%
Julia Eastland .....	25	20	10	10	10	10	5	10
Gary Christianson .....	5	5	10	10	40	15	10	5
Diana Hausman .....	5	5	45	10	10	10	10	5
Scott Peterson .....	5	5	10	40	10	15	10	5

- (1) Have cash and investments as of December 31, 2015 sufficient to fund the Company for the following 18 months.
- (2) Improve investor perception of the Company.
- (3) Timely complete enrollment in Phase 1b ONT-380 trials; initiate a Phase 2 trial of ONT-380; if indicated, obtain FDA input for treatment of CNS metastases and timely initiate registration trial or other trial; timely complete enrollment in combination study of ONT-10 and CDX-1127.
- (4) Timely complete studies in connection with ONT-380, ONT-10, Chk1 inhibitor and immune oncology antibody discovery program.
- (5) Timely complete supply, formulation and manufacturing goals with respect to ONT-380, ONT-10, and Chk1 inhibitor.
- (6) Timely complete studies and manufacturing goals in connection with protocell technology.
- (7) Timely file IND for Chk1 inhibitor.
- (8) Timely complete a collaboration with respect to protocell technology and complete an evaluation agreement relating to PET Lipid A.

Dr. Kirkman, Ms. Eastland, Mr. Christianson, Dr. Hausman and Dr. Peterson were eligible to receive incentive bonuses of up to 50%, 35%, 35%, 35% and 35%, respectively, of their base salary. In 2015, the compensation committee increased Ms. Eastland's and Dr. Peterson's bonus targets from 30% to 35% to reflect the relative importance of their contributions to the company and increase parity in the executive officer bonus targets.

In January 2016, the compensation committee determined the achievement of the 2015 performance goals. Specifically, the compensation committee determined the following: (1) the cash position goal was not achieved; (2) the investor perception goal was fully achieved; (3) clinical goals were 75% achieved; (4) preclinical goals were fully achieved; (5) technical operations goals were 75% achieved; (6) protocol goals were 50% achieved; (7) the regulatory goal was not achieved and (8) business development goals were 20% achieved. Additionally, in its discretion, the compensation committee determined to increase the percentage of the goals achieved by Ms. Eastland from 52% to 65% to reflect her significant contributions to the company that were not reflected in the 2015 performance goals. The target and actual bonus amounts for 2015 for our named executive officers are set forth below.

<b>Named Executive Officer</b>	<b>Base Salary (\$)</b>	<b>2015 Annual Target as Percentage of Base Salary</b>	<b>Target Bonus (\$)</b>	<b>Target Goals Achieved</b>	<b>2015 Incentive Bonus (\$)</b>
Robert Kirkman .....	\$ 448,050	50%	\$224,025	52.0%	\$116,493
Julia Eastland .....	300,000	35	105,000	65.0	68,250
Gary Christianson .....	319,300	35	111,755	61.0	68,171
Diana Hausman .....	366,165	35	128,158	62.25	79,778
Scott Peterson .....	315,000	35	110,250	68.5	75,521

### ***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 named executive officers to acquire an equity position in our company.

Historically, we have granted options to our executive officers under our share option plan. Our share option plan permits the grant of stock options for shares of common stock. All equity incentive programs are administered by our compensation committee (other than grants of restricted share units to non-employee directors, which are overseen by the corporate governance and nominating committee and grants of stock options to certain new employees, which are overseen by the new employee option committee). To date, our equity incentive grants to executive officers have consisted of options under the share option plan. We use stock options as a long-term incentive vehicle because stock options align the interests of executives with those of our stockholders, support a pay-for-performance culture, foster employee stock ownership and focus the management team on increasing value for our stockholders. In addition, stock options help to provide a balance to the overall executive compensation program as base salary and our bonus program focus on nearer-term achievements, while the grant and vesting of stock options is intended to focus executive efforts toward increasing stockholder value over the longer term.

The practice of our compensation committee has been to consider the annual grant of options to our executive officers in connection with the annual compensation review process. In making its determination of the size of annual option grants for our executive officers, the compensation committee considers the individual performance of the executive officer in the prior year, the industry experience and background of the executive officer, and the value of the executive officer's outstanding equity grants in the then-current competitive environment, including the value of such outstanding equity grants as a retention tool. Adjustments may be made as the compensation committee deems reasonable to attract and retain executive officers in the competitive environment for highly qualified employees in which we operate.

In determining the 2015 annual option grants to executive officers, the compensation committee considered the roles and performance of each executive officer in the context of the company's goals and priorities, the long-term retention value of the overall outstanding option grants held by each of the executive officers, and an analysis prepared by Compensia of the long-term incentive value of equity awards held by executive officers in comparable positions in the company's peer group. The analysis prepared by Compensia indicated that the long-term incentive value of the equity awards held by each of our named executive officers fell below the 10<sup>th</sup> percentile of our peer group. In order to achieve a long-term incentive value for each of our named executive officers that is consistent with approximately the 50<sup>th</sup> percentile of our peer group, the compensation committee awarded stock option grants to the executive officers as set forth in the table below, which it believed was appropriate in light of our long-term retention objectives.

<u>Named Executive Officer</u>	<u>Options (#)</u>
Dr. Robert Kirkman .....	750,000
Julia Eastland .....	250,000
Gary Christianson .....	250,000
Dr. Diana Hausman .....	250,000
Dr. Scott Peterson .....	250,000

These options vest as follows: 25% of the shares underlying the option will vest and become exercisable on the first anniversary of the grant date and thereafter 1/48<sup>th</sup> of the shares underlying the option will vest and become exercisable on each monthly anniversary of the grant date, subject to the executive officer's continued service, such that the option will be fully exercisable on the fourth anniversary of the grant date.

The exercise price of these options is the closing sales price of our common stock on the date of grant, September 24, 2015, or \$3.51.

Our practice has been to provide equity incentives principally in the form of stock option grants that vest over time. The stock option vesting period encourages executive retention over the term of the option. Our compensation committee may also 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.

***Benefits***

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

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

***Severance/Termination Protection***

We are a party to agreements with our executive officers that provide for 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. When establishing the retention, termination and change of control provisions in our agreements with our

executive officers, the compensation committee considered industry practice and an analysis of current market trends.

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. Additionally, in January 2016, we adopted a Retention Payment Plan (as described below) that is intended to incentivize and retain our officers while we conduct a search for a permanent chief executive officer and integrate such person into our operations. The compensation committee believes that the recent loss of our chief executive officer and any future proposed or actual change in control transaction 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 hiring of a new chief executive officer or the closing of a change in control, especially if they do not wish to remain with the entity after such events. Such departures could jeopardize our clinical development plans or the consummation of a transaction or our interests if a 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, 2015, are described in “— Termination and Change of Control Provisions under 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 Internal Revenue Code (Section 162(m)) limits the amount that we may deduct for compensation paid to our chief executive officer and the next three most highly compensated executive officers (other than the principal financial officer) to \$1 million per person per year, unless such compensation satisfies the conditions of an exemption from Section 162(m). If we pay compensation that is “performance-based,” under Section 162(m) we can receive a federal income tax deduction for the compensation paid even if such compensation exceeds \$1 million per person in a single year, subject to certain conditions. Cash compensation in excess of \$1 million in addition to any spread at the time of exercise of stock options we have granted through 2015 do not meet the general requirements for exemption from the deduction limit.

However, our compensation committee cannot determine with certainty how the deduction limit may impact our executive compensation program in future years. While our compensation committee has not adopted a formal policy regarding tax deductibility of the compensation paid to our executive officers, it intends to consider tax deductibility under Section 162(m) as a factor in compensation decisions. Nevertheless, our compensation committee may, in its judgment, approve compensation for our executive officers that does not comply with an exemption from the deduction limit when it believes that such compensation is in the best interests of the company and our stockholders.

#### ***Securities Trading Policies***

Our Insider Trading Policy includes that, except for trades pursuant to approved Rule 10b5-1 plans, directors, officers and employees may not trade in our securities while possessing material nonpublic information concerning us or trade in our securities outside of the applicable trading windows. Our securities trading policy further includes that directors and executive officers may not purchase or sell puts or calls that underly a purchase or sell of our common stock, engage in short sales or any other hedging transactions with respect to our common stock, or buy our common stock on margin or pledge shares of our common stock. Except for trades pursuant to approved Rule 10b5-1

plans, our policy restricts trading in our securities by directors, officers and employees to open window periods following the widespread public release of our quarterly and annual financial results.

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

During 2015, Richard Jackson, Christopher Henney and Ted W. Love served on our compensation committee. During 2015, 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 Exchange Act. 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.

### **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 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

Dr. Ted W. Love, Chairman  
Dr. Richard Jackson  
Dr. Christopher Henney (former member)



## Summary Compensation Table — 2015, 2014 and 2013

The following table sets forth the compensation earned by or awarded to, as applicable, our named executive officers during each of 2015, 2014 and 2013.

Name and Principal Position	Year	Salary (\$)	Option Awards \$(1)	Non-Equity Incentive Plan Compensation \$(2)	All Other Compensation \$(3)	Total (\$)
Robert Kirkman . . . . . Former President, Chief Executive Officer and Director	2015	\$ 448,050	\$1,687,500	\$ 116,493	\$ 8,442	\$2,260,485
	2014	435,000	360,000	217,500	12,455	1,024,955
	2013	422,300	756,000	202,704	13,161	1,394,165
Julia Eastland . . . . . Chief Financial Officer, Secretary and Vice President, Corporate Development	2015	300,000	562,500	68,250	8,442	939,192
	2014	276,000	120,000	82,800	8,292	487,092
	2013	267,800	189,000	76,725	8,526	542,051
Gary Christianson . . . . . Chief Operating Officer	2015	319,300	562,500	68,171	8,442	958,413
	2014	310,000	120,000	108,500	9,017	547,517
	2013	300,760	189,000	100,529	9,515	599,804
Diana Hausman . . . . . Chief Medical Officer	2015	366,165	562,500	79,778	8,442	1,016,885
	2014	355,500	180,000	124,425	10,268	670,193
	2013	345,050	189,000	96,787	10,843	641,680
Scott Peterson . . . . . Chief Scientific Officer	2015	315,000	562,500	75,521	8,442	961,463
	2014	270,500	180,000	81,150	8,292	539,942
	2013	262,650	189,000	76,825	8,371	536,847

- (1) These amounts represent the aggregate grant date fair value of option awards for fiscal years 2015, 2014 and 2013. These amounts do not represent the actual amounts paid to or realized by the named executive officer for these awards during fiscal years 2015, 2014 and 2013. 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 “Note 7 — Share-based Compensation” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.
- (2) The amounts in this column represent total performance-based cash bonuses earned for services rendered during the year by our named executive officers, which performance-based cash bonuses were awarded based on the achievement of corporate goals and objectives determined each year by our compensation committee. 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 performance-based cash bonuses for named executive officers.
- (3) The amounts in this column consist of contributions made by us pursuant to our 401(k) plan and life insurance premiums.

## Grants of Plan-Based Awards

The following table sets forth each grant of an award made to an executive officer during 2015 under any of our incentive plans or equity plans.

Name	Grant Date (1)	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards \$(2)	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 \$(3)
Robert L. Kirkman . . .	September 24, 2015	\$224,025(4)	750,000	\$3.51	\$1,687,500
Julia Eastland . . . . .	September 24, 2015	105,000(5)	250,000	3.51	562,500
Gary Christianson . . .	September 24, 2015	111,755(6)	250,000	3.51	562,500
Diana Hausman . . . . .	September 24, 2015	128,158(7)	250,000	3.51	562,500
Scott Peterson . . . . .	September 24, 2015	110,250(8)	250,000	3.51	562,500

(1) Except as otherwise noted below and consistent with the provisions of our share option plan in effect at the date of grant, all options reflected in the table had an exercise price equal to the closing sales price of our common stock as reported by The NASDAQ Global Market on the grant date. All options were granted under our share option plan.

(2) Amounts represent the “Target” amount of each award. There was no set “Threshold” or “Maximum” performance bonus amounts established with respect to our 2015 non-equity incentive plan awards. In January 2016, our compensation committee awarded non-equity incentive plan awards based on achievement of our 2015 performance goals. The actual amounts paid to each of the executive officers for 2015 are set forth in the individual footnotes below. For more information regarding the 2015 non-equity incentive plan awards, see “— Compensation Discussion and Analysis — Variable Cash Compensation — Incentive Bonuses” included elsewhere in this Annual Report on Form 10-K.

(3) These amounts represent the grant date fair value of option awards granted in 2015. These amounts do not represent the actual amounts paid to or realized by the named executive officer for these awards during fiscal year 2015. The value as of the grant date for stock options is recognized over the number of days of service required for the grant to become vested. For a more detailed description of the assumptions used for purposes of determining grant date fair value, see “Part II — Item 7 — Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Significant Judgments and Estimates — Share-based Compensation” and “Note 7 — Share-based Compensation” of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

(4) On January 9, 2016, the compensation committee awarded Dr. Kirkman a performance bonus of \$116,493 based upon achievement of our 2015 performance goals.

(5) On January 9, 2016, the compensation committee awarded Ms. Eastland a performance bonus of \$68,250 based upon achievement of our 2015 performance goals.

(6) On January 9, 2016, the compensation committee awarded Dr. Christianson a performance bonus of \$68,171 based upon achievement of our 2015 performance goals.

(7) On January 9, 2016, the compensation committee awarded Dr. Hausman a performance bonus of \$79,778 based upon achievement of our 2015 performance goals.

(8) On January 9, 2016, the compensation committee awarded Dr. Peterson a performance bonus of \$75,521 based upon achievement of our 2015 performance goals.

## Outstanding Equity Awards at 2015 Fiscal Year-End

The following table sets forth the equity awards outstanding at December 31, 2015 for each of the named executive officers. Except as set forth in the footnotes to the following table, each stock option is fully vested.

Name	Option Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Robert Kirkman . . . .	45,000	—(2)	\$ 3.43	June 4, 2016
	100,000	—(3)	\$ 1.10	March 11, 2017
	200,000	—(4)	\$ 4.71	December 3, 2017
	100,000	—(5)	\$ 3.32	December 1, 2018
	100,000	—(9)	\$ 6.92	December 1, 2019
	75,000	25,000(10)	\$ 4.74	December 12, 2020
	300,000	300,000(11)	\$ 1.74	December 12, 2021
	75,000	225,000(12)	\$ 1.76	December 16, 2022
	—	750,000(13)	\$ 3.51	September 24, 2023
Julia Eastland . . . . .	40,000	—(6)	\$ 3.31	November 10, 2018
	50,000	—(5)	\$ 3.32	December 1, 2018
	50,000	—(9)	\$ 6.92	December 1, 2019
	37,500	12,500(10)	\$ 4.74	December 12, 2020
	75,000	75,000(11)	\$ 1.74	December 12, 2021
	25,000	75,000(12)	\$ 1.76	December 16, 2022
	—	250,000(13)	\$ 3.51	September 24, 2023
Gary Christianson . . .	15,000	—(2)	\$ 3.43	June 4, 2016
	30,000	—(3)	\$ 1.10	March 11, 2017
	100,000	—(4)	\$ 4.71	December 3, 2017
	50,000	—(5)	\$ 3.32	December 1, 2018
	50,000	—(9)	\$ 6.92	December 1, 2019
	37,500	12,500(10)	\$ 4.74	December 12, 2020
	75,000	75,000(11)	\$ 1.74	December 12, 2021
	25,000	75,000(12)	\$ 1.76	December 16, 2022
	—	250,000(13)	\$ 3.51	September 24, 2023
Diana Hausman . . . . .	30,000	—(7)	\$ 4.96	October 1, 2017
	50,000	—(4)	\$ 4.71	December 3, 2017
	50,000	—(5)	\$ 3.32	December 1, 2018
	50,000	—(9)	\$ 6.92	December 1, 2019
	37,500	12,500(10)	\$ 4.74	December 12, 2020
	75,000	75,000(11)	\$ 1.74	December 12, 2021
	37,500	112,500(12)	\$ 1.76	December 16, 2022
	—	250,000(13)	\$ 3.51	September 24, 2023
Scott Peterson . . . . .	25,000	—(8)	\$ 6.56	August 1, 2017
	50,000	—(4)	\$ 4.71	December 3, 2017
	50,000	—(5)	\$ 3.32	December 1, 2018
	50,000	—(9)	\$ 6.92	December 1, 2019
	37,500	12,500(10)	\$ 4.74	December 12, 2020
	75,000	75,000(11)	\$ 1.74	December 12, 2021
	37,500	112,500(12)	\$ 1.76	December 16, 2022
	—	250,000(13)	\$ 3.51	September 24, 2023

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- (1) In April 2008, the board of directors approved an amendment to our 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.
  - (2) This stock option fully vested on June 4, 2012.
  - (3) This stock option fully vested on March 11, 2013.
  - (4) This stock option fully vested on December 3, 2013.
  - (5) This stock option fully vested on December 1, 2014.
  - (6) This stock option fully vested on September 7, 2014.
  - (7) This stock option fully vested on September 1, 2013.
  - (8) This stock option fully vested on August 1, 2013.
  - (9) This stock option fully vested on December 1, 2015.
  - (10) This stock option fully vests on December 12, 2016, and  $\frac{1}{4}$  vests on the first anniversary of grant, with the balance vesting in monthly increments for 36 months following the first anniversary of grant.
  - (11) This stock option fully vests on December 12, 2017, and  $\frac{1}{4}$  vests on the first anniversary of grant, with the balance vesting in monthly increments for 36 months following the first anniversary of grant.
  - (12) This stock option fully vests on December 16, 2018, and  $\frac{1}{4}$  vests on the first anniversary of grant, with the balance vesting in monthly increments for 36 months following the first anniversary of grant.
  - (13) This stock option fully vests on September 24, 2019, and  $\frac{1}{4}$  vests on the first anniversary of grant, with the balance vesting in monthly increments for 36 months following the first anniversary of grant.

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

None of our named executive officers exercised stock options during 2015. We have not granted any stock awards to date to any of our named executive officers.

### **Share Option Plan**

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

Also under our share option plan, stock options held by employees at the level of Vice President or above who are terminated by us without cause (as defined in the share option plan) will remain outstanding and continue to vest and be exercisable for two years following the termination date. In addition, under our share option plan, stock options held by employees who retire (as defined in the share option plan) will remain outstanding and continue to vest and be exercisable for the term of the stock option.

## **Termination and Change of Control Agreements**

### ***Dr. Robert Kirkman***

As of December 31, 2015, we were a party to an offer letter with Dr. Kirkman, our president and chief executive officer, dated August 29, 2006 as amended in December 2008 and December 2009. Pursuant to the terms of the offer letter as amended, Dr. Kirkman was entitled to receive the following benefits if we underwent 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 was terminated for reasons other than cause (as defined in the December 2009 amendment), he was entitled to receive the following benefits, in addition to the continued stock option vesting and exercisability 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.

In January 2016, Dr. Kirkman retired from his role as president and chief executive officer. In connection with his resignation, we and Dr. Kirkman entered into a Retirement and Separation Agreement, and pursuant to such agreement, Dr. Kirkman received the following severance benefits:

- accrued compensation, including (i) earned salary, (ii) any earned bonus that would have been paid to Dr. Kirkman with respect to fiscal year 2015, (iii) any accrued, but unused vacation and (iv) reimbursement of outstanding expenses;
- a cash payment equal to \$1,620,000, payable in one lump sum;
- full acceleration of all shares of our common stock underlying any then-outstanding unvested stock options held by Dr. Kirkman; and
- 100% of the COBRA premium that would otherwise be due under our group health plan through December 31, 2016.

### ***Julia Eastland***

We are a party to an offer letter dated August 17, 2010 with Julia Eastland, our chief financial officer, secretary and vice president, corporate development.

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 for reasons other than cause (as defined in the offer letter), she will receive the following benefits, in addition to the continued stock option vesting and exercisability described above:

- 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 a party to an offer letter dated June 29, 2007 as amended in December 2008 and December 2009, with Gary Christianson, our chief operating officer. Pursuant to the terms of the offer letter as amended, 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 for reasons other than cause (as defined in the June 2007 offer letter), he will receive the following benefits, in addition to the continued stock option vesting and exercisability described above:

- 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.

### ***Dr. Diana Hausman***

We are a party to an offer letter dated July 6, 2009, as amended December 2009 and December 2015, with Diana Hausman, M.D., our chief medical officer. Pursuant to the terms of the offer letter as amended, 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 for reasons other than cause (as defined in the December 2015 amendment), she will receive the following benefits, in addition to the continued stock option vesting and exercisability described above:

- 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.

### ***Dr. Scott Peterson***

We are a party to an offer letter dated June 4, 2009, as amended December 2009 and January 2015, with Scott Peterson, Ph.D., our chief scientific officer. Pursuant to the terms of his offer letter as amended, 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.

Additionally, if Dr. Peterson is terminated for reasons other than cause (as defined in the January 2015 amendment), he will receive the following benefits, in addition to the continued stock option vesting and exercisability described above:

- 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.

### **Retention Payment Plan**

In January 2016, we adopted a Retention Plan to provide cash retention payments to our named executive officers (other than our Chief Executive Officer) and certain other employees in order to induce them to remain employed by us through the transition of our Chief Executive Officer. Any named executive officers who participate in the Retention Plan and (i) remain continuously employed by us through January 10, 2017 or (ii) are terminated by us other than for "cause" prior to January 10, 2017, shall be paid a lump-sum cash payment in an amount equal to eight months of their base salary effective as of January 10, 2016.

For purposes of the Retention Plan, "cause" means (i) failure or refusal by such named executive officer to substantially perform his or her duties (except where the failure results from incapacity due to disability); or (ii) severe misconduct or activity deemed detrimental to our interests, as further described in the Retention Plan.

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

The tables below describe the payments and benefits our executive officers would be entitled to receive assuming the occurrence on December 31, 2015 of either a change of control transaction or termination of their employment without "cause" (as defined below) as well as payments our executive officers would be entitled to receive assuming termination of their employment without cause made after January 11, 2016 in accordance with the Retention Plan. For additional details regarding the payments and benefits our named executive officers are entitled to, please see "— Termination and Change of Control Agreements" included elsewhere in this Annual Report on Form 10-K.

#### **Dr. Robert Kirkman**

<u>Name</u>	<u>Change of Control</u>			<u>Termination Other Than for Cause(4)</u>		
	<u>Equity Acceleration (2)</u>	<u>Salary (3)</u>	<u>Insurance Benefits</u>	<u>Equity Acceleration (5)</u>	<u>Salary (6)</u>	<u>Insurance Benefits</u>
Robert Kirkman(1) . . .	\$247,500	\$1,344,150	\$—	\$—	\$672,075	\$—

(1) The amounts in this table reflect what would have been paid to Dr. Kirkman upon a change of control or termination other than for cause as of December 31, 2015 based on the agreement that was effective as of such date.

On January 11, 2016, Dr. Kirkman retired from his role as president and chief executive officer. In connection with his retirement, we and Dr. Kirkman entered into a Retirement and Separation Agreement, as described above under "— Termination and Change of Control Agreements — Dr. Robert Kirkman." Pursuant to such agreement, Dr. Kirkman received the following payments:

<u>Named</u>	<u>Equity Acceleration</u>	<u>Salary</u>	<u>Bonus (a)</u>	<u>Insurance Benefits</u>
Robert Kirkman . . . . .	\$—	\$1,620,000	\$116,493	\$27,100

(a) Amount represented 2015 bonus earned and paid in January 2016.

(2) The amount shown in this column is calculated as the spread value of all unvested stock options held by Dr. Kirkman on December 31, 2015, assuming a stock price of \$2.22 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 31, 2015.

- (3) The amount shown in this column is a lump sum payment equal to two times Dr. Kirkman's base salary for 2015 plus two year's equivalent of his performance review bonus at target. Such payments would have been made within 60 days following a change of control, provided that, within 45 days of a change of control, Dr. Kirkman signed a separation agreement in a form reasonably satisfactory to us, which would have included a general release of all claims against us.
- (4) For purposes of Dr. Kirkman's offer letter, "cause" included, among other things (a) willfully 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.
- (5) Pursuant to the terms of our share option plan, there was no acceleration of vesting if Dr. Kirkman was terminated without cause, but stock option vesting and exercisability would have continued as described above under "— Share Option Plan".
- (6) The amount shown in this column is a lump sum payment equal to Dr. Kirkman's base salary for 2015 plus one year's equivalent of his performance review bonus at target. Such payments would have been made within 60 days following termination other than for cause, subject to any payment delay in order to comply with Section 409A of the Internal Revenue Code.

### **Julia Eastland**

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 . . . . .	\$70,500	\$405,000	\$—	\$—	\$530,417	\$—

- (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, 2015, assuming a stock price of \$2.22 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 31, 2015.
- (2) The amount shown in this column is a lump sum payment equal to Ms. Eastland's base salary for 2015 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, but stock option vesting and exercisability will continue as described above under "— Share Option Plan".
- (5) The amount shown in this column is a lump sum payment equal to nine months of Ms. Eastland's base salary for 2015, nine month's equivalent of her performance review bonus at target and a lump sum payment equal to eight months of Ms. Eastland's base salary pursuant to the Retention Plan.

### **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 . . . .	\$70,500	\$431,055	\$—	\$—	\$543,608	\$22,174

- (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, 2015, assuming a stock price of \$2.22 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 31, 2015.



- (2) The amount shown in this column is a lump sum payment equal to Mr. Christianson's base salary for 2015 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, but stock option vesting and exercisability will continue as described above under "— Share Option Plan".
- (5) The amount shown in this column is a lump sum payment equal to nine months of Mr. Christianson's base salary for 2015, nine month's equivalent of his performance review bonus at target and a lump sum payment equal to eight months of Mr. Christianson's base salary for 2016 pursuant to the Retention Plan.

**Dr. 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 . . . . .	\$87,750	\$494,323	\$—	\$—	\$ 630,742	\$—

- (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, 2015, assuming a stock price of \$2.22 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 31, 2015.
- (2) The amount shown in this column is a lump sum payment equal to Dr. Hausman's base salary for 2015 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, but stock option vesting and exercisability will continue as described above under "— Share Option Plan".
- (5) The amount shown in this column is a lump sum payment equal to nine months of Dr. Hausman's base salary for 2015, nine month's equivalent of her performance review bonus at target and a lump sum payment equal to eight months of Dr. Hausman's base salary for 2016 pursuant to the Retention Plan.

**Dr. Scott Peterson**

Name	Change of Control			Termination Other Than for Cause(3)		
	Equity Acceleration (1)	Salary (2)	Insurance Benefits	Equity Acceleration (4)	Salary (5)	Insurance Benefits
Scott Peterson . . . . .	\$87,750	\$425,250	\$—	\$—	\$558,938	\$—

- (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, 2015, assuming a stock price of \$2.22 per share, the last reported sale price of our common stock on The NASDAQ Global Market on December 31, 2015.
- (2) The amount shown in this column is a lump sum payment equal to Dr. Peterson's base salary for 2015 plus one year's equivalent of his performance review bonus at target. Such payments will be

made within 60 days following a change of control, provided that, within 45 days of a change of control, Dr. Peterson signs a separation agreement in a form reasonably satisfactory to us, which shall include a general release of all claims against us.

- (3) For purposes of Dr. Peterson'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 his 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. Peterson is terminated without cause, but stock option vesting and exercisability will continue as described above under "— Share Option Plan".
- (5) The amount shown in this column is a lump sum payment equal to nine months of Dr. Peterson's base salary for 2015, nine month's equivalent of her performance review bonus at target and a lump sum payment equal to eight months of Dr. Peterson's base salary for 2016 pursuant to the Retention Plan.

### **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, December 1, 2011 and December 4, 2014. 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 9,160,135 shares of our common stock for issuance pursuant to our share option plan as of December 31, 2015. As of December 31, 2015, options to purchase 7,350,500 shares of our common stock were outstanding and 1,765,777 shares of our common stock were available for future grant under our share option plan.

#### ***Administration***

Our compensation committee 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 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.

### ***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) or voluntary termination, 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 a voluntary termination or 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 have continued to vest for 180 days, but would have been exercisable at any time prior to the close of business on the expiry date of the option.

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

Our share option plan provides that, if a change in control occurs, as such term is defined in our share option plan, including our merger with or into another corporation or the sale of all or substantially all of our assets, or if there is an offer to purchase, a solicitation of an offer to sell, or an acceptance of an offer to sell our shares of common stock made to all or substantially all of the holders of shares of common stock, a participant, who at the time of the change of control is an employee, director or service provider, shall have the right to

immediately exercise his or her option as to all shares of common stock subject to such option, including as to those shares of common stock with respect to which such option cannot be exercised immediately prior to the occurrence of the change of control, and the participant shall have 90 days from the date of the change of control to exercise his or her option (unless the option expires prior to such date).

### ***Transferability***

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

### ***Additional Provisions***

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

During the period from January 1 to December 31, 2015, options to purchase 2,574,000 shares of common stock were granted under our share option plan at a weighted average exercise price of \$3.48 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 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 withhold 25% of the shares of our common stock otherwise deliverable in connection with the vesting of any RSU and instead deliver to each non-employee director an amount in cash equal to the fair market value of the withheld shares on the vesting date. The amendment is intended to facilitate satisfaction of the non-employee directors' income tax obligation with respect to the vested RSUs. On June 6, 2014, our stockholders approved an increase of 500,000 shares in the number of shares of our common stock reserved for issuance under the RSU Plan and our board approved an administrative amendment to our RSU plan. The directors who receive RSUs under our restricted share unit plan are referred to below as participants.

### ***Share Reserve***

As of December 31, 2015, we have reserved a total of 966,666 of our shares of common stock for issuance pursuant to our RSU Plan. As of December 31, 2015, grants covering 228,943 shares of our common stock were outstanding, 391,788 shares of our common stock were available for future grant under our restricted share unit plan and 345,935 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, along 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 15<sup>th</sup> 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 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 15<sup>th</sup> 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 30<sup>th</sup> 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 RSU Plan), with respect to all grants of RSUs that are outstanding as of the date of such change in control, all unvested RSUs 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 RSU covered by the grant. Such amount will be either one share of our common stock for each RSU, 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 RSU Plan) for each covered RSU.

#### ***Transferability***

The rights or interests of a participant under our RSU 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 RSU Plan in whole or in part from time to time.

## 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 director is entitled to annual restricted share unit grant equal to the greater of (1) 7,500 and (2) \$50,000 divided by the closing price of our common stock on the NASDAQ Global Market on the date of grant. In September 2015, to align our annual equity awards to non-employee directors with the 50<sup>th</sup> percentile of our peer group (as described above under “Compensation Discussion and Analysis – Competitive Market Review for 2015”), our Board also granted each non-employee director a second restricted share unit award equal to the greater of (1) 7,500 and (2) \$50,000 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 2015 Director Compensation

The following table sets forth compensation information for our non-employee directors for the year ended December 31, 2015. The table excludes Dr. Kirkman who did not receive any compensation from us in his role as director in the year ended December 31, 2015. All compensation numbers are expressed in U.S. dollars.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Stock Awards (\$)(1)(2)(3)</u>	<u>Total (\$)</u>
Christopher Henney .....	\$105,000	\$100,000	\$ 205,000
Daniel Spiegelman .....	75,000	100,000	175,000
Richard Jackson .....	52,500	100,000	152,500
Ted W. Love .....	52,500	100,000	152,500
Steven James .....	50,000	150,000	200,000

- (1) These amounts represent the aggregate grant date fair value of RSUs granted in 2015.
- (2) As of December 31, 2015, our non-employee directors held the following outstanding RSUs: Dr. Henney (43,470 RSUs); Dr. Jackson (43,470 RSUs); Mr. Spiegelman (43,470 RSUs); Dr. Love (43,470 RSUs); Mr. James (55,063 RSUs).
- (3) 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.

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

**Equity Compensation Plan Information as of December 31, 2015**

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

<u>Plan Category</u>	<u>(A) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>(B) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>(C) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A))(1)</u>
Equity compensation plans approved by security holders:			
Share option plan (\$Cdn.)(2) .....	4,500	\$4.60	—
Share option plan (\$U.S.)(2) .....	7,346,000	\$ 3.18	1,765,777
RSU plan .....	228,943	N.A.	391,788
Equity compensation plans not approved by security holders .....	—	N.A.	—
<b>Total .....</b>	<b>7,579,443</b>	<b>N.A.</b>	<b>2,157,565</b>

(1) All of these are available for issuance under the respective plans pursuant to the grant of restricted stock, restricted share units and other equity awards, as well as for grants of stock options and stock appreciation rights.

(2) Under the terms of the 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 share option plan.

For more information regarding our share option plan and amended and restated restricted share unit plan, see Note 7 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

## Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding beneficial ownership of our capital stock as of February 29, 2016 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, 2016. Beneficial ownership excludes stockholders of Series A convertible preferred stock, Series B convertible preferred stock and Series C convertible preferred stock, each of which are convertible into 1,000 shares of the Company's common stock at any time at the holder's option, provided the holder would not beneficially own in the aggregate more than 4.99%, 4.99% or 9.99% of the company's securities, respectively, subject to an exception that may permit beneficial ownership up to 19.99% upon 61 day's written notice.

Name of Beneficial Owner(1)	Common Stock Beneficially Owned	
	Number of Shares(2)	Percent of Class(3)
5% Stockholders:		
BVF, Inc.(4) .....	18,799,368	19.8%
BlackRock, Inc.(5) .....	7,036,336	7.4%
Franklin Resource, Inc.(6) .....	6,899,600	7.3%
Directors and Named Executive Officers:		
Christopher Henney(7) .....	135,807	*
Richard Jackson(8) .....	59,557	*
Steven P. James .....	—	—
Ted W. Love(9) .....	13,005	*
Daniel Spiegelman(10) .....	25,960	*
Mark Lampert .....	—	—
Gwen Fyfe(11) .....	10,000	*
Robert Kirkman(12) .....	2,303,333	2.4%
Gary Christianson(13) .....	431,674	*
Julia Eastland(14) .....	320,432	*
Diana Hausman(15) .....	362,830	*
Scott Peterson(16) .....	362,507	*
All directors and executive officers as a group (12 persons)(17) .....	4,025,105	4.1%

\* 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, RSUs and warrants exercisable within 60 days after February 29, 2016 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 94,961,859 shares of common stock issued and outstanding as of February 29, 2016.
- (4) Based on information of beneficial ownership as of December 31, 2015, included in a Schedule 13D/A filed with the SEC on January 12, 2016. Includes 18,799,368 shares of common stock beneficially owned by BVF Inc. and various affiliated entities and one individual. BVF Partners L.P. is the general partner of Biotechnology Value Fund, L.P. and Biotechnology Value Fund II, L.P., the sole member of BVF Partners OS Ltd. and the investment manager of Biotechnology Value Trading Fund OS, L.P. and of certain management accounts, each of which may be deemed to beneficially own the shares. Mark Lampert is the sole officer and director of BVF Inc. and may be deemed to beneficially own the shares. Excludes 5,000,000 shares issuable upon the exercise of warrants, 7,500,000 shares issuable upon the conversion of Series C convertible preferred stock, 5,333,000 shares issuable upon the conversion of Series B convertible preferred stock and 2,500,000 shares issuable upon the conversion of Series A



convertible preferred stock, none of which can be exercised or converted within 60 days of February 29, 2016. The address of BVF Inc. is 1 Sansome Street, 30<sup>th</sup> Floor, San Francisco, California 94104.

- (5) Based on information of beneficial ownership as of December 31, 2015, included in a Schedule 13G/A filed with the SEC on January 27, 2016. The address of BlackRock, Inc. is 55 East 52<sup>nd</sup> Street, New York, New York 10022.
- (6) Based on information of beneficial ownership as of December 31, 2015, included in a Schedule 13G filed with the SEC on February 9, 2016. The shares are beneficially owned by one or more open- or closed-end investment companies or other managed accounts that are investment management clients of investment managers that are direct and indirect subsidiaries of Franklin Resources Inc. (FRI). Charles B. Johnson and Rupert H. Johnson, Jr. each own in excess of 10% of the outstanding common stock of FRI and are the principal stockholders of FRI. Accordingly, they may be deemed to be beneficial owners of these shares. The address of Franklin Resources, Inc. is One Franklin Parkway, San Mateo, CA 94403-1906.
- (7) Shares attributable to restricted stock units owned by Dr. Henney are not reflected as none of the shares underlying the RSUs have vested or will vest within 60 days after February 29, 2016.
- (8) Shares attributable to restricted stock units owned by Dr. Jackson are not reflected as none of the shares underlying the RSUs have vested or will vest within 60 days after February 29, 2016.
- (9) Shares attributable to restricted stock units owned Dr. Love are not reflected as none of the shares underlying the RSUs have vested or will vest within 60 days after February 29, 2016.
- (10) Shares attributable to restricted stock units owned by Mr. Spiegelman are not reflected as none of the shares underlying the RSUs have vested or will vest within 60 days after February 29, 2016.
- (11) Includes 10,000 shares of common stock that Dr. Fyfe has the right to acquire under outstanding options exercisable within 60 days after February 29, 2016.
- (12) Includes 2,295,000 shares of common stock that Dr. Kirkman has the right to acquire under outstanding options exercisable within 60 days after February 29, 2016.
- (13) Includes 405,416 shares of common stock that Mr. Christianson has the right to acquire under outstanding options exercisable within 60 days after February 29, 2016.
- (14) Includes 300,416 shares of common stock that Ms. Eastland has the right to acquire under outstanding options exercisable within 60 days after February 29, 2016.
- (15) Includes 357,083 shares of common stock that Dr. Hausman has the right to acquire under outstanding options exercisable within 60 days after February 26, 2016.
- (16) Includes 352,083 shares of common stock that Dr. Peterson has the right to acquire under outstanding options exercisable within 60 days after February 29, 2016.
- (17) Includes 3,709,998 shares of common stock issuable upon exercise of options within 60 days after February 29, 2016 and zero shares of common stock that would be fully vested and issuable upon the vesting of RSUs within 60 days after February 29, 2016.

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

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

We have entered into the arrangements which are described where required under the heading titled “Part III — Item 11 — Executive Compensation — “Termination and Change of Control Provisions under Offer Letters” and “Item 11 — Executive Compensation — Potential Payments Upon Termination or Change in Control” included elsewhere in this Annual Report on Form 10-K.

In February 2015 we closed concurrent but separate underwritten offerings of 13,500,000 shares of our common stock at a price of \$1.50 per share, for gross proceeds of \$20.3 million, and 1,333 shares of our Series B convertible preferred stock at a price of \$1,500 per share for gross proceeds of \$2.0 million. In these offerings, affiliates of BVF, Inc., a holder of more than 5% of our outstanding common stock, purchased 2,500 shares of our Series A preferred stock and 1,333 shares of our Series B preferred stock for an aggregate purchase price of \$7.0 million. Separate but concurrent with the February offering, affiliates of BVF, Inc. also exchanged 4,000,000 shares of common stock for 4,000 shares of Series B preferred stock. Additionally, in connection with our public offering, an affiliate of Ayer Capital Management, L.P., the managing member of which is Dr. Venkatesan, our former executive officer, purchased 250,000 shares of our common stock for a purchase price of \$0.5 million.

In May 2015, affiliates of BVF, Inc. exchanged 7,500,000 shares of common stock for 7,500 shares of Series B preferred stock.

In February 2016, our compensation committee granted an option to purchase 150,000 shares of common stock to Dr. Henney, effective as of the first day of our next open trading window, as compensation for his services as our Interim Chief Executive Officer. The exercise price of the option will be equal to the closing price of our common stock on the NASDAQ Global Market as the effective date of the grant. Assuming the stock option had an exercise price equal to \$1.03, the closing price of our common stock on the NASDAQ Global Market as of March 1, 2016, the aggregate grant date fair value of the stock option would have been \$102,000. The stock option vests in six equal monthly installments, subject to 100% acceleration if Dr. Henney is terminated without cause or a permanent Chief Executive Officer commences employment prior to the stock option being vested in full.

#### ***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 \$120,000, (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.

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

The board of directors has determined that each of our current directors, except Dr. Henney, Dr. Fyfe and Mr. Lampert, is an "independent director" as that term is defined by the applicable rules and regulations of The NASDAQ Stock Market. 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 applicable rules and regulations of The NASDAQ Stock Market, the SEC, and the Internal Revenue Service.

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

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

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

Fees and related expenses for the 2015 audit by Ernst & Young LLP of our annual financial statements, its review of the financial statements included in our 2015 quarterly reports and other services, which include comfort letters, consents and accounting consultations that are provided in connection with statutory and regulatory filings totaled \$480,365. Fees and related expenses for 2014 totaled \$594,935.

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

None.

##### ***Tax Fees***

For the years 2015 and 2014, Ernst & Young LLP billed us zero and \$21,000, respectively, for professional services related to preparation of our tax return and tax consultations on tax related matters.

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

Ernst & Young LLP billed us \$1,995 for each of the years 2015 and 2014 for a subscription to their technical accounting database.

#### **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	Form	<u>Incorporated by Reference</u>		Filed/ Furnished Herewith
			Exhibit No.	Filing Date	
2.1(a)	Agreement and Plan of Reorganization, dated August 8, 2014, among Oncothyreon Inc., AB Acquisition (DE) Corp., Alpine Biosciences, Inc. and Mitchell H. Gold, M.D., as Stockholders' Agent . . . . .	8-K	2.1	August 11, 2014	
3.1	Amended and Restated Certificate of Incorporation of Oncothyreon Inc. . . . .	S-4/A	3.1	September 27, 2007	
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Oncothyreon Inc. . . . .	8-K	3.1	June 10, 2014	
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock . . . . .	8-K	3.1	September 23, 2014	
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock . . . . .	8-K	3.1	February 11, 2014	
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock Limitations . . . . .	8-K	3.1	May 14, 2015	
3.6	Bylaws of Oncothyreon Inc. . . . .	10-Q	3.1	August 14, 2009	
3.7	Amendment to Bylaws of Oncothyreon Inc. . . . .	8-K	3.1	February 24, 2016	

Exhibit No.	Exhibit Description	Form	Incorporated by Reference		Filed/ Furnished Herewith
			Exhibit No.	Filing Date	
4.1	Form of registrant's common stock certificate . . . . .	S-4/A	4.1	September 27, 2007	
4.2	Form of Series A Convertible Preferred Stock Certificate . . . . .	8-K	4.1	September 23, 2014	
4.3	Form of Series B Convertible Preferred Stock Certificate . . . . .	8-K	4.1	February 1, 2014	
4.4	Form of Series C Convertible Preferred Stock Certificate . . . . .	8-K	4.1	May 14, 2015	
4.5	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	
4.6	Form of Warrant issued by Oncothyreon Inc. to BVF Partners L.P. and certain of its affiliates. . . . .	8-K	4.1	May 30, 2013	
4.7	Piggyback Registration Rights Agreement, dated August 8, 2014, by and between Oncothyreon and each of Jay Venkatesan and Mitchell H. Gold. . . . .	10-Q	4.2	November 6, 2014	
10.1*	Amended and Restated Share Option Plan. . . . .	10-K	10.1	March 10, 2015	
10.2*	Form of Stock Option Agreement under the Amended and Restated Share Option Plan. . . . .	10-K	10.2	March 10, 2015	
10.3*	Amended and Restated Restricted Share Unit Plan. . . . .	S-8	99.2	June 6, 2014	
10.4*	Form of Restricted Share Unit Agreement under the Amended and Restated Restricted Share Unit Plan. . . . .	10-K	10.4	March 9, 2012	
10.5*	2010 Employee Stock Purchase Plan. . . . .	8-K	10.1	June 8, 2010	
10.6*	Form of Subscription Agreement and Notice of Withdrawal under the 2010 Employee Stock Purchase Plan. . . . .	8-K	10.2	June 8, 2010	
10.7*	Oncothyreon Inc. Retention Payment Plan. . . . .	8-K	10.3	January 11, 2016	
10.8*	Form of Indemnification Agreement. . . . .	S-4/A	10.1	September 27, 2007	
10.9*	Retirement and Separation Agreement, by and between Oncothyreon Inc. and Robert Kirkman, effective as of January 11, 2016. . . . .	8-K	10.2	January 11, 2016	

Exhibit No.	Exhibit Description	Form	Incorporated by Reference		Filed/ Furnished Herewith
			Exhibit No.	Filing Date	
10.10*	Offer Letter with Gary Christianson, dated June 29, 2007.....	10-Q	10.1	November 10, 2008	
10.10(a)*	Amendment to Gary Christianson Offer Letter dated December 31, 2008.....	10-K	10.40(a)	March 30, 2009	
10.10(b)*	Amendment to Gary Christianson Offer Letter dated December 3, 2009.....	8-K	10.2	December 7, 2009	
10.11*	Offer Letter dated June 9, 2009 between Oncothyreon Inc. and Scott Peterson, Ph.D. ....	8-K	10.2	June 15, 2009	
10.11(a)*	Amendment to Scott Peterson Offer Letter dated December 3, 2009.....	8-K	10.4	December 7, 2009	
10.11(b)*	Amendment to Scott Peterson Offer Letter dated January 8, 2015. ....	8-K	10.1	January 8, 2015	
10.12*	Offer Letter dated July 6, 2009 between Oncothyreon Inc. and Diana Hausman, M.D. ....	8-K	10.1	August 4, 2009	
10.12(a)*	Amendment to Diana Hausman Offer Letter dated December 3, 2009.....	8-K	10.3	December 7, 2009	
10.12(b)*	Amendment to Diana Hausman Offer Letter dated December 21, 2015. ....				X
10.13*	Offer letter with dated August 17, 2010 between Oncothyreon Inc. and Julia M. Eastland . . . . .	8-K	10.1	August 31, 2010	
10.14	Lease Agreement between Selig Holdings Company and Oncothyreon Inc., dated May 9, 2008.....	10-Q	10.3	November 10, 2008	
10.15	Form of Subscription Agreement between BVF Partners L.P. and certain of its affiliates and Oncothyreon Inc. ....	8-K	10-1	May 30, 2013	
10.16 <sup>†</sup>	Patent License Agreement, effective June 30, 2014, between STC.UNM and Oncothyreon Inc. . .	10-Q	10.1	November 6, 2014	
10.17 <sup>†</sup>	First Amendment to Patent License Agreement, dated February 2, 2015, between STC.UNM and Oncothyreon Inc. . .	10-Q	10.1	May 11, 2015	
10.18 <sup>†</sup>	Second Amendment to Patent License Agreement, effective September 15, 2015, between STC.UNM and Oncothyreon Inc. . .	10-Q	10.1	November 5, 2015	

Exhibit No.	Exhibit Description	Form	Incorporated by Reference		Filed/ Furnished Herewith
			Exhibit No.	Filing Date	
10.19 <sup>++</sup>	Third Amendment to Patent License Agreement, effective October 13, 2015, between STC.UNM and Oncothyreon Inc. . .				X
10.20 <sup>+</sup>	License Agreement, dated December 11, 2014, between Oncothyreon and Array BioPharma Inc. . . . .	10-K	10.26	March 10, 2015	
10.21	Securities Exchange Agreement, effective February 5, 2015, between Oncothyreon Inc. and Biotechnology Value Fund, L.P. and Biotechnology Value Fund II, L.P. . . . .	8-K	10.1	February 6, 2015	
10.22	Securities Exchange Agreement, effective May 13, 2015, between Oncothyreon Inc. and Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Investment 10, L.L.C. and MSI BVF SPV, L.L.C.. . . . .	8-K	10.1	May 14, 2015	
10.23	Letter Agreement, by and among Oncothyreon Inc., BVF Partners L.P., Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P., BVF Partners OS Ltd. and BVF Inc., dated January 11, 2016. . . . .	8-K	10.1	January 11, 2016	
21.1	Subsidiaries of Oncothyreon Inc.. .				X
23.1	Consent of Independent Registered Public Accounting Firm. . . . .				X
24.1	Power of Attorney (included on signature page). . . . .				X
31.1	Certification of Christopher Henney, Ph.D., Interim President and Chief Executive Officer, pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.. . . .				X
31.2	Certification of Julia Eastland, Chief Financial Officer, pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. . . . .				X



Exhibit No.	Exhibit Description	Incorporated by Reference		Filed/ Furnished Herewith
		Form	Exhibit No. Filing Date	
32.1	Certification of Christopher Henney, Ph.D., Interim President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(1). . .			X
32.2	Certification of Julia Eastland, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002(1). . . . .			X
101.INS	XBRL Instance Document. . . . .			X
101.SCH	XBRL Taxonomy Extension Schema Document. . . . .			X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document. . .			X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document. . .			X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document. . . . .			X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document..			X

(1) This certification is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, or Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or Securities Act or the Exchange Act.

\* Executive Compensation Plan or Agreement.

† Confidential treatment has been granted for portions of this exhibit.

†† Confidential treatment has been requested for portions of this exhibit pursuant to Rule 24b-2 under the Exchange Act. The omitted portions of this exhibit have been filed separately with the SEC.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Seattle, County of King, State of Washington on March 14, 2016.

ONCOTHYREON INC.

By: /s/ Christopher Henney, Ph.D

Christopher Henney, Ph.D  
Interim President and  
Chief Executive Officer  
(Principal Executive Officer)

## POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints Christopher Henney, Ph.D 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/ Christopher Henney, Ph.D</u> Christopher Henney, Ph.D	Interim President and Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2016
<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 14, 2016
<u>/s/ Gwen A. Fyfe, M.D.</u> Gwen A. Fyfe, M.D.	Director	March 14, 2016
<u>/s/ Richard L. Jackson, Ph.D.</u> Richard L. Jackson, Ph.D.	Director	March 14, 2016
<u>/s/ Steven P. James</u> Steven P. James	Director	March 14, 2016
<u>/s/ Ted W. Love, M.D.</u> Ted W. Love, M.D.	Director	March 14, 2016
<u>/s/ Mark N. Lampert</u> Mark N. Lampert	Director	March 14, 2016
<u>/s/ Daniel K. Spiegelman</u> Daniel K. Spiegelman	Director	March 14, 2016

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Index to Consolidated Financial Statements .....	F-1
Report of Independent Registered Public Accounting Firm .....	F-2
Consolidated Balance Sheets as of December 31, 2015 and 2014 .....	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2015, 2014 and 2013 .....	F-4
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2015, 2014 and 2013 .....	F-5
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2015, 2014 and 2013 .....	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2015, 2014 and 2013 .....	F-7
Notes to the Consolidated Financial Statements .....	F-8

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of  
Oncothyreon Inc.

We have audited the accompanying consolidated balance sheets of Oncothyreon Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. 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, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, 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, 2015, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 14, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington  
March 14, 2016

**ONCOTHYREON INC.**

**Consolidated Balance Sheets  
(In thousands, except share and per share amounts)**

	<b>As of December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>ASSETS</b>		
Current:		
Cash and cash equivalents .....	<b>\$ 27,850</b>	\$ 10,454
Short-term investments .....	<b>28,510</b>	47,217
Accounts and other receivables .....	<b>200</b>	298
Prepaid and other current assets .....	<b>1,418</b>	888
Total current assets .....	<b>57,978</b>	58,857
Long-term investments .....	<b>—</b>	6,043
Property and equipment, net .....	<b>1,845</b>	1,576
Indefinite-lived intangible assets .....	<b>19,738</b>	19,738
Goodwill .....	<b>16,659</b>	16,659
Other assets .....	<b>354</b>	230
Total assets .....	<b>\$ 96,574</b>	\$ 103,103
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current:		
Accounts payable .....	<b>\$ 439</b>	\$ 689
Accrued and other liabilities .....	<b>2,689</b>	1,821
Accrued compensation and related liabilities .....	<b>1,522</b>	1,614
Current portion of restricted share unit liability .....	<b>145</b>	155
Current portion of warrant liability .....	<b>—</b>	128
Total current liabilities .....	<b>4,795</b>	4,407
Other liabilities .....	<b>743</b>	337
Restricted share unit liability .....	<b>363</b>	155
Deferred tax liability .....	<b>6,908</b>	6,908
Class UA preferred stock, 12,500 shares authorized, 12,500 shares issued and outstanding .....	<b>30</b>	30
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized as of December 31, 2015 and 2014; Series A Convertible Preferred Stock – 10,000 shares issued and outstanding as of December 31, 2015 and 2014; Series B Convertible Preferred Stock – 5,333 shares and zero shares issued and outstanding as of December 31, 2015 and 2014, respectively; Series C Convertible Preferred Stock – 7,500 shares and zero shares issued and outstanding as of December 31, 2015 and 2014, respectively .....	<b>—</b>	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized as of December 31, 2015 and 2014; 94,961,859 shares and 91,601,352 shares issued and outstanding as of December 31, 2015 and 2014, respectively .....	<b>353,856</b>	353,856
Additional paid-in capital .....	<b>249,572</b>	224,549
Accumulated deficit .....	<b>(514,629)</b>	(482,048)
Accumulated other comprehensive loss .....	<b>(5,064)</b>	(5,091)
Total stockholders' equity .....	<b>83,735</b>	91,266
Total liabilities and stockholders' equity .....	<b>\$ 96,574</b>	\$ 103,103

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,		
	2015	2014	2013
<b>Operating expenses</b>			
Research and development .....	\$ 23,468	\$ 41,884	\$ 33,221
General and administrative .....	9,321	8,951	8,002
Total operating expenses .....	<u>32,789</u>	<u>50,835</u>	<u>41,223</u>
Loss from operations .....	<b>(32,789)</b>	(50,835)	(41,223)
<b>Other income (expense)</b>			
Investment and other income (expense), net .....	80	76	137
Change in fair value of warrant liability ...	128	796	2,327
Total other income (expense), net .....	<u>208</u>	<u>872</u>	<u>2,464</u>
<b>Loss before income taxes</b> .....	<b>(32,581)</b>	(49,963)	(38,759)
<b>Net loss</b> .....	<b>\$ (32,581)</b>	<b>\$ (49,963)</b>	<b>\$ (38,759)</b>
<b>Net loss per share – basic and diluted</b> .....	<b>\$ (0.34)</b>	<b>\$ (0.64)</b>	<b>\$ (0.62)</b>
<b>Shares used to compute basic and diluted net loss per share</b> .....	<u>96,617,119</u>	<u>77,619,807</u>	<u>62,387,616</u>

See accompanying notes to the consolidated financial statements

**ONCOTHYREON INC.**

**Consolidated Statements of Comprehensive Loss  
(In thousands)**

	Years Ended December 31,		
	2015	2014	2013
<b>Net loss</b> .....	<b>\$ (32,581)</b>	\$ (49,963)	\$(38,759)
<b>Other comprehensive income (loss):</b>			
Available-for-sale securities:			
Unrealized gains (loss) during the period, net .....	27	(34)	(15)
Reclassification adjustment .....	—	(6)	—
Other comprehensive income (loss) .....	27	(40)	(15)
<b>Comprehensive loss</b> .....	<b>\$(32,554)</b>	\$(50,003)	\$(38,774)

See accompanying notes to the consolidated financial statements

**ONCOTHYREON INC.**

**Consolidated Statements of Stockholders' Equity**  
(In thousands, except share amounts)

	Common Stock		Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Stockholders' Equity
	Shares	Amount	Shares	Amount				
<b>Balance at December 31, 2012</b> .....	<u>57,216,237</u>	<u>\$353,853</u>	<u>—</u>	<u>\$—</u>	<u>\$ 126,832</u>	<u>\$ (393,326)</u>	<u>\$ (5,036)</u>	<u>\$ 82,323</u>
Net loss .....	—	—	—	—	—	(38,759)	—	(38,759)
Unrealized gains on available-for-sale securities .....	—	—	—	—	—	—	(15)	(15)
Common stock issued, net of offering costs of \$0.6 million .....	13,346,901	1	—	—	25,955	—	—	25,956
Issuances under employee stock purchase plan .....	74,829	—	—	—	113	—	—	113
Restricted stock units converted .....	35,176	—	—	—	66	—	—	66
Share-based compensation expense .....	—	—	—	—	1,866	—	—	1,866
<b>Balance at December 31, 2013</b> .....	<u>70,673,143</u>	<u>353,854</u>	<u>—</u>	<u>—</u>	<u>154,832</u>	<u>(432,085)</u>	<u>(5,051)</u>	<u>71,550</u>
Net loss .....	—	—	—	—	—	(49,963)	—	(49,963)
Unrealized losses on available-for-sale securities .....	—	—	—	—	—	—	(40)	(40)
Common stock issued, net of offering costs of \$1.4 million .....	11,517,478	1	—	—	21,552	—	—	21,553
Series A Convertible Preferred Stock issued, net of offering costs of \$1.4 million .....	—	—	10,000	—	18,693	—	—	18,693
Acquisition of Alpine Biosciences, Inc. (Alpine) ..	9,245,344	1	—	—	27,232	—	—	27,233
Issuances under employee stock purchase plan .....	76,811	—	—	—	114	—	—	114
Restricted stock units converted .....	82,576	—	—	—	287	—	—	287
Share-based compensation expense .....	—	—	—	—	1,832	—	—	1,832
Stock options exercised .....	6,000	—	—	—	7	—	—	7
<b>Balance at December 31, 2014</b> .....	<u>91,601,352</u>	<u>353,856</u>	<u>10,000</u>	<u>—</u>	<u>224,549</u>	<u>(482,048)</u>	<u>(5,091)</u>	<u>91,266</u>
Net loss .....	—	—	—	—	—	(32,581)	—	(32,581)
Unrealized gains on available-for-sale securities .....	—	—	—	—	—	—	27	27
Common stock issued, net of offering costs of \$1.5 million .....	14,699,660	1	—	—	20,557	—	—	20,558
Series B Convertible Preferred Stock issued, net of offering costs of \$0.1 million .....	(4,000,000)	—	5,333	—	1,863	—	—	1,863
Series C Convertible Preferred Stock issued .....	(7,500,000)	(1)	7,500	—	—	—	—	(1)
Issuances under employee stock purchase plan .....	67,527	—	—	—	112	—	—	112
Restricted stock units converted .....	73,383	—	—	—	278	—	—	278
Share-based compensation expense .....	—	—	—	—	2,179	—	—	2,179
Stock options exercised .....	19,937	—	—	—	34	—	—	34
<b>Balance at December 31, 2015</b> .....	<u>94,961,859</u>	<u>\$353,856</u>	<u>22,833</u>	<u>\$—</u>	<u>\$249,572</u>	<u>\$ (514,629)</u>	<u>\$ (5,064)</u>	<u>\$ 83,735</u>

See accompanying notes to the consolidated financial statements



**ONCOTHYREON INC.**

**Consolidated Statements of Cash Flows  
(In thousands)**

	Years Ended December 31,		
	2015	2014	2013
<b>Cash flows from operating activities</b>			
Net loss .....	<b>\$ (32,581)</b>	\$(49,963)	\$(38,759)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	<b>613</b>	512	489
Amortization of premiums and accretion of discounts on securities .....	<b>305</b>	533	651
Share-based compensation expense .....	<b>2,748</b>	2,187	2,021
Change in fair value of warrant liability .....	<b>(128)</b>	(796)	(2,327)
Cash settled on conversion of restricted share units .....	<b>(93)</b>	(96)	(22)
Other .....	<b>(7)</b>	(1)	(45)
Net changes in assets and liabilities:			
Accounts and other receivables .....	<b>98</b>	(101)	126
Prepaid and other current assets .....	<b>(530)</b>	(168)	120
Other long-term assets .....	<b>(124)</b>	(9)	(16)
Accounts payable .....	<b>(250)</b>	144	(600)
Accrued and other liabilities .....	<b>765</b>	(810)	1,843
Accrued compensation and related liabilities .....	<b>(92)</b>	303	269
Other long-term liabilities .....	<b>406</b>	(102)	(94)
Net cash used in operating activities .....	<b>(28,870)</b>	(48,367)	(36,344)
<b>Cash flows from investing activities</b>			
Purchases of investments .....	<b>(61,556)</b>	(62,411)	(70,775)
Redemption of investments .....	<b>86,027</b>	71,861	68,315
Purchases of property and equipment .....	<b>(771)</b>	(380)	(252)
Cash assumed in connection with the acquisition of Alpine .....	<b>—</b>	104	—
Net cash provided by (used in) investing activities .....	<b>23,700</b>	9,174	(2,712)
<b>Cash flows from financing activities</b>			
Proceeds from issuance of common stock and warrants, net of issuance costs .....	<b>20,669</b>	21,668	26,069
Proceeds from issuance of Series A, B convertible preferred stock, net of issuance cost .....	<b>1,863</b>	18,693	—
Proceeds from stock options exercised .....	<b>34</b>	7	—
Net cash provided by financing activities .....	<b>22,566</b>	40,368	26,069
<b>Increase (decrease) in cash and cash equivalents ..</b>	<b>17,396</b>	1,175	(12,987)
<b>Cash and cash equivalents, beginning of year .....</b>	<b>10,454</b>	9,279	22,266
<b>Cash and cash equivalents, end of year .....</b>	<b>\$ 27,850</b>	\$ 10,454	\$ 9,279
<b>Non-cash activities</b>			
Issuance of common stock in connection with the acquisition of Alpine .....	<b>\$ —</b>	\$ 27,233	\$ —

See accompanying notes to the consolidated financial statements

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

#### 1. DESCRIPTION OF BUSINESS

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

#### 2. SIGNIFICANT ACCOUNTING POLICIES

##### *Basis of presentation*

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

##### *Reclassifications*

Certain prior year amounts totaling \$0.3 million on the Company's Consolidated Balance Sheet as of December 31, 2014 have been reclassified from current liabilities to conform to the current year presentation in the Consolidated Balance Sheet as of December 31, 2015. Additionally, prior year amounts totaling \$0.3 million and \$0.2 million, on the Company's Consolidated Statement of Cash Flows for the years ended December 31, 2014 and 2013, respectively, have been reclassified from the change in current liabilities to conform to the current year presentation in the Consolidated Statements of Cash Flows. These reclassifications relate to the adoption of ASU No. 2015-17 "Balance Sheet Classification of Deferred Taxes." The amendments in this update require that tax liabilities and assets be classified as noncurrent in the classified statement of financial position. These reclassifications had no effect on reported operating expenses, loss from operations, net loss, loss per share, financial position or change in cash used in or provided by operating, investing, or financing activities.

##### *Basis of consolidation*

The Company's consolidated financial statements include the accounts of the company and its wholly-owned subsidiaries, including Procell Therapeutics Inc., 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.

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

#### ***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, 2015, cash and cash equivalents was comprised of \$6.2 million in cash, and \$21.7 million in money market funds and government securities. As of December 31, 2014, cash and cash equivalents was comprised of \$6.4 million in cash and \$4.1 million in money market funds. The carrying value of cash equivalents approximates their fair value.

#### ***Investments***

Investments are classified as available-for-sale securities and are carried at fair value with unrealized temporary holding gains and losses, where applicable, excluded from net income or loss and reported in other comprehensive income or loss and also as a net amount in accumulated other comprehensive income or 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. The Company determined that the unrealized losses on its marketable securities as of December 31, 2015 were temporary in nature, and the Company currently does not intend to sell these securities before recovery of their amortized cost basis. All short-term investments are limited to a final maturity of less than one year from the reporting date. The Company's long-term investments are investments with maturities exceeding 12 months but less than five years from the reporting date. The Company is exposed to credit risk on its cash equivalents, short-term investments and long-term investments in the event of non-performance by counterparties, but does not anticipate such non-performance and mitigates exposure to concentration of credit risk through the nature of its portfolio holdings. If a security falls out of compliance with the Company's investment policy, it may be necessary to sell the security before its maturity date in order to bring the investment portfolio back into compliance. The cost basis of any securities sold is determined by specific identification. The fair value of available-for-sale securities is based on prices obtained from a third-party pricing service. The Company utilizes third-party pricing services for all of its marketable debt security valuations. The Company reviews the pricing methodology used by the third-party pricing services including the manner employed to collect market information. On a periodic basis, the Company also performs review and validation procedures on the pricing information received from the third-party pricing services. These procedures help ensure that the fair value information used by the Company is determined in accordance with applicable accounting guidance. Proceeds from sales of available-for-sale securities were zero and \$12.5 million for the year ended December 31, 2015 and 2014, respectively. The amortized cost, unrealized gain or losses and fair value of the Company's cash, cash equivalents and investments for the periods presented are summarized below:

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
	(In thousands)			
As of December 31, 2015:				
Cash .....	<b>\$ 6,152</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 6,152</b>
Money market funds .....	<b>9,199</b>	<b>—</b>	<b>—</b>	<b>9,199</b>
Debt securities of U.S. government agencies .....	<b>31,511</b>	<b>3</b>	<b>(7)</b>	<b>31,507</b>
Corporate bonds .....	<b>9,496</b>	<b>7</b>	<b>(1)</b>	<b>9,502</b>
<b>Total .....</b>	<b><u>\$56,358</u></b>	<b><u>\$10</u></b>	<b><u>\$(8)</u></b>	<b><u>\$56,360</u></b>

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements**

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
	(In thousands)			
As of December 31, 2014:				
Cash .....	\$ 6,351	\$—	\$ —	\$ 6,351
Money market funds .....	4,103	—	—	4,103
Debt securities of U.S. government agencies .....	43,862	1	(19)	43,844
Corporate bonds .....	9,423	2	(9)	9,416
Total .....	<u>\$63,739</u>	<u>\$ 3</u>	<u>\$(28)</u>	<u>\$ 63,714</u>

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

	<u>As of December 31, 2015</u>		<u>As of December 31, 2014</u>	
	<u>Amortized Cost</u>	<u>Fair Value</u>	<u>Amortized Cost</u>	<u>Fair Value</u>
	(In thousands)			
Less than one year .....	<b>\$50,206</b>	<b>\$50,208</b>	\$ 51,338	\$ 51,319
Greater than one year but less than five years .....	—	—	6,050	6,044
Total .....	<u><b>\$50,206</b></u>	<u><b>\$50,208</b></u>	<u>\$57,388</u>	<u>\$57,363</u>

***Warrants***

Warrants issued in connection with the Company's May 2009 and September 2010 financings are recorded as liabilities as both have the potential for cash settlement upon the occurrence of a fundamental transaction (as defined in the warrant; see "Note 6 — Share Capital"). Changes in the fair value of the warrants are recognized as other income (expense) in the consolidated statements of operations. Warrants issued in connection with the Company's September 2010 financing expired on October 12, 2015 and warrants issued in connection with the Company's May 2009 financing expired on May 26, 2014. None of the liability-classified warrants were outstanding as of December 31, 2015.

***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

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

#### ***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, 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. No impairment charges were recorded for any of the periods presented.

#### ***Indefinite-lived intangible assets — IPR&D***

Intangible assets related to In Process Research & Development (IPR&D) are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. Upon completion of the project, the Company will make a separate determination of useful life of the IPR&D and the related amortization will be recorded as an expense over the estimated useful life. If the IPR&D is abandoned, the carrying value of the asset will be expensed. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested 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 IPR&D exceeds its fair value, an impairment loss would be recognized. Subsequent research and development costs associated with the initial recognition of IPR&D assets are expensed as incurred. No impairment charges were recorded for any of the periods presented.

#### ***Goodwill***

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

#### ***Other liabilities***

Other liabilities includes the long-term portion of accrued milestone payments and deferred rent. Certain milestone payments under our agreement with STC.UNM are accrued on a straight-line basis from initiation of the license agreement to the milestone payment date. Also included in this line item is the long-term portion of deferred rent. Rent expense is recognized on a straight-line basis over the term of the lease. Lease incentives, including rent holidays provided by lessors, and rent escalation provisions are accounted for as deferred rent.

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

The Company recognizes revenue when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured.

#### ***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

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

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, licensing arrangements 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.

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

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding for the period. Diluted net loss per share is calculated by adjusting the numerator and denominator of the basic net loss per share calculation for the effects of all potentially dilutive common shares. Potential dilutive shares of the Company's common stock include stock options, restricted share units, warrants, Series A, B and C convertible preferred stock and shares granted under the 2010 ESPP. The calculation of diluted loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of such securities are dilutive to loss per share for the period, adjustments to net loss used in the calculation are required to remove the change in fair value of the warrants for the period. Furthermore, adjustments to the denominator are required to reflect the addition of the related dilutive shares. Basic net loss per share equaled the diluted loss per share for the year ended December 31, 2015, 2014 and 2013, since the effect of the shares potentially issuable upon the exercise or conversion was anti-dilutive. For additional information regarding the income or loss per share, see "Note 6 — Share Capital."

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

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

The Company recognizes the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. The Company does not believe any uncertain tax positions currently pending will have a material adverse effect on its consolidated financial statements nor expects any

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

material change in its position in the next twelve months. Penalties and interest, of which there are none, would be reflected in income tax expense. Tax years are open to the extent the Company has net operating loss carryforwards available to be utilized currently.

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

Comprehensive income or loss is comprised of net income or loss and other comprehensive income or loss. Other comprehensive income or loss includes unrealized gains and losses on the Company's available-for-sale investments. In addition to unrealized gains and losses on investments, accumulated other comprehensive income or 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. 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 statements of operations and comprehensive loss.

There were no reclassifications out of accumulated other comprehensive loss during the twelve months ended December 31, 2015. The table below shows the changes in accumulated balances of each component of accumulated other comprehensive loss for the twelve months ended December 31, 2015, 2014 and 2013:

	Net unrealized gains/(losses) on Available- for-sale Securities	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
	(In thousands)		
Balance at December 31, 2012 .....	\$ 30	\$(5,066)	\$(5,036)
Other comprehensive loss .....	(15)	—	(15)
Balance at December 31, 2013 .....	15	(5,066)	(5,051)
Other comprehensive loss .....	(40)	—	(40)
Balance at December 31, 2014 .....	\$(25)	\$(5,066)	\$ (5,091)
Other comprehensive income .....	27	—	27
Balance at December 31, 2015 .....	\$ 2	\$(5,066)	\$(5,064)

#### ***Share-based compensation***

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

For non-employee directors, the Company sponsors a RSU Plan that was established in 2005. According to an amendment to the RSU Plan in October 2011, approximately 25% of each RSU represents a contingent right to receive cash upon vesting, and the Company is required to deliver an amount in cash equal to the fair market value of the shares on the vesting date to facilitate the satisfaction of the non-employee directors' U.S. federal income

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

tax obligation with respect to the vested RSUs. This amendment resulted in the RSUs being classified as a liability. The outstanding RSU awards are required to be re-measured at each reporting date until settlement of the award, and changes in valuation are recorded as compensation expense for the period. To the extent that the liability recorded in the balance sheet is less than the original award value, the difference is recognized in equity. The Company uses the closing share price of its shares on the NASDAQ Global Market at the reporting or settlement date to determine the fair value of RSUs. In June 2014, the Company's stockholders approved an increase of 500,000 shares in the number of shares of the Company's common stock reserved for issuance under the RSU Plan.

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

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

#### ***Business Combinations***

In a business combination, the Company determines if the acquired property and activities meet the definition of a business under current accounting guidance. If the combination meets the definition of a business, the Company measures the significance of the combination to determine the required reporting and disclosure requirements for the transaction. Business combinations are required to be accounted for under the acquisition method which requires that identifiable assets acquired, liabilities assumed and any non-controlling interest in the acquiree be recognized and measured as of the acquisition date at fair value. In addition, all consideration transferred must be measured at its acquisition-date fair value.

When necessary, the Company uses a third party valuation expert to determine the fair value of the identifiable assets and liabilities acquired. The estimated fair values of in-process research and development acquired in a business combination which have not been fully developed are capitalized as indefinite-lived intangible assets and impairment testing is conducted periodically.

#### ***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 February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), to improve financial reporting for leasing transactions. The new standard requires lessees to recognize on the balance sheets for a right of use asset and related lease liability. Lessor accounting under the new standard remains similar under current GAAP. The ASU also requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. The effective date for public entities is fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted for all entities. The Company is currently evaluating any impact this standard may have on its consolidated financial position and results of operations.

In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes, to simplify the presentation of deferred income taxes. The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a



## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

classified statement of financial position. The amendments in this update apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update. The new guidance has been adopted retrospectively by the Company beginning with the year ended December 31, 2012, and applied consistently through the year ended December 31, 2015. The retrospective adoption of this update had no effect on reported operating expenses, loss from operations, net loss, loss per share, financial position or change in cash used in or provided by operating, investing, or financing activities.

In August 2015, FASB issued Accounting Standards Update (ASU) 2015-14, Revenue from Contracts with Customers (Topic 606) — Deferral of the Effective Date, which defers by one year the effective date of ASU 2014-09, Revenue from Contracts with Customers. For public entities, the standard is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Early adoption is permitted as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. The Company is currently evaluating any impact this standard may have on its consolidated financial position and results of operations.

In April 2015, FASB issued ASU 2015-05, Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40) Customer's Accounting for Fees Paid in a Cloud Computing Arrangement, to clarify the accounting treatment for cloud computing arrangements. The new standard provides guidance on how customers should evaluate whether a cloud computing arrangement contains a software license that should be accounted for separately. Customers will need to apply the same criteria as vendors to determine whether an arrangement contains a software license or is solely a service contract. This standard is effective for public entities for annual periods, including interim periods within those annual periods, beginning after December 15, 2015. An entity can elect to adopt the standard either prospectively for all arrangements entered into or materially modified after the effective date, or retrospectively. Early adoption is permitted for all entities. The Company adopted this standard on January 1, 2016. The adoption of this standard had no impact on the Company's consolidated financial position or results of operations.

In November 2014, FASB issued Accounting Standards Update 2014-16, Derivatives and Hedging (Topic 815), Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share is More Akin to Debt or Equity, a consensus of the FASB Emerging Issues Task Force. The standard eliminates diversity in the practice of determining whether the nature of a host contract with a hybrid financial instrument issued in the form of a share is more akin to debt or equity and applies to all reporting entities that are issuers of hybrid financial instruments issued in the form of a share. This standard provides that the determination would be based on a consideration of all economic characteristics and the risk of the entire hybrid financial instrument, including the embedded derivative function. Upon adoption, each issued hybrid share instrument must be evaluated to determine whether it contains embedded features that require bifurcation or no longer require bifurcation under the new standard. Retrospective application and early adoption would both be permitted. The standard is effective for public business entities for fiscal years, and interim periods within those years, beginning after December 15, 2015. The Company adopted this standard on January 1, 2016. The adoption of this standard had no impact on the Company's consolidated financial position or results of operations.

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

#### 3. FAIR VALUE MEASUREMENTS

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

- Level 1 – quoted prices in active markets for identical assets or liabilities;
- Level 2 – observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3 – unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's financial assets and liabilities measured at fair value on a recurring basis consisted of the following as of December 31, 2015 and 2014:

	December 31, 2015				December 31, 2014			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
	(In thousands)							
Financial Assets:								
Money market funds . . . . .	\$9,199	\$ —	\$—	\$ 9,199	\$4,103	\$ —	\$ —	\$ 4,103
Debt securities of U.S. government agencies . . . . .	—	31,507	—	31,507	—	43,844	—	43,844
Corporate bonds . . . . .	—	9,502	—	9,502	—	9,416	—	9,416
	<u>\$9,199</u>	<u>\$41,009</u>	<u>\$—</u>	<u>\$50,208</u>	<u>\$4,103</u>	<u>\$53,260</u>	<u>\$ —</u>	<u>\$ 57,363</u>
Financial Liability:								
Restricted Share Units . . . . .	\$ 508	\$ —	\$—	\$ 508	\$ 310	\$ —	\$ —	\$ 310
Warrants . . . . .	—	—	—	—	—	—	128	128

If quoted market prices in active markets for identical assets are not available to determine fair value, then the Company uses quoted prices of similar instruments and other significant inputs derived from observable market data obtained from third-party data providers. These investments are included in Level 2 and consist of debt securities of U.S government agencies and corporate bonds.

There were no transfers between Level 1 and Level 2 during 2015. The Company classifies its warrant liability within Level 3 because the warrant liability is valued using valuation models with significant unobservable inputs. The estimated fair value of warrants accounted for as liabilities was determined on the issuance date and are subsequently re-measured to fair value at each reporting date. The warrants issued from a September 2010 financing expired on October 12, 2015 and the warrants issued from a May 2009 financing expired on May 26, 2014. None of the liability-classified warrants were outstanding as of December 31, 2015.

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements**

The change in fair value of the warrants is recorded in the statement of operations as other income or other expense by using the Black-Scholes option-pricing model with the following inputs:

	<b>As of December 31, 2014</b>
	<b>September 2010 Warrants</b>
Exercise price .....	\$4.24
Market value of stock at end of period .....	\$ 1.90
Expected dividend rate .....	0.0%
Expected volatility .....	60.3%
Risk-free interest rate .....	0.2%
Expected life (in years) .....	0.78

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

	<b>Years Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(In thousands)</b>	
Balance at beginning of period .....	<b>\$ 128</b>	\$ 924
Change in fair value of warrant liability included in Other expense (income) .....	<b>(128)</b>	(796)
Balance at the end of period .....	<b>\$ —</b>	<b>\$ 128</b>

Expected volatility is an unobservable input that is inter-related with the market value or price of the Company's stock, since the calculation of volatility is based on the Company's historical closing prices. There would be no impact on the value of the warrant liability if volatility were to increase or decrease by 10%.

**4. PROPERTY AND EQUIPMENT**

The table below outlines the cost, accumulated depreciation and amortization and net carrying value of the Company's property and equipment for the years ended December 31, 2015 and 2014:

	<b>2015</b>		
	<b>Cost</b>	<b>Accumulated Depreciation and Amortization</b>	<b>Net Carrying Value</b>
	<b>(In thousands)</b>		
Scientific equipment .....	<b>\$ 3,155</b>	<b>\$ (1,847)</b>	<b>\$1,308</b>
Leasehold improvements .....	<b>1,590</b>	<b>(1,109)</b>	<b>481</b>
Computer software and equipment .....	<b>375</b>	<b>(320)</b>	<b>55</b>
Office equipment .....	<b>34</b>	<b>(33)</b>	<b>1</b>
	<b><u>\$5,154</u></b>	<b><u>\$(3,309)</u></b>	<b><u>\$1,845</u></b>

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

	2014	
Cost	Accumulated Depreciation and Amortization	Net Carrying Value
	(In thousands)	
Scientific equipment .....	\$2,273	\$ (1,429)
Leasehold improvements .....	1,590	(948)
Computer software and equipment .....	414	(327)
Office equipment .....	34	(31)
	\$ 4,311	\$(2,735)

Depreciation and leasehold improvement amortization expense was \$0.6 million, \$0.5 million and \$0.5 million for the years ended December 31, 2015, 2014 and 2013, respectively.

#### 5. ACQUISITION

On August 8, 2014, the Company entered into an Agreement and Plan of Reorganization (Merger Agreement) with Alpine Biosciences, Inc. (Alpine), a privately held biotechnology company developing protocells, a nanoparticle capable of delivery of nucleic acids, proteins, peptides and small molecules. Pursuant to the terms and conditions set forth in the Merger Agreement, on August 8, 2014, the Company, through a reverse-triangular merger with Alpine into a fully-owned subsidiary of the Company, known as Protocell Therapeutics Inc, consummated the acquisition of Alpine. The merger consideration received by Alpine stockholders was 10% of the Company's total capital stock determined on a fully-diluted basis immediately following the closing of the merger (Merger Consideration). The total value of the acquisition was approximately \$27.2 million based on the closing price of Oncothyreon's common stock on the day of the merger, which was \$2.93 per share. An amount of stock equal to 12.5% of the Merger Consideration was placed in escrow as security for the indemnification obligations of Alpine's stockholders. The Company intends to utilize the protocell technology to develop new product candidates for the treatment of cancer, either on its own or with partners.

The transaction has been accounted for using the acquisition method of accounting. This method requires, among other things, that assets acquired and liabilities assumed in a business combination be recognized at their estimated fair values as of the acquisition date and that intangible assets with indefinite lives be recorded at fair value on the balance sheet for IPR&D activities, regardless of the likelihood of success of the related product or technology. The excess of the aggregate fair value of consideration exchanged for an acquired business over the fair value of assets acquired including tangible assets and indefinite-lived intangible assets and liabilities assumed is recorded as Goodwill. Goodwill represents the anticipated synergies from combining the acquired assets with the Company.

#### ***Recognition and Measurement of Assets Acquired and Liabilities Assumed at Estimated Fair Value***

The total purchase consideration has been allocated to the assets acquired and liabilities assumed, including identifiable intangible assets, based on their respective fair values at the acquisition date. Goodwill was derived from the excess of the aggregate fair value of consideration exchanged for the acquisition of Alpine over the fair value of assets acquired and liabilities assumed. Based upon the fair values determined by the Company, in which the Company considered or relied in part upon a valuation report of a third-party expert.

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

These fair value measurements were based on Level 3 measurements under the fair value hierarchy. The following table summarizes the allocation of the purchase price for the acquisition (in thousands):

Indefinite-lived intangible assets .....	\$ 19,738
Goodwill .....	14,542
Net tangible assets .....	(139)
Deferred tax liabilities .....	<u>(6,908)</u>
Total purchase price allocation .....	<u>\$27,233</u>

#### **Goodwill**

There was no change in the carrying amount of goodwill for the year ended December 31, 2015. The changes in the carrying amount of goodwill for the year ended December 31, 2014 were as follows (in thousands):

Balance as of December 31, 2013 .....	\$ 2,117
Goodwill recorded in connection with the acquisition of Alpine .....	<u>14,542</u>
Balance as of December 31, 2014 .....	<u>\$16,659</u>

The goodwill recognized from the acquisition of Alpine is not deductible for tax purposes.

#### **Indefinite-lived Intangible Assets – IPR&D**

Intangible assets with indefinite lives represent the value assigned to IPR&D that, as of the acquisition date, the Company determined that technological feasibility had not been established, and the IPR&D had no alternative future use. IPR&D represents a series of awarded patents and filed patent applications that are the basis of the platform which forms a major part of the planned future products. The indefinite-lived intangible assets will be subject to annual impairment testing until completion or abandonment of the projects. Upon completion of the project, the Company will make a separate determination of useful life of the indefinite-lived intangible assets and the related amortization will be recorded as an expense over the estimated useful life.

The fair value of the indefinite-lived intangible assets of \$19.7 million was determined by the Company, which relied upon a valuation report from an independent third party valuation expert using the income approach and estimates and assumptions provided by the Company's management. The income approach is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. The rates utilized to discount net cash flows to their present values were based on a range of discount rates of 40% to 60% applied to the intangible assets to reflect the risk of the asset revenues derived from the respective intangible asset. Subsequent to the closing of the merger, research and development cost incurred on the IPR&D and general and administrative expenses associated with salaries and legal costs are expensed as incurred.

#### **Deferred Tax Liabilities**

Deferred tax liabilities of \$6.9 million were the result of book versus tax difference attributable to the identifiable intangible asset multiplied by the statutory tax rate for the relevant jurisdiction.

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

#### **Acquisition-Related Expenses**

Acquisition-related expenses of \$0.5 million, including legal and regulatory costs, were expensed as incurred and recorded in general and administrative expense in the Company's condensed consolidated statements of operations for the year ended December 31, 2014. There was no acquisition-related expenses for the year ended December 31, 2015.

#### **Unaudited Pro Forma Financial Information**

The following pro forma condensed combined financial information gives effect to the acquisition of Alpine as if it were consummated on January 1, 2013 (the beginning of the comparable prior reporting period), and includes pro forma adjustments related to share-based compensation expense and direct and incremental transaction costs reflected in the historical financial statements. The pro forma condensed combined financial information is presented for informational purposes only. The pro forma condensed combined financial information is not intended to represent or be indicative of the results of operations that would have been reported had the acquisition occurred on January 1, 2013 and should not be taken as representative of future results of operations of the combined company.

The following table presents the unaudited pro forma condensed combined financial information (in thousands, except per share amounts):

	<u>Year Ended December 31,</u>	
	<u>2014</u>	<u>2013</u>
Net loss .....	<b>\$(51,297)</b>	\$(39,287)
Net loss per share – basic and diluted .....	<b>\$ (0.66)</b>	\$ (0.63)

## **6. SHARE CAPITAL**

#### **Class UA preferred stock**

As of December 31, 2015 and 2014, 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

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

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, 2015 and 2014, the Company had authorized 10,000,000 shares of undesignated preferred stock, \$0.0001 par value per share. As of December 31, 2015, the Company had 10,000 shares of Series A convertible preferred stock, 5,333 shares of Series B convertible preferred stock and 7,500 shares of Series C convertible preferred stock issued and outstanding. As of December 31, 2014, the Company had 10,000 shares of Series A convertible preferred stock, zero shares of Series B convertible preferred stock and zero shares of Series C convertible preferred stock issued and 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.

#### **Series A Convertible Preferred Stock**

As of December 31, 2015 and 2014, the Company had 10,000 shares of Series A convertible preferred stock issued and outstanding.

On September 22, 2014, in connection with the public offering of 10,000 shares of the Company’s Series A convertible preferred stock, the Company designated 10,000 shares of its authorized and unissued preferred stock as Series A convertible preferred stock and filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock with the Delaware Secretary of State. Each share of Series A convertible preferred stock is convertible into 1,000 shares of the Company’s common stock at any time at the holder’s option. The holder, however, will be prohibited from converting Series A convertible preferred stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the shares of the Company’s common stock then issued and outstanding. In the event of

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

the Company's liquidation, dissolution, or winding up, holders of Series A convertible preferred stock will receive a payment equal to \$0.0001 per share of Series A convertible preferred stock before any proceeds are distributed to the holders of common stock, after any proceeds are distributed to the holder of the Company's Class UA preferred stock and on parity with any distributions to the holders of the Company's Series B convertible preferred stock and Series C convertible preferred stock. Shares of Series A convertible preferred stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A convertible preferred stock will be required to amend the terms of the Series A convertible preferred stock. Shares of Series A convertible preferred stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors, and will rank:

- senior to all common stock;
- senior to any class or series of capital stock created specifically ranking by its terms junior to the Series A convertible preferred stock;
- on parity with the Company's Series B convertible preferred stock, Series C convertible preferred stock any class or series of capital stock created specifically ranking by its terms on parity with the Series A convertible preferred stock; and
- junior to the Company's Class UA preferred stock and any class or series of capital stock created specifically ranking by its terms senior to the Series A convertible preferred stock;

in each case, as to distribution of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily.

#### **Series B Convertible Preferred Stock**

As of December 31, 2015, the Company had 5,333 shares of Series B convertible preferred stock issued and outstanding.

On February 11, 2015, in connection with the public offering of 1,333 shares of the Company's Series B convertible preferred stock, the Company designated 5,333 shares of its authorized and unissued preferred stock as Series B convertible preferred stock and filed a Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock with the Delaware Secretary of State. Each share of Series B convertible preferred stock is convertible into 1,000 shares of the Company's common stock at any time at the holder's option. The holder, however, will be prohibited from converting Series B convertible preferred stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the shares of the Company's common stock then issued and outstanding. In the event of the Company's liquidation, dissolution, or winding up, holders of Series B convertible preferred stock will receive a payment equal to \$0.0001 per share of Series B convertible preferred stock before any proceeds are distributed to the holders of common stock, after any proceeds are distributed to the holder of the Company's Class UA preferred stock and on parity with any distributions to the holders of the Company's Series A convertible preferred stock and Series C convertible preferred stock. Shares of Series B convertible preferred stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B convertible preferred stock will be required to amend the terms of the Series B convertible preferred



## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

stock. Shares of Series B convertible preferred stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors, and will rank:

- senior to all common stock;
- senior to any class or series of capital stock created specifically ranking by its terms junior to the Series B convertible preferred stock;
- on parity with the Company's Series A convertible preferred stock, Series C convertible preferred stock and any class or series of capital stock created specifically ranking by its terms on parity with the Series B convertible preferred stock; and
- junior to the Company's Class UA preferred stock and any class or series of capital stock created specifically ranking by its terms senior to the Series B convertible preferred stock;

in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily.

#### **Series C Convertible Preferred Stock**

As of December 31, 2015, the Company had 7,500 shares of Series C convertible preferred stock issued and outstanding.

On May 14, 2015, the Company designated 7,500 shares of its authorized and unissued preferred stock as Series C Convertible Preferred Stock and filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock with the Delaware Secretary of State. The Company entered into an exchange agreement with certain affiliates of Biotechnology Value Fund (BVF) to exchange 7,500,000 shares of common stock previously purchased by BVF for 7,500 shares of Series C Convertible Preferred Stock. Each share of Series C Convertible Preferred Stock is convertible into 1,000 shares of the Company's Common Stock at any time at the holder's option. The holder, however, will be prohibited from converting Series C Convertible Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the shares of the Company's Common Stock then issued and outstanding. In the event of the Company's liquidation, dissolution, or winding up, holders of Series C Convertible Preferred Stock will receive a payment equal to \$0.0001 per share of Series C Convertible Preferred Stock before any proceeds are distributed to the holders of common stock, after any proceeds are distributed to the holder of the Company's Class UA Preferred Stock and on parity with any distributions to the holders of the Company's Series A Convertible Preferred Stock and Series B Convertible Preferred Stock. Shares of Series C Convertible Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series C Convertible Preferred Stock will be required to amend the terms of the Series C Convertible Preferred Stock. Shares of Series C Convertible Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors, and will rank:

- senior to all common stock;
- senior to any class or series of capital stock hereafter created specifically ranking by its terms junior to the Series C Convertible Preferred Stock;

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

- on parity with the Company's Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and any class or series of capital stock hereafter created specifically ranking by its terms on parity with the Series C Convertible Preferred Stock; and
- junior to the Company's Class UA Preferred Stock and any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series C Convertible Preferred Stock;

in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily.

#### ***Common stock***

On June 6, 2014, the stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of the Company's authorized common shares from 100,000,000 to 200,000,000. On June 6, 2014, the Company filed a Certificate of Amendment with the Delaware Secretary of State to effect such amendment.

As of December 31, 2015 and 2014, the Company had 200,000,000 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 \$9,496 and \$9,160 of which represents par value of common stock as of December 31, 2015 and 2014, respectively. Additional paid-in capital primarily relates to amounts for equity financings and share-based compensation.

#### ***Warrants***

In connection with certain equity and debt financings, the Company issued warrants to purchase shares of its common stock.

Warrants to purchase 3,182,147 shares of the Company's common stock from a September 2010 financing expired on October 12, 2015. Warrants to purchase 2,691,242 shares of the Company's common stock from a May 2009 financing expired on May 26, 2014.

In February 2011, the Company issued 48,701 warrants, which were classified as equity, to purchase shares of common stock in connection with a Loan and Security Agreement entered into with General Electric Capital Corporation.

In June 2013, the Company issued warrants to purchase 5,000,000 shares of common stock, which were classified as equity, in connection with a registered direct offering to Biotechnology Value Fund, L.P. and other affiliates of BVF Partners L.P. (collectively, "BVF").

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements**

A summary of outstanding warrants as of December 31, 2015 and 2014 and changes during the years are presented below.

	<b>2015</b>	<b>2014</b>
	<b>Shares Underlying Warrants</b>	<b>Shares Underlying Warrants</b>
Balance, beginning of year .....	<b>8,230,848</b>	<b>10,922,090</b>
Warrants expired .....	<b>(3,182,147)</b>	<b>(2,691,242)</b>
Balance, end of year .....	<b>5,048,701</b>	<b>8,230,848</b>

The following table summarizes information regarding warrants outstanding at December 31, 2015:

<b>Exercise Prices</b>	<b>Shares Underlying Outstanding Warrants</b>	<b>Expiry Date</b>
\$3.08 .....	48,701	February 8, 2018
\$5.00 .....	5,000,000	December 5, 2018
	5,048,701	

	<b>Years Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Shares underlying warrants outstanding classified as liabilities .....	—	3,182,147
Shares underlying warrants outstanding classified as equity .....	5,048,701	5,048,701

**Equity Financings**

On February 6, 2015, the Company entered into two underwriting agreements with Jefferies LLC, as underwriter, for separate but concurrent offerings of the Company's securities. On February 11, 2015, the Company closed concurrent but separate underwritten offerings of 13,500,000 shares of its common stock at a price to the public of \$1.50 per share, for gross proceeds of approximately \$20.3 million and 1,333 shares of its Series B convertible preferred stock at a price to the public of \$1,500 per share, for gross proceeds of approximately \$2.0 million. Each share of Series B convertible preferred stock is non-voting and convertible into 1,000 shares of the Company's common stock, provided that conversion will be prohibited if, as a result, the holder and its affiliates would beneficially own more than 4.99% of the common stock then outstanding. As part of the common stock offering, the Company also granted the underwriters a 30-day option to purchase 2,025,000 additional shares of its common stock. On February 18, 2015, the Company closed a partial exercise of the underwriter's option to purchase 1,199,660 additional shares of its common stock, at a price to the public of \$1.50 per share, less underwriting discounts and commissions, which resulted in net proceeds to the Company of approximately \$1.7 million. Aggregate gross proceeds from the offerings were approximately \$24.0 million. Aggregate net proceeds from the offerings, after underwriting discounts and commissions and estimated expenses of \$1.6 million, were approximately \$22.4 million.

On September 18, 2014, the Company entered into two underwriting agreements with Cowen and Company, LLC as representative of the underwriters named therein for concurrent but separate offerings of the Company's securities. On September 23, 2014, the

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements**

Company closed concurrent but separate underwritten offerings of 10,000,000 shares of its common stock at a price of \$2.00 per share, for gross proceeds of \$20 million, and 10,000 shares of its Series A convertible preferred stock at a price of \$2,000 per share, for gross proceeds of \$20 million. Each share of Series A convertible preferred stock is non-voting and convertible into 1,000 shares of the Company's common stock at any time at the option of the holder, provided that conversion will be prohibited if, as a result, the holder and its affiliates would beneficially own more than 4.99% of the common stock then outstanding. As part of the common stock offering, the Company also granted the underwriters, and the underwriters exercised, a 30-day option to purchase 1,500,000 additional shares of the Company's common stock. Aggregate gross proceeds from the offerings were approximately \$43.0 million. Aggregate net proceeds from the offerings, after commissions and estimated expenses of \$2.8 million, was approximately \$40.2 million which included \$21.6 million from the Company's common stock offering and \$18.6 million from the Company's Series A convertible preferred stock offering.

**Net loss per share**

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding for the period. Diluted net loss per share is calculated by adjusting the numerator and denominator of the basic net loss per share calculation for the effects of all potentially dilutive common shares. Potential dilutive shares of the Company's common stock include stock options, restricted share units, warrants, Series A, B and C convertible preferred stock and shares granted under the 2010 ESPP. The calculation of diluted loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of such securities are dilutive to loss per share for the period, adjustments to net loss used in the calculation are required to remove the change in fair value of the warrants for the period. Furthermore, adjustments to the denominator are required to reflect the addition of the related dilutive shares.

The following table is a reconciliation of the numerators and denominators used in the calculation of basic and diluted net loss per share computations for the years ended December 31, 2015, 2014 and 2013:

	<u>Years Ended December 31,</u>		
	<u>2015</u>	<u>2014</u>	<u>2013</u>
	<u>(in thousands, except share and per share amounts)</u>		
Numerator:			
Net loss used to compute net loss per share			
Basic .....	\$ (32,581)	\$ (49,963)	\$ (38,759)
Adjustments for change in fair value of warrant liability .....	<u>—</u>	<u>—</u>	<u>—</u>
Diluted .....	<u>\$ (32,581)</u>	<u>\$ (49,963)</u>	<u>\$ (38,759)</u>
Denominator:			
Weighted average shares outstanding used to compute net loss per share:			
Basic .....	96,617,119	77,619,807	62,387,616
Dilutive effect of warrants .....	<u>—</u>	<u>—</u>	<u>—</u>
Diluted .....	<u>96,617,119</u>	<u>77,619,807</u>	<u>62,387,616</u>
Net loss per share – basic and diluted .....	<u>\$ (0.34)</u>	<u>\$ (0.64)</u>	<u>\$ (0.62)</u>

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

The following table presents the number of shares that were excluded from the number of shares used to calculate diluted net loss per share:

	Years Ended December 31,		
	2015	2014	2013
Director and employee stock options .....	<b>7,350,500</b>	5,217,535	4,415,033
Warrants .....	<b>5,048,701</b>	8,230,848	10,922,090
Series A convertible preferred stock (as converted to common stock) ..	<b>10,000,000</b>	10,000,000	—
Series B convertible preferred stock (as converted to common stock) ..	<b>5,333,000</b>	—	—
Series C convertible preferred stock (as converted to common stock) ..	<b>7,500,000</b>	—	—
Non-employee director restricted share units .....	<b>228,943</b>	163,204	191,613
Employee stock purchase plan .....	<b>2,696</b>	3,997	2,765

## 7. SHARE-BASED COMPENSATION

### *Share option plan*

The Company sponsors a Share Option Plan (Option Plan) under which a maximum fixed reloading percentage of 10% of the issued and outstanding common shares of the Company may be granted to employees, directors, and service providers. Prior to April 1, 2008, options were granted with a per share exercise price, in Canadian dollars, equal to the closing market price of the Company's shares of common stock on the Toronto Stock Exchange on the date immediately preceding the date of the grant. After April 1, 2008, options were granted with a per share exercise price, in U.S. dollars, equal to the closing price of the Company's shares of common stock on The NASDAQ Global Market on the date of grant. Canadian dollar amounts reflected in the tables below, which approximates their U.S. dollar equivalents as differences between the U.S. dollar and Canadian dollar exchange rates for the periods reflected below are not material. Prior to January 2010, options granted under the Option Plan begin to vest after one year from the date of the grant, are exercisable in equal amounts over four years on the anniversary date of the grant, and expire eight years following the date of grant. After January 2010, options granted under the Option Plan begin to vest 25% on the first anniversary of the hiring date, with the balance vesting in monthly increments for 36 months following the first anniversary of hiring, and expire eight years following the date of grant. The Option Plan expires on May 3, 2017. The current maximum number of shares of common stock reserved for issuance under the Option Plan is 9,496,186. As of December 31, 2015, 1,765,777 shares of common stock remain available for future grant under the Option Plan. A summary of option activity under the Option Plan as of December 31, 2015, 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.

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements**

<u>Options</u>	<u>Stock Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
<b>In Canadian dollars (\$CDN):</b>				
Outstanding at January 1, 2015 ..	172,535	\$7.80		
Granted .....	—	—		
Exercised .....	—	—		
Forfeited .....	—	—		
Expired .....	<u>(168,035)</u>	7.89		
Outstanding at December 31, 2015 .....	<u>4,500</u>	\$ 4.6	0.23	\$ —
Vested or expected to vest at December 31, 2015 .....	<u>4,500</u>	\$ 4.6	0.23	\$ —
Vested and exercisable at December 31, 2015 .....	<u>4,500</u>	\$ 4.6	0.23	\$ —
<b>In US dollars (\$US):</b>				
Outstanding at January 1, 2015 ..	5,045,000	\$2.97		
Granted .....	2,574,000	3.48		
Exercised .....	(19,937)	1.73		
Forfeited .....	(253,063)	2.10		
Expired .....	<u>—</u>	—		
Outstanding at December 31, 2015 .....	<u>7,346,000</u>	\$ 3.18	5.90	\$1,417,060
Vested or expected to vest at December 31, 2015 .....	<u>7,085,191</u>	\$ 3.18	5.84	\$1,396,593
Vested and exercisable at December 31, 2015 .....	<u>3,050,031</u>	\$3.62	4.08	\$ 659,515

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, 2015. The total fair value of stock options vested during the years ended December 31, 2015, 2014 and 2013 was \$8.00 million, \$6.29 million and \$4.73 million, respectively. There were 19,937, 6,000 and zero stock options exercised for the year ended December 31, 2015, 2014 and 2013, respectively. Cash received from stock option exercises and the total intrinsic value of stock option exercises for the years ended December 31, 2015 were \$34,568 and \$39,859, respectively. Cash received from stock option exercises and the total intrinsic value of stock option exercises for the years ended December 31, 2014 were immaterial and for the year ended December 31, 2013 were zero. As of December 31, 2015, there were 1,176,229 exercisable, in-the-money stock options based on the Company's closing share price of \$2.22 on The NASDAQ Global Market.

Share-based compensation expense related to the stock option plan of \$2.1 million, \$1.7 million and \$1.7 million was recognized for the years ended December 31, 2015, 2014 and 2013, respectively. Total compensation cost related to non-vested stock options not yet recognized was \$6.6 million as of December 31, 2015, which is expected to be

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

recognized over the next 39 months on a weighted-average basis. The Company uses the Black-Scholes option pricing model to value options upon grant date, under the following weighted average assumptions:

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Expected dividend rate .....	<b>0.00%</b>	0.00%	0.00%
Expected volatility .....	<b>72.15%</b>	78.67%	86.53%
Risk-free interest rate .....	<b>1.63%</b>	1.65%	1.90%
Expected life of options in years .....	<b>6.00</b>	5.82	6.00

The expected term represents the period that the Company's stock options are expected to be outstanding and was determined based on the simplified method, which calculates the expected life as the average of the vesting term and the contractual term of the option. The Company's historical stock option exercise data was impacted by a restructuring of its business in 2008. Because the Company does not have sufficient historical stock option exercise data to accurately estimate the expected term used for its valuation of stock options, the Company continues to use the simplified method to calculate the expected term of new stock option grants. As the Company accumulates more data and history related to the exercises of stock option awards, the Company will reassess its use of the simplified method to determine the expected term. The expected volatility is based on the historical volatility of the Company's common stock for a period equal to the stock option's expected life. The risk-free interest rate is based on the yield at the time of grant of a U.S. Treasury security with an equivalent expected term of the option. The Company does not expect to pay dividends on its common stock. The amounts estimated according to the Black-Scholes option pricing model may not be indicative of the actual values realized upon the exercise of these options by the holders.

Share-based compensation guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. The Company estimates forfeitures based on its historical experience.

#### ***Restricted share unit plan***

The Company also sponsors a RSU Plan for non-employee directors that was established in 2005. The RSU Plan provides for grants to be made from time to time by the Board of Directors or a committee thereof. Each restricted stock unit granted will be made in accordance with the RSU Plan and terms specific to that grant and will be converted into one share of common stock less the cash payment provisions described below at the end of the grant period (not to exceed five years) without any further consideration payable to the Company in respect thereof. On June 6, 2014, the Company's stockholders approved an increase of 500,000 shares in the number of shares of the Company's common stock reserved for issuance under the RSU Plan. The RSU Plan expires on February 22, 2017. The current maximum number of common shares of the Company reserved for issuance pursuant to the RSU Plan is 966,666. As of December 31, 2015, 391,788 shares of common stock remain available for future grant under the RSU Plan. The fair value of the restricted share units has been determined to be the equivalent of the Company's common share closing trading price on the date of grant as quoted on the NASDAQ Global Market.

Approximately 25% of each RSU represents a contingent right to receive cash upon vesting, and the Company is required to deliver an amount in cash equal to the fair market value of such shares on the vesting date to facilitate the satisfaction of the non-employee directors' U.S. federal income tax obligation with respect to the vested RSUs. The outstanding RSU awards are required to be re-measured at each reporting date until

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

settlement of the award, and changes in valuation are recorded as compensation expense for the period. To the extent that the liability recorded in the balance sheet is less than the original award value, the difference is recognized in equity. The fair value of the outstanding RSUs on the reporting date is determined to be the closing trading price of the Company's common shares on that date.

Upon vesting, RSUs of 97,848, 110,104 and 46,906 with a weighted average fair value of \$3.79, \$3.47 and \$1.84 were converted into 97,848, 110,104 and 46,906 shares of common stock for the years ended December 31, 2015, 2014 and 2013, respectively. Pursuant to an October 2011 amendment to the Company's RSU Plan, the Company withheld 24,465 shares of the 97,848 RSUs for the year ended December 31, 2015, 27,528 shares of the 110,104 RSUs for the year ended December 31, 2014 and 11,730 shares of the 46,906 RSUs for the year ended December 31, 2013. The Company delivered to non-employee directors cash totaling \$92,759, \$95,653 and \$21,636, which was equal to the fair value of the shares withheld on the vesting date in order to facilitate satisfaction of the non-employee directors' income tax obligation with respect to the vested RSUs for the years ended December 31, 2015, 2014 and 2013, respectively.

A summary of the RSU activity under the Company's RSU Plan as of December 31, 2015, and changes during such year is presented below:

<u>Restricted Share Units</u>	<u>Restricted Share Units</u>	<u>Weighted Average Fair Value per Unit</u>
Outstanding at January 1, 2015 .....	163,204	\$1.90
Granted .....	163,587	3.36
Converted .....	(97,848)	3.79
Outstanding at December 31, 2015 .....	<u>228,943</u>	<u>\$2.22</u>
Expected to vest at December 31, 2015 .....	<u>228,943</u>	\$2.22

As of December 31, 2015, there was no unrecognized compensation cost related to unvested RSUs. The re-measurement of the outstanding RSUs together with the grant and conversion of the RSUs resulted in an additional \$0.6 million, \$0.4 million and \$0.2 million in share-based compensation expense recorded in general and administrative expenses in the consolidated statement of operations for the years ended December 31, 2015, 2014 and 2013, respectively.

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

The Company adopted an 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.



## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

Fair value of shares purchases under the Company's ESPP was estimated at subscription dates using a Black-Scholes valuation model, which requires the input of highly subjective assumptions including expected stock price volatility and expected term. The expected volatility is based on the historical volatility of the Company's common stock for a period equal to the ESPP's expected life, which is determined by length of time between the subscription date and the purchase date. The risk-free interest rate is based on the yield at the time of grant of a U.S. Treasury security with an equivalent expected term of the ESPP. The Company does not expect to pay dividends on its common stock.

For the year ended December 31, 2015, 2014 and 2013, expense related to this plan was \$95,764, \$101,796 and \$149,674, respectively. As of December 31, 2015, there are 533,006 shares reserved for future purchases and there was approximately \$111,000 of unrecognized compensation cost related to the ESPP, which is expected to be recognized over an estimated weighted-average period of 1.49 year. The following table summarizes information for shares issued under the ESPP for the years ended December 31, 2015, 2014 and 2013:

<u>Purchase Prices</u>	<b>Shares Issued for the Years Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
\$1.46 .....	—	—	38,934
\$1.49 .....	<b>28,192</b>	76,811	—
\$1.57 .....	—	—	35,895
\$1.62 .....	<b>11,394</b>	—	—
\$1.85 .....	<b>27,941</b>	—	—
Total .....	<b>67,527</b>	76,811	74,829

#### **8. COLLABORATIVE AND LICENSE AGREEMENTS**

##### ***Array BioPharma Agreements***

On December 11, 2014, the Company entered into a License Agreement (the License Agreement) with Array BioPharma Inc. (Array). Pursuant to the License Agreement, Array granted the Company an exclusive license to develop, manufacture and commercialize ONT-380, an orally active, reversible and selective small-molecule HER2 inhibitor.

Under the terms of the License Agreement, the Company paid Array an upfront fee of \$20 million, which was recorded as part of research and development expense upon initiation of the exclusive license agreement. In addition, if the Company sublicenses rights to ONT-380 to a third party, the Company will pay Array a percentage of any sublicense payments it receives, with the percentage varying according to the stage of development of ONT-380 at the time of the sublicense. If the Company is acquired within three years of the effective date of the License Agreement, and ONT-380 has not been sublicensed to another entity prior to such acquisition, then the acquirer will be required to make certain milestone payments of up to \$280 million to Array, which are primarily based on potential ONT-380 sales. Array is also entitled to receive up to a double-digit royalty based on net sales of ONT-380.

The License Agreement will expire on a country-by-country basis ten years following the first commercial sale of the product in each respective country, but may be terminated earlier by either party upon material breach of the License Agreement by the other party or the other party's insolvency, or by the Company on 180 days' notice to Array. The Company and Array have also agreed to indemnify the other party for certain of their respective warranties and obligations under the License Agreement.

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

#### ***Celldex Therapeutics, Inc.***

On May 28, 2014, the Company entered into a Co-Development Agreement with Celldex Therapeutics, Inc. (Celldex) to collaborate on a combined Phase 1b clinical trial of ONT-10 and varlilumab. The primary objective of the trial was to determine the safety and tolerability of the combined therapy. Additional objectives included evaluations of the impact of combination treatment on MUC1-specific humoral and cellular immune responses and anti-tumor effects.

The agreement provided that the Company would supply ONT-10 and Celldex would supply varlilumab. The Phase 1b trial would be conducted and funded by the Company. The Company and Celldex would jointly own the data from the trial. We do not plan to conduct any further trials with ONT-10 and in February 2016, we concluded our collaboration with Celldex. No payments were made or are due under this agreement.

#### ***STC.UNM***

Effective June 30, 2014, Alpine Biosciences, Inc. (Alpine) entered into an exclusive license agreement with STC.UNM, by assignment from The Regents of the University of New Mexico, to license the rights to use certain technology relating to protocells, a mesoporous silica nanoparticle delivery platform. The Company subsequently acquired Alpine in August 2014. Under the terms of the license agreement, the Company, as successor to Alpine, has the right to conduct research, clinical development and commercialize all inventions and products that are developed from the platform technology in certain fields of use as described in the license agreement. In exchange for the exclusive license, the Company is obligated to make a series of payments including on-going annual license payments, reimbursement of patent costs, success and time-based milestones up to \$5 million of which \$1.2 million has been accrued and recorded in research and development expenses for the year ended December 31, 2015. Royalty obligations under the license agreement include a double-digit royalty on commercial sublicensing income and a low single-digit royalty based on net sales.

#### ***Sentinel Oncology Ltd.***

In April 2014, the Company entered into an exclusive license and research collaboration agreement with Sentinel Oncology Limited (Sentinel) for the development of novel small molecule Chk1 kinase inhibitors. Under the agreement, the Company makes payments to Sentinel to support their chemistry research. The Company is responsible for pre-clinical and clinical development, manufacture and commercialization of any resulting compounds. Sentinel is eligible to receive success-based development and commercial milestone payments up to approximately \$90 million based on development and commercialization events, including a \$1.0 million milestone for the initiation of cGMP toxicology studies expected in the fourth quarter of 2016, the initiation of certain clinical trials, regulatory approval and first commercial sale. Sentinel is also entitled to a single-digit royalty based on net sales.

#### ***Merck KGaA***

In May 2001, the Company and Merck KGaA entered into a collaborative arrangement to pursue joint global product research, clinical development and commercialization for two product candidates, including tecemotide (formerly known as L-BLP25 or Stimuvax), a MUC1-based liposomal cancer vaccine. This collaboration agreement was subsequently revised and ultimately replaced in 2008 with a license agreement. Under the 2008 license agreement, (1) the Company licensed to Merck KGaA the exclusive right to develop, commercialize and manufacture tecemotide and the right to sublicense to other persons all

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

rights licensed to Merck KGaA by the Company, (2) the Company transferred certain manufacturing know-how, (3) the Company agreed not to develop any product, other than ONT-10, that is competitive with tecemotide and (4) if the Company intends to license the development or commercialization rights to ONT-10, Merck KGaA will have a right of first negotiation with respect to such rights. In 2014, Merck KGaA announced that it does not intend to continue the clinical development of tecemotide.

#### 9. NET INVESTMENT AND OTHER INCOME (EXPENSE)

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

	Years Ended December 31,		
	2015	2014	2013
	(In thousands)		
Investment income, net .....	<b>\$ 73</b>	\$ 73	\$ 95
Net foreign exchange gain (loss) .....	<b>(5)</b>	(4)	(3)
Gain on sale of equipment .....	<b>7</b>	1	45
Gain on sale of investment .....	<b>—</b>	6	—
Other income .....	<b>5</b>	—	—
Total investment and other income (expense), net .....	<b><u>\$80</u></b>	<b><u>\$76</u></b>	<b><u>\$137</u></b>

#### 10. INCOME TAX

There was no income tax provision or benefit for the years ended December 31, 2015, 2014 and 2013.

The provision for income taxes was different from the expected statutory federal income tax rate as follows:

	2015	2014	2013
Tax benefit at statutory rate .....	<b>35.0%</b>	35.0%	35.0%
Change in fair value of warrant liability .....	<b>0.1</b>	0.6	2.1
Stock based compensation .....	<b>0.8</b>	(2.1)	(0.1)
Other .....	<b>0.4</b>	(0.5)	(0.0)
Change in valuation allowance .....	<b>(40.0)</b>	(30.1)	(37.0)
Net operating loss expiration and true ups .....	<b>3.7</b>	(2.9)	(0.0)
Income tax benefit (provision) .....	<b><u>0.0%</u></b>	<b><u>0.0%</u></b>	<b><u>0.0%</u></b>

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements**

The Company's net deferred tax assets and deferred tax liabilities were recorded in other assets and accrued and other liabilities, respectively on the Consolidated Balance Sheets and consist of the following as of December 31, 2015 and 2014:

	2015	2014
	(In thousands)	
Deferred tax assets		
Accrued expenses and other .....	\$ 602	\$ 676
Tax benefits from losses carried forward and tax credits .....	148,759	154,559
Stock based compensation .....	3,143	2,088
Intangible assets .....	11,049	11,449
Other .....	167	107
Total deferred tax assets .....	\$ 163,720	\$ 168,879
Valuation allowance .....	(163,527)	(168,568)
Net deferred tax assets .....	193	311
Deferred tax liabilities		
Prepaid expenses .....	193	311
Intangible asset .....	6,908	6,908
Total deferred tax liabilities .....	7,101	7,219
Net deferred tax liability .....	\$ 6,908	\$ 6,908

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 decreased by \$5.0 million and increased by \$7.6 million during the years ended December 31, 2015 and December 31, 2014, respectively.

The Company has recorded the following reserve for uncertain tax positions as of December 31, 2015, 2014 and 2013:

	2015	2014	2013
	(In thousands)		
Balance at January 1 .....	\$545	\$662	\$662
Increase related to prior year tax positions .....	117	—	—
Decrease related to current year tax positions .....	—	(117)	—
Lapses of statute of limitations .....	—	—	—
Balance at December 31 .....	\$662	\$545	\$662

None of the unrecognized tax benefits that, if recognized, would affect the effective tax rate due to valuation allowance. We are currently not under audit by the federal, state and foreign tax authorities. We do not believe that it is reasonably possible that the total amounts of unrecognized tax benefit will materially increase or decrease within the next 12 months.

**United States**

The Company has accumulated net operating losses in the United States of \$218.7 million and \$183.9 million for United States federal tax purposes at December 31, 2015 and 2014, respectively, some of which are restricted 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

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

fiscal years 2018 through 2035. The Company has federal research and development tax credit carryforwards of \$0.7 million that will expire in fiscal years 2018 through 2023, if not utilized.

#### ***Canada***

The Company has unclaimed Canada federal investment tax credits of \$14.7 million and \$17.6 million at December 31, 2015 and 2014, respectively, that expire in fiscal years 2018 through 2029. The Company has scientific research & experimental development expenditures of \$99.0 million and \$118.0 million for Canada federal purposes and \$43.3 million and \$51.7 million for provincial purposes at December 31, 2015 and 2014, respectively. These expenditures may be utilized in any period and may be carried forward indefinitely. The Company also has Canada federal capital losses of \$134.5 million and \$160.3 million and provincial capital losses of \$134.5 million and \$160.4 million at December 31, 2015 and 2014, respectively, which can be carried forward indefinitely to offset future capital gains. The Company has accumulated net operating losses of \$4.7 million and \$5.5 million at December 31, 2015 and 2014 for Canada federal tax purposes and \$3.0 million and \$3.5 million at December 31, 2015 and 2014 for provincial purposes which expire between 2027 and 2033. The Company is subject to examination by the Canada Revenue Agency for years after 2008. However carryforward attributes that were generated prior to 2008 may still be adjusted by a taxing authority upon examination if the attributes have been or will be used in a future period.

#### ***Other***

The Company files federal and foreign income tax returns in the United States and abroad. For U.S. federal income tax purposes, the statute of limitations is open for 1998 and onward for the United States and Canada due to net operating loss carried forwards.

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

#### ***Royalties***

Pursuant to various license agreements, the Company is obligated to make payments based both on the achievement of certain event or time-based milestones and a percentage of revenues derived from the licensed technology and royalties on net sales. As of December 31, 2015, none of the milestones, as defined in the agreements, were achieved and, as such, the Company is not currently contractually committed to any significant quantifiable payments for licensing fees, royalties or other contingent payments.

#### ***Employee benefit plan***

Under a defined contribution plan available to permanent employees, the Company is committed to matching employee contributions up to limits set by the terms of the plan, as well as limits set by U.S. tax authorities. The Company's matching contributions to the plan totaled \$0.2 million for each of the three year ended December 31, 2015, 2014 and 2013. There were no changes to the plan during the year ended December 31, 2015.

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

#### ***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>	
2016 .....	\$ 652
2017 .....	661
2018 .....	621
Thereafter .....	—
Total .....	<u>\$1,934</u>

Rental expense for operating leases in the amount of \$0.5 million has been recorded in the consolidated statements of operations for each of the years ended December 31, 2015, 2014 and 2013. In May 2008, the Company entered into a lease agreement to lease office and laboratory space for its headquarters in Seattle, Washington totaling approximately 17,000 square feet. The lease, which expires in December 2018, provides for a monthly base rent of \$47,715 increasing to \$52,259 in 2018. The Company has also entered into operating lease obligations through May 2018 for certain office equipment, which are included in the table above.

#### ***Guarantees***

In the ordinary course of business, the Company has entered into agreements with its collaboration partners, vendors, and other persons and entities that include guarantees or indemnity provisions. For example, the Company's agreements with clinical trial sites and third party manufacturers contain certain customary indemnification provisions, and the Company has entered into indemnification agreements with its officers and directors. Based on information known to the Company as of December 31, 2015, the Company believes that its exposure related to these guarantees and indemnification obligations is not material.

## **12. RELATED PARTY TRANSACTIONS**

Certain of the Company's affiliates participated in the Company's public underwritten offering in early 2015. In February 2015, the Company closed concurrent but separate underwritten offerings, (see the "Note 6 — Share Capital" of the audited financial statements included elsewhere in this Annual Report on Form 10-K for additional information), in which affiliates of BVF, a holder of more than 5% of the Company's outstanding common stock, purchased 1,333 shares of the Company's Series B preferred stock for an aggregate purchase price of \$2.0 million. Separate but concurrent with these offerings, affiliates of BVF also exchanged 4,000,000 shares of common stock for 4,000 shares of Series B preferred stock. In addition, in May 2015, the Company entered into an exchange agreement with certain affiliates of BVF to exchange 7,500,000 shares of common stock previously purchased by BVF for 7,500 shares of Series C Convertible Preferred Stock.

In January 2016, the Company appointed Mr. Mark Lampert as a member of the Board as a Class I director of the Company. Mr. Lampert also is an affiliate of BVF.

In January 2016, the Company appointed Dr. Gwen Fyfe as a member of the Board as a Class III director of the Company. Dr. Fyfe also is a consultant to the Company.

## ONCOTHYREON INC.

### Notes to the Consolidated Financial Statements

In February 2016, the Company granted an option to purchase 150,000 shares of common stock to Dr. Henney, effective as of the first day of the Company's next open trading window, as compensation for his services as the Company's Interim Chief Executive Officer.

#### 13. SUBSEQUENT EVENTS

##### ***Entry into a Material Definitive Agreement; Election of Directors***

On January 11, 2016, the Company entered into a letter agreement (Letter Agreement) with each of BVF Partners L.P. (BVF Partners), Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P., BVF Partners OS Ltd. and BVF Inc. (collectively, BVF). Under the Letter Agreement, the Company agreed to nominate for election up to two individuals designated by BVF for the Company's board of directors.

Pursuant to the Letter Agreement, in January 2016, the Company's board of directors appointed Mark Lampert, President of BVF Partners to the board of directors as a Class I director with a term expiring at the 2017 annual meeting and appointed Dr. Gwen Fyfe, M.D., a Class III Director with a term expiring at the 2016 annual meeting.

##### ***Appointment of Interim Chief Executive Officer***

On January 11, 2016, Dr. Robert Kirkman, M.D., retired from his roles of President, Chief Executive Officer and director, and the independent members of the Company's board of directors appointed Dr. Christopher Henney, Ph.D., as Interim Chief Executive Officer and President. The Company has begun a search for a replacement for Dr. Kirkman and the board of directors has established a new committee to oversee a search to identify a new President and Chief Executive Officer.

The Company expects to incur approximately \$3.9 million in expenses in 2016 related to the retirement and separation agreement with Dr. Kirkman. The expenses will be recorded in general and administrative expense and relate to cash severance, option award acceleration and insurance benefits.

##### ***Retention Payment Plan***

On January 9, 2016, the Company adopted a Retention Payment Plan, effective as of January 11, 2016 (the Retention Plan), to provide cash retention payments to certain employees in order to induce such employees to remain employed through January 10, 2017 (Retention Date). Any employee who participates in the Retention Plan and (i) remains continuously employed by the Company through the Retention Date or (ii) has been terminated by the Company other than for cause prior to the Retention Date, shall be paid a lump-sum cash payment as determined on an individual basis. If such employee terminates service for any reason other than termination of employment by the Company without cause prior to the Retention Date, no such payments shall be made. Expenses related to this plan are expected to be \$3.0 million and will be recorded in 2016.

**ONCOTHYREON INC.**

**Notes to the Consolidated Financial Statements**

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

The following table contains selected unaudited statement of operations information for each quarter of 2015 and 2014. The unaudited information should be read in conjunction with the Company's audited financial statements and related notes included elsewhere in this report. The Company believes that the following unaudited information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

**Quarterly Financial Data:**

	Three Months Ended,			
	March 31	June 30	September 30	December 31
(In thousands, except per share data)				
<b>2015</b>				
Operating expenses(4) . . . . .	\$ 8,079	\$ 8,337	\$ 7,222	\$ 9,151
Net loss(1) . . . . .	(7,935)	(10,896)	(4,619)	(9,131)
Net loss per share – basic and diluted . . . . .	(0.08)	(0.11)	(0.05)	(0.10)
<b>2014</b>				
Operating expenses(2) . . . . .	\$ 7,160	\$ 7,797	\$ 8,020	\$ 27,858
Net loss(2)(3) . . . . .	(9,616)	(6,032)	(6,736)	(27,578)
Net loss per share – basic and diluted . . . . .	(0.14)	(0.09)	(0.09)	(0.30)

- (1) Net loss for the three months ended March 31, June 30, September 30 and December 31, 2015 includes change in fair value of warrants income (expense) of approximately \$0.1 million, \$(2.6) million, \$2.6 million and zero respectively (see Note 3).
- (2) Operating expenses and net loss for the three months ended December 31, 2014 includes an upfront fee of \$20.0 million paid to Array in connection with our license agreement in December 2014 (see Note 8).
- (3) Net loss for the three months ended March 31, June 30, September 30 and December 31, 2014 includes change in fair value of warrants income (expense) of approximately \$(2.5) million, \$1.7 million, \$1.3 million and \$0.3 million respectively (see Note 3).
- (4) Operating expenses for the three months ended December 31, 2015 includes a \$1.0 million cumulative adjustment related to the STC.UNM milestones (see Note 8).



**SUBSIDIARIES OF ONCOTHYREON INC.****Name of Subsidiary**

Oncothyreon Canada ULC  
Biomira Management, Inc.  
ProIX Pharmaceuticals Corporation  
Biomira B.V.  
0811769 B.C. ULC  
Oncothyreon Luxembourg s.a.r.l.  
Protocell Therapeutics Inc.

**Jurisdiction of Incorporation**

Alberta  
Delaware  
Delaware  
Netherlands  
British Columbia  
Luxembourg  
Delaware

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in Registration Statement No. 333-201317 of Oncothyreon Inc. on Form S-3, Registration Statement Nos. 333-167302, 333-162640, 333-172814, 333-180025, 333-187257, 333-196581, and 333-202647 of Oncothyreon Inc. on Form S-8, and Registration Statement Nos. 333-146964 and 333-146966 of Biomira Inc., on Form S-8 of our reports dated March 14, 2016, relating to the consolidated financial statements of Oncothyreon Inc., and the effectiveness of internal control over financial reporting of Oncothyreon Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2015.

/s/ Ernst & Young LLP

Seattle, Washington  
March 14, 2016

**CERTIFICATION**

I, Christopher Henney, Ph.D, certify that:

1. I have reviewed this annual report on Form 10-K of Oncothyreon Inc., (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

March 14, 2016

/s/ Christopher Henney, Ph.D

Christopher Henney, Ph.D  
Interim President and Chief Executive Officer

## CERTIFICATION

I, Julia M. Eastland, certify that:

1. I have reviewed this annual report on Form 10-K of Oncothyreon Inc., (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

March 14, 2016

/s/ Julia M. Eastland

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Julia M. Eastland,  
Chief Financial Officer, Secretary and  
Vice President of Corporate Development

**CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. SECTION 1350)**

I, Christopher Henney, Ph.D, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Oncothyreon Inc. on Form 10-K for the fiscal year ended December 31, 2015, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Oncothyreon Inc.

March 14, 2016

/s/ Christopher Henney, Ph.D

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Christopher Henney, Ph.D  
*Interim President and Chief Executive Officer  
(Principal Executive Officer)*

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Oncothyreon Inc. and will be retained by Oncothyreon Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by Oncothyreon Inc. for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that Oncothyreon Inc. specifically incorporates it by reference.

**CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. SECTION 1350)**

I, Julia M. Eastland, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Oncothyreon Inc. on Form 10-K for the fiscal year ended December 31, 2015, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Oncothyreon Inc.

March 14, 2016

/s/ Julia M. Eastland

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Julia M. Eastland,  
*Chief Financial Officer, Secretary and  
Vice President of Corporate Development  
(Principal Financial and Accounting Officer)*

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Oncothyreon Inc. and will be retained by Oncothyreon Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by Oncothyreon Inc. for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that Oncothyreon Inc. specifically incorporates it by reference.

## **Forward-Looking Statements**

*This annual report contains statements that are forward-looking. Any statements contained in this annual report that are not statements of historical fact may be deemed to be forward-looking statements. Words such as “believes,” “anticipates,” “plans,” “expects,” “will,” “intends,” “potential,” “possible,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements include Oncothyreon’s expectations regarding clinical development activities, such as expected clinical trial completion and design, potential benefits of its product candidates, the expected expansion of its clinical development programs and broadening of its pipeline of product candidates, and the use and adequacy of its financial resources.*

*Forward-looking statements involve risks and uncertainties related to Oncothyreon’s business and the general economic environment, many of which are beyond its control. These risks, uncertainties and other factors could cause Oncothyreon’s actual results to differ materially from those projected in forward-looking statements, including the risks associated with the costs and expenses of developing our product candidates, the adequacy of financing and cash, cash equivalents and investments, changes in general accounting policies, general economic factors, the timing, duration and results of clinical trials, the timing and results of regulatory reviews, the safety and efficacy of our product candidates, and the indications for which our product candidates might be developed. There can be no guarantee that the results of preclinical studies or clinical trials will be predictive of either safety or efficacy in future clinical trials. Although Oncothyreon believes that the forward-looking statements contained herein are reasonable, we can give no assurance that our expectations are correct. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. For a detailed description of Oncothyreon’s risks and uncertainties, you are encouraged to review the documents filed with the securities regulators in the United States on EDGAR and in Canada on SEDAR. Except as required by law, Oncothyreon does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.*

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