

**TRANSITION THERAPEUTICS INC.**

**2015 First Quarter Financial Report**

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## TO OUR SHAREHOLDERS

The first quarter of fiscal 2015 is highlighted by the continued advancement of lead neuropsychiatric drug candidate ELND005 and diabetes drug candidate TT401 (LY2944876). Our wholly owned subsidiary, Transition Therapeutics Ireland Limited (“TTIL”) has been focused on the execution of the ELND005 Phase 2 study of agitation and aggression in Alzheimer’s disease (AD) patients. As well, our development partner Lilly has achieved 50% enrolment in the 375 patient Phase 2 study of TT401. Finally, we have also reported the findings from the ELND005 bipolar study, a study that TTIL terminated for business reasons.

### ***Neuropsychiatric Drug Candidate ELND005***

The central operational focus of TTIL has been the execution of the Phase 2 study of ELND005 in agitation and/or aggression associated with AD. The study will enrol up to 400 AD patients that are experiencing moderate levels of agitation and aggression. The study is being performed at more than 70 clinical sites in North America and Europe. The primary endpoint of the study is the change from baseline of the agitation/aggression clinical endpoint, NPI-C (“Neuropsychiatric Inventory – Clinician”) test. The enrolment of this study has been steady and the participating clinical sites have been very supportive in recruiting subjects for the study. As these agitated AD patients can be a greater burden to care for, we must acknowledge the commitment of both the caregivers and clinical staffs in their tireless efforts to support the participation of the enrolled AD patients.

Announcements of ELND005 data from the bipolar disorder and Down syndrome clinical studies have occurred in Q2 fiscal 2015 and will continue through the remainder of that quarter. The Down syndrome pharmacokinetic clinical study (DS-201) completed enrolment this summer and results from this study will likely be announced before the end of November 2014. Subsequent to the quarter-end, the findings from the bipolar disorder Phase 2 clinical study (BPD201) were announced. TTIL had terminated the BPD201 study for business reasons on April 7, 2014, so that development resources were fully focused on the completion of the current on-going Phase 2 study of ELND005 in agitation and aggression associated with Alzheimer’s disease. Overall in BPD201, ELND005 had an acceptable safety and tolerability profile in the study, and showed numerical differences in the number of mood event recurrences and in the time to mood event favoring ELND005. From a mechanism of action standpoint, observed plasma levels showed that ELND005 achieved targeted exposures and effects on pharmacodynamic measures, namely reduction of brain myo-inositol levels. In addition to these announcements, there will be multiple ELND005 presentations at the Clinical Trials in Alzheimer’s disease (“CTaD”) conference November 20-22, 2014 in Philadelphia, Pennsylvania.

### ***Diabetes Drug Candidate TT401 (LY2944876)***

The GLP-1 single agonist market continues to expand with multiple products either completing Phase 3 studies or receiving regulatory approval. An important growth driver for this market has been the emergence of once-weekly administered GLP-1 single agonist peptides that provide diabetes patients additional convenience through reduced injections. There is great investment from large pharmaceutical companies in this area with many of these companies developing GLP-1 single agonist drug candidates. However, the diabetes clinical research community and large pharmaceutical companies are now looking for the next generation of products that can provide additional benefits to diabetes patients. A key therapeutic focus of these communities has been to identify candidates that can provide weight loss. It is in this environment that oxyntomodulin analogues and other therapeutic strategies are targeted to meet this need. TT401 is well-positioned as a leading oxyntomodulin analogue that has demonstrated statistically significant weight loss and blood-glucose lowering in obese type 2 diabetes patients. We are very pleased to have chosen Lilly as our development partner for TT401. Their strong commitment to diabetes and the TT401 program will be key success factors to the development as this program moves forward.

## TO OUR SHAREHOLDERS

The current TT401 Phase 2 study has been progressing in a very efficient and effective manner. Lilly has been performing the Phase 2 study at multiple clinical sites in North America and Europe. In October 2014, Lilly achieved the clinical milestone of 50% study enrolment. This enrolment milestone triggered a payment of US\$ 4 million to Lilly as part of Transition's financial contribution to the clinical study.

The Phase 2 study is designed to enrol up to 375 type 2 diabetes patients and includes four TT401 study arms, a placebo study arm and an active comparator, extended-release exenatide. The main efficacy outcome measures will be the change in HbA1c (a measure of blood-glucose levels) at week 12 and 24 and change in body weight over the course of the study. With the active comparator study arm of extended-release exenatide, this study will provide an important commercial benchmark of TT401 relative to the first approved once-weekly GLP-1 single agonist.

### ***Growth Through In-Licensed Programs***

The progress for the clinical development of the ELND005 and TT401 programs has been on schedule and each of these programs is positioned to have clinical data announcements in calendar 2015. However, the vision for the growth of Transition is to fully leverage its development resources to diversify its risk across a number of therapeutic programs. With this in mind, Transition remains active in identifying and in-licensing additional programs for development. A part of this activity is to enter into agreements with potential partners to jointly de-risk development assets. In this way, Transition will only enter into full licensing agreements at a point where drug candidates have an appropriate risk-reward development profile.

### **OUTLOOK**

This quarter saw important progress across all aspects of the businesses of Transition. TTIL has been focusing efforts to work toward the completion of enrolment of the ELND005 Phase 2 study of agitation and aggression in AD patients. This progress remains on track for enrolment to be completed in Q1 calendar 2015 with data release to follow. TT401 development partner, Lilly, has achieved 50% enrolment of the diabetes Phase 2 study and topline data from this study is expected in calendar 2015. Transition also continues activities to in-license one or two additional development programs during fiscal 2015. Overall, the Company is well-positioned with near-term catalysts in the form of data from the ELND005 and TT401 clinical studies balanced with a long-term view of growth through the addition of new development programs.

I would like to take this opportunity to thank our employees and our Board of Directors and scientific advisors for their contribution. We look forward to reporting on these events over the next year and thank our shareholders for their commitment, continued support and confidence.



Tony Cruz  
Chairman and CEO  
Transition Therapeutics Inc.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

The following information should be read in conjunction with the Company's unaudited consolidated financial statements for the three-month period ended September 30, 2014 and the related notes, which are prepared in accordance with International Financial Reporting Standards for interim financial statements, including IAS 34, Interim Reporting (IFRS), as well as the audited consolidated financial statements for the year ended June 30, 2014, including the notes thereto, prepared in accordance with IFRS, and the annual fiscal 2014 MD&A. This Management's Discussion and Analysis ("MD&A") provides a review of the performance of the Company for the three-month period ended September 30, 2014 as compared to the three-month period ended September 30, 2013. This review was performed by management with information available as of November 7, 2014.

Where "we", "us", "our", "Transition" or the "Company" is used, it is referring to Transition Therapeutics Inc. and its wholly-owned subsidiaries, unless otherwise indicated. All amounts are in Canadian dollars, unless otherwise indicated.

Additional information relating to the Company, including the Company's most recently filed Annual Information Form, can be found on SEDAR at [www.sedar.com](http://www.sedar.com).

## CAUTION REGARDING FORWARD LOOKING STATEMENTS

This MD&A contains certain forward looking statements within the meaning of applicable securities laws. Forward looking information typically contains statements with words such as "anticipate", "believe", "expect", "plan", "estimate", "intend", "may" or similar words suggesting future outcomes. Forward-looking statements in this MD&A include, but are not limited to statements with respect to: the clinical study phases of the Company's product candidates which the Company expects to complete in fiscal 2015 and beyond; the ability of the Company's business model to maximize shareholder returns; the potential for ELND005 to slow the progression of Alzheimer's disease and improve symptoms; the potential for ELND005 to be effective for the treatment of agitation and or aggression in patients with Alzheimer's disease; the potential for ELND005 to be effective for the treatment of Down syndrome; the timing and manner of future clinical development of ELND005; the global population size of those affected by Alzheimer's disease; the demand for a product that can slow or reverse the progression of Alzheimer's disease; the demand for a product that can reduce the emergence of neuropsychiatric symptoms like depression, anxiety, agitation and aggression in Alzheimer's disease; the potential clinical benefit of ELND005 in the treatment of other disease indications; the development of TT401 and the series of preclinical compounds in-licensed from Eli Lilly and Company ("Lilly") and their potential benefit in type 2 diabetes patients and obese individuals; the timing and manner of future clinical development of TT401 performed by Lilly; the engagement of third party manufacturers to produce the Company's drug substances and products; the potential future in-licensing of additional drug candidates to expand the development pipeline; the intention of the Company to make collaborative arrangements for the marketing and distribution of its products and the impact of human capital on the growth and success of the Company.

This forward-looking information is subject to various risks and uncertainties, including those discussed below, that could cause actual results and experience to differ materially from the anticipated results or other expectations expressed. Readers are cautioned not to place undue reliance on this forward-looking information, which is provided as of the date of this MD&A unless otherwise stated, and the Company will not undertake any obligation to publicly update or revise any forward-looking information, whether as a result of new information, future events, or otherwise, except as required by securities laws.

Some of the assumptions, risks and factors which could cause future outcomes to differ materially from those set forth in the forward-looking information include, but are not limited to: (i) the assumption that the Company will be able to obtain sufficient and suitable financing to support operations, clinical trials and commercialization of products, (ii) the risk that the Company may not be able to capitalize on partnering and acquisition opportunities, (iii) the assumption that the Company will obtain favourable clinical trial results in the expected timeframe, (iv) the assumption that the

# MANAGEMENT'S DISCUSSION AND ANALYSIS

Company will be able to adequately protect proprietary information and technology from competitors, (v) the risks relating to the uncertainties of the regulatory approval process, (vi) the impact of competitive products and pricing and the assumption that the Company will be able to compete in the targeted markets, and (vii) the risk that the Company may be unable to retain key personnel or maintain third party relationships, including relationships with key collaborators.

By its nature, forward-looking information involves numerous assumptions, inherent risks and uncertainties, both general and specific, that contribute to the possibility that the predictions, forecasts, projections or other forward-looking statements will not occur. Prospective investors should carefully consider the information contained under the heading "RISKS AND UNCERTAINTIES" as described in the MD&A for the year ended June 30, 2014.

## OVERVIEW

Transition is a biopharmaceutical development company, advancing novel therapeutics for CNS and metabolic disease indications. The Company's wholly-owned subsidiary, Transition Therapeutics Ireland Limited is developing CNS drug candidate ELND005 for the treatment of Alzheimer's disease and Down syndrome. Transition's lead metabolic drug candidate is TT401 for the treatment of type 2 diabetes and accompanying obesity.

Highlights for the Company during the three month period ended September 30, 2014 and up to the date of this MD&A include the following:

### ELND005:

- **November 4, 2014 - Transition announced findings from a Phase 2 study of neuropsychiatric drug candidate, ELND005, as an adjunctive maintenance treatment for bipolar disorder type I patients (BPD).** Transition's wholly-owned subsidiary, Transition Therapeutics Ireland Limited ("TTIL") terminated the bipolar disorder Phase 2 study on April 7, 2014 for business reasons. TTIL has completed a review of the data from this bipolar disorder Phase 2 study. Overall, ELND005 had an acceptable safety and tolerability profile in the study, and showed numerical differences in the number of mood event recurrences favoring ELND005.

### TT401:

- **Transition has paid two of three installment payments totaling US\$10 million to diabetes drug candidate development partner Lilly upon the achievement of 50% patient enrollment for the currently on-going Phase 2 clinical trial in type 2 diabetic patients.**

### Corporate Developments:

- **July 11, 2014 – Transition announced that Carl Damiani has been appointed to the role of Chief Operating Officer of Transition.**

## STRATEGIC COLLABORATIONS

### Perrigo Company plc ("Perrigo")

In 2006, Transition exclusively licensed the ELND005 technology to Elan for worldwide development and commercialization. Following amendment of that agreement in 2010, Elan held all development and commercialization rights to ELND005 and Transition became eligible to receive milestone and royalty payments with the successful advancement of ELND005. Transition has received US\$40 million from Elan in upfront and achieved milestone payments. Perrigo acquired Elan in December 2013, including all Elan's rights and obligations to the development of ELND005.

On February 28, 2014, Transition announced that after a series of transactions, Perrigo had transferred all of its ELND005 rights and assets under the collaboration agreement to the Company's wholly owned subsidiary, Transition Therapeutics Ireland Limited. In parallel with this acquisition, Perrigo invested US\$15 million and received 2,255,640 Transition common shares representing approximately a 6.4% ownership stake in Transition. Perrigo will also be eligible to receive up to US\$40 million in approval and commercial milestone payments and a 6.5% royalty on net sales of ELND005 products and sublicense fees received. Going forward, Transition Therapeutics Ireland Limited will be responsible for all future development and commercialization activities of the ELND005 drug candidate.

## **Lilly**

### **Diabetes**

On March 3, 2010, Transition and Lilly entered into a licensing and collaboration agreement granting Transition the rights to a series of preclinical compounds in the area of diabetes. Under the licensing and collaboration agreement, Transition received exclusive worldwide rights to develop and potentially commercialize a class of compounds that, in preclinical models, showed potential to provide glycemic control and other beneficial effects including weight loss.

Under the terms of the agreement, Lilly received an up-front payment of \$1,055,900 (US\$1 million) which has been capitalized as a license acquired from Lilly and is being amortized over 20 years which represents the estimated life of the underlying compounds and patents.

In June 2013, Lilly exercised its option and assumed all development and commercialization rights to type 2 diabetes drug candidate TT401. In conjunction with this assumption of rights, Transition received a US\$7 million milestone payment. Lilly has assumed all costs and will perform all future development and commercialization activities of TT401, and Transition will pay US\$14 million to Lilly in three separate installments during the Phase 2 clinical study; the first installment of US\$6 million was paid during the three month period ended September 30, 2014 when the study achieved 20% patient enrollment. The second installment of US\$4 million was paid subsequent to the end of the three month period ended September 30, 2014 when the study achieved 50% patient enrollment. The third and final installment of US\$4 million is expected to be paid before December 31, 2014.

Transition is eligible to receive up to approximately US\$240 million in additional milestone payments. Transition will also be eligible to receive a double-digit royalty on sales of TT401 products and a low single digit royalty on related compounds.

## **PROGRAMS**

Transition is focused on developing innovative therapies in several distinct areas of opportunity. Transition's vision is to build a company that has a strong foundation for growth based on multiple technologies and product opportunities, which reduces risk and enhances return. The Company's technologies are as follows:

### **Alzheimer's disease:**

Alzheimer's disease is a progressive brain disorder that gradually destroys a person's memory and ability to learn, reason, make judgments, communicate and carry out daily activities. As Alzheimer's disease progresses, individuals may also experience changes in personality and behavior, such as anxiety, suspiciousness or agitation, as well as delusions or hallucinations. Approximately 90% of Alzheimer's disease patients develop neuropsychiatric symptoms, and up to 60% develop agitation/aggression over the course of their disease. Agitation/aggression are among the most disruptive neuropsychiatric symptoms in Alzheimer's disease and are associated with increased morbidity and caregiver burden.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

The disease mainly affects individuals over age 65 and it is estimated over 18 million people are suffering from Alzheimer's disease worldwide. In the U.S., Alzheimer's disease is the sixth leading cause of death and current direct/indirect costs of caring for an estimated 5.4 million Alzheimer's disease patients are at least US\$100 billion annually.

Current U.S. Food and Drug Administration approved Alzheimer's disease medications may temporarily delay memory decline for some individuals, but none of the currently approved drugs are known to stop the underlying degeneration of brain cells. Certain drugs approved to treat other illnesses may sometimes help with the emotional and behavioral symptoms of Alzheimer's disease. With an aging population, there is a great need for therapies to address Alzheimer's disease patient's neuropsychiatric symptoms and declines in cognitive ability.

## **Down Syndrome:**

Down syndrome (DS, Trisomy 21), caused by an extra copy of chromosome 21, is the most common genetic form of intellectual disability with a prevalence of approximately 1 in 700 live births in the US. Children with DS exhibit developmental delay and various degrees of intellectual disability, while adults are at increased risk of Alzheimer's dementia. There are currently no drugs approved for the treatment of cognitive dysfunction in DS.

Excess activity of genes on chromosome 21, such as amyloid precursor protein (APP) and sodium-myoinositol active transporter (SMIT), are thought to play a role in the cognitive dysfunction of DS. Life-long exposure to increased amyloid and myo-inositol levels in the brain are thought to lead to synaptic dysfunction and cognitive disability. ELND005 may have the potential to improve cognition in DS by decreasing amyloid levels and regulating myo-inositol-dependent neuronal signaling.

## **CLINICAL DEVELOPMENT UPDATE**

### **ELND005 for Neuropsychiatric Diseases**

Transition Therapeutics Ireland Limited is developing neuropsychiatric drug candidate ELND005, (scyllo-inositol). ELND005 is an orally bioavailable small molecule that is being investigated for multiple neuropsychiatric indications on the basis of its proposed dual mechanism of action, which includes  $\beta$ -amyloid anti-aggregation and regulation of brain myo-inositol levels. An extensive clinical program of Phase 1 and Phase 2 studies have been completed with ELND005 to support clinical development. The Phase 2 study (ELND005-AD201) which evaluated ELND005 in more than 350 mild to moderate AD patients was published in the peer-reviewed journal, *Neurology*. The *Neurology* article was entitled "A Phase 2 randomized trial of ELND005, scyllo-inositol, in mild-moderate Alzheimer's disease".

Currently, there are two Phase 2 clinical studies of ELND005 being performed:

#### **(a) Agitation and Aggression in Alzheimer's Disease**

On November 27, 2012, the first patient was enrolled in a Phase 2 clinical trial of ELND005 for the treatment of agitation/aggression in patients with mild to severe Alzheimer's disease. The objectives of the study are to evaluate the efficacy, safety and tolerability of ELND005 over 12 weeks of treatment in patients with mild to severe AD, who are experiencing at least moderate levels of agitation/aggression. This ongoing clinical study (AG201) is called the "Harmony AD" study ([www.harmonyadstudy.com](http://www.harmonyadstudy.com)) and has a projected enrollment of up to 400 subjects. Enrollment is expected to be completed by the first quarter of calendar 2015 with results from the study expected around the middle of the calendar year. A safety extension study (Study "AG251") is ongoing and is enrolling subjects who have completed the placebo-controlled "HarmonyAD" study. To date, the large majority of subjects completing the "HarmonyAD" study are participating in the AG251 extension study.

## (b) Down Syndrome

On September 4, 2013, Transition announced the first patient was dosed in a Phase 2a study of ELND005 in Down syndrome. This study evaluates the safety, pharmacokinetics of ELND005 and includes selected cognitive and behavioral measures over a one-month treatment period. The Phase 2a study of ELND005 in young adult subjects with Down syndrome has completed enrollment and the data from this study are expected to be available before the end of calendar 2014. Following the completion of this study, depending on the data and the advice from regulatory agencies and experts in the field, the next step in development would be a larger Phase 2b study in Down syndrome subjects.

The ELND005 technology is claimed in multiple issued patents and pending patent applications in many jurisdictions throughout the world.

### ***Expenditures for the ELND005 Program***

On February 28, 2014, Transition announced that after a series of transactions, Perrigo has transferred all of its ELND005 rights and assets to the Company's wholly owned subsidiary, Transition Therapeutics Ireland Limited. As a result, effective March 1, 2014, Transition Therapeutics Ireland Limited is responsible for all future development and commercialization activities of the ELND005 drug candidate.

During the three month periods ended September 30, 2014 and 2013, the Company incurred direct research and development costs for this program as follows.

<b>ELND005 Program<sup>(1)</sup></b>	<b>Three month period ended September 30, 2014 \$</b>	<b>Three month period ended September 30, 2013 \$</b>
Pre-clinical studies	-	-
Clinical studies	5,488,126	-
Manufacturing	217,778	-
Other direct research	695,323	-
<b>TOTAL</b>	<b>6,401,227</b>	<b>-</b>

<sup>(1)</sup> These costs are direct research and development costs only and do not include patent costs, investment tax credits, salaries and benefits, amortization of intangible assets or an allocation of Company overhead.

Prior to the acquisition, Transition was not required to fund the development or commercialization of ELND005 and accordingly, development costs were nil during the three month period ended September 30, 2013.

## **TT401 / TT402**

### ***Development of TT401 and TT402 for Diabetes***

Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone released from islet cells located in the pancreas that is needed to convert sugar, starches and other food into energy needed for daily life. There are two primary forms of diabetes; type 1 diabetes and type 2 diabetes.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

Type 2 diabetes usually begins as insulin resistance, a disorder in which the cells do not use insulin properly. As the need for insulin increases, the pancreas gradually loses its ability to produce it. Current treatments for type 2 diabetes include lifestyle changes, oral medications, incretin therapy and insulin therapy. Type 2 diabetes accounts for about 90-95% of all diagnosed cases of diabetes.

## **Clinical Development of TT401 (LY2944876)**

On March 3, 2010, Transition announced that it had acquired the exclusive worldwide rights to develop and potentially commercialize a series of preclinical compounds from Lilly in the area of diabetes. In preclinical diabetes models, these compounds showed potential to provide glycemic control and other beneficial effects including weight loss.

On June 18, 2012, Transition announced the results of the Phase 1 clinical study of type 2 diabetes drug candidate, TT401. The Phase 1, double-blind, placebo-controlled randomized study enrolled 48 non-diabetic obese subjects in six cohorts evaluating six escalating subcutaneous single doses of TT401. TT401 demonstrated an acceptable safety and tolerability profile in non-diabetic obese subjects in the study. TT401 exhibited the expected pharmacological effect on glucose and pharmacodynamic biomarkers at doses that were safe and tolerable. The pharmacokinetic profile, assessed over 28 days, demonstrated a half-life consistent with once-weekly dosing.

On April 30, 2013, Transition announced the results of a five-week proof of concept clinical study of TT401 in type 2 diabetes and obese non-diabetic subjects. The study enrolled diabetic patients at five dosing levels and non-diabetic obese patients at one dose level. All dosing cohorts received five doses over a five week period. Diabetic patients were on stable doses of metformin.

At the end of the treatment period, TT401-treated patients in the 3 highest dose groups experienced statistically significant reductions in mean fasting plasma glucose relative to placebo. Statistically significant mean body weight reduction relative to baseline occurred in the three highest dose groups. A similar reduction in body weight was also observed in the obese non-diabetic cohort. TT401 demonstrated an acceptable safety and tolerability profile at all doses evaluated in diabetic and non-diabetic obese subjects. The most common adverse event noted in the study was decreased appetite. Some subjects in the highest three dose groups experienced mild nausea and vomiting, which are consistent with studies of other GLP-1 agonist drug candidates. The pharmacokinetic profile, assessed over the five week study, demonstrated a half-life consistent with once-weekly dosing.

On June 17, 2013, Lilly exercised its option to assume all development and commercialization rights to type 2 diabetes drug candidate TT401. In conjunction with this assumption of rights, Transition received a US\$7 million milestone payment. Lilly and Transition have amended their agreement to address future development of TT401 and associated financial arrangements. Lilly has assumed all costs and will perform all future development and commercialization activities of TT401. In May, 2014, Transition announced the dosing of the first patient in a Phase 2 clinical study of TT401. The study is expected to enroll up to 375 type 2 diabetes subjects and will be performed by Transition's development partner Lilly. The objectives of the study will be to evaluate the safety and effectiveness of TT401 compared to once-weekly exenatide extended release and placebo.

Transition will contribute payment of US\$14 million to Lilly in three separate installments during the Phase 2 clinical study. The first installment of US\$6 million has been paid in September 2014 when the study achieved 20% patient enrollment. The second installment of US\$4 million was paid subsequent to the end of the three month period ended September 30, 2014 when the study achieved 50% patient enrollment. The third and final installment of US\$4 million is expected to be paid before December 31, 2014.

### Expenditures for the TT401/402 Program

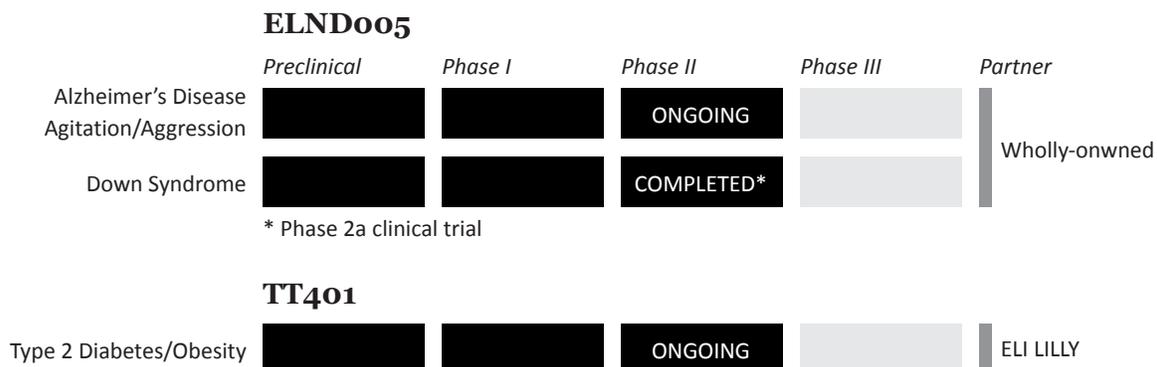
During the three and six month period ended December 31, 2013 and 2012, the Company incurred direct research and development costs for this program as follows:

TT401/402 Program <sup>(1)</sup>	Three month period ended September 30, 2014 \$	Three month period ended September 30, 2013 \$
Pre-clinical studies	-	7,488
Clinical studies	-	87,567
Manufacturing	-	(37,444)
Other direct research	-	18,108
Development payments to Lilly	6,553,200	18,108
<b>TOTAL</b>	<b>6,553,200</b>	<b>75,719</b>

<sup>(1)</sup> These costs are direct research and development costs only and do not include patent costs, investment tax credits, salaries and benefits, amortization of intangible assets or an allocation of Company overhead.

### The Next Steps

Transition's goal for its programs is to achieve product approval and ultimately significant revenues or royalties. To achieve product approval, the Company and or its partners, must successfully complete clinical trials and achieve regulatory approval. The stages of development of the Company's technologies are illustrated below:



# MANAGEMENT'S DISCUSSION AND ANALYSIS

## **RESULTS OF OPERATIONS**

For the three month period ended September 30, 2014, the Company recorded a net loss of \$15,695,324 (\$0.45 loss per common share) compared to a net loss of \$2,331,186 (\$0.08 loss per common share) for the three month period ended September 30, 2013.

The increase in net loss of \$13,364,138 is due to the significant increase in research and development expenses resulting from the reacquisition of the rights to develop the drug candidate ELND005, as well as the US\$6 million milestone payment made to Lilly. The increase in net loss has been partially offset by an increased foreign exchange gain.

### **Research and Development**

Research and development expenses increased to \$16,034,891 for the three month period ended September 30, 2014 from \$1,007,846 for the three month period ended September 30, 2013. The increase in research and development expenses is primarily due to an increase in clinical development costs related to the re-acquired rights to the drug candidate ELND005. The increase is also attributed to an increase in development costs associated with diabetes drug candidate TT401 as the Company paid Lilly US\$6 million upon the achievement of the first milestone when 20% patient enrollment was achieved.

The Company anticipates research and development expenses for the second quarter of fiscal 2015 will be relatively consistent with the first quarter as the Company continues to advance the development of ELND005 and has paid Lilly the second installment of US\$4 million resulting from the 50% patient enrollment milestone being achieved.

### **General and Administrative**

General and administrative expenses increased to \$1,305,832 for the three month period ended September 30, 2014 from \$947,360 for the three month period ended September 30, 2013. The increase in general and administrative expenses is primarily due to increases in professional fees and compensation costs.

The Company anticipates that general and administrative expenses in the second quarter of fiscal 2015 will remain relatively consistent with the first quarter expense.

### **Change in Fair Value of Contingent Consideration Payable**

Contingent consideration is required to be measured as a financial liability at fair value and re-measured at each reporting date. There were no significant changes in the assumptions used in the valuation of the contingent consideration payable during the three month period ended September 30, 2014. The Company has recognized a change in fair value of contingent consideration payable of \$225,301 due to the passage of time during the three month period ended September 30, 2014. There was no change in fair value recognized during the comparative period ended September 30, 2013.

## SUMMARY OF QUARTERLY RESULTS

The following table is a summary of selected quarterly consolidated financial information of the Company for each of the eight most recently completed quarters ending at September 30, 2014.

	First Quarter \$	Second Quarter \$	Third Quarter \$	Fourth Quarter \$
<b>2015</b>				
Revenue	-			
Net income (loss) <sup>(1)</sup>	(15,695,324)			
Basic and diluted net income (loss) per common share	(0.45)			
<b>2014</b>				
Revenue	-	-	-	-
Net income (loss) <sup>(1)</sup>	(2,331,186)	(1,253,772)	(5,067,292)	(13,130,005)
Basic and diluted net income (loss) per common share	(0.08)	(0.04)	(0.17)	(0.43)
<b>2012</b>				
Revenue		-	-	7,118,300
Net income (loss) <sup>(1)</sup>		(2,754,534)	(2,903,331)	(2,054,884)
Basic and diluted net income (loss) per common share		(0.10)	(0.11)	(0.08)

<sup>(1)</sup> Net income (loss) before discontinued operations was equivalent to the net income (loss) for such periods.

The fluctuations of Transition's quarterly results are primarily due to the recognition of up-front and licensing fees relating to the Lilly agreements, recognition of an impairment loss relating to the NMX technology, and changes in: activity levels of the clinical trials being performed by the Company; foreign exchange gains and losses; and corporate development costs.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

## CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

The preparation of consolidated financial statements in accordance with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results can differ from those estimates. We have identified the following areas which we believe require management's most subjective estimates and judgments, often requiring the need to make estimates about the effects of matters that are inherently uncertain and may change in subsequent periods.

### (a) Estimates

#### Valuation and Amortization of Intangible Assets

The Company's intangible assets are comprised of purchased or licensed pharmaceutical compounds, technology and patents. The costs of the Company's intangible assets are amortized over the estimated useful life of 20 years. Factors considered in estimating the useful life of the intangible asset include the expected use of the asset by the Company, legal, regulatory and contractual provisions that may limit the useful life, the effects of competition and other economic factors, and the level of expenditures required to obtain the expected future cash flows from the intangible asset. The Company re-evaluates the useful life when there has been a change in these factors. In light of the series of agreements the Company entered into with Perrigo relating to the ELND005 technology, management reviewed the estimate of the remaining useful life of the ELND005 technology and extended it to 12 years. Accordingly, the change in estimate resulted in a decrease in amortization expense of \$108,774 being recognized during the three month period ended June 30, 2014.

The Company assesses its intangible assets for recoverability whenever indicators of impairment exist. When the carrying value of an asset is greater than its recoverable amount, which is the higher of its value in use or fair value less costs to sell, an impairment loss is recognized.

#### Valuation of Contingent Consideration Payable

The contingent consideration is measured at fair value based on level 3 inputs. The contingent consideration is not based on observable inputs and is measured using a discounted cash flow analysis of expected payments in future periods. The significant estimates used in the fair value calculations are as follows:

- (a) Management has estimated the timing of the milestone payments based on current expectations and plans for the development of ELND005. The milestone payments are assigned a probability based on industry statistics for the successful development of pharmaceutical products including regulatory approval and achievement of revenue targets. An increase of 10% applied to the probability assumptions, with all other variables held constant, will increase the contingent consideration payable by \$701,000. Conversely a decrease of 10% applied to the probability assumptions, with all other variables held constant, would decrease the contingent consideration payable by \$701,000; and
- (b) The probability adjusted cash flows are discounted at a rate of 23% which is management's best estimate of the Company's cost of capital. An increase of 5% to the discount rate would decrease the contingent consideration payable by \$1,370,000. Conversely, a decrease of 5% to the discount rate would increase the contingent consideration payable by \$727,000.

### **Share Based Payments and Warrants**

When the Company issues stock options and warrants, an estimate of fair value is derived for the equity instrument using the Black-Scholes option pricing model. The application of this option pricing model requires management to make assumptions regarding several variables, including the period for which the instrument will be outstanding, the price volatility of the Company's stock over a relevant timeframe, the determination of a relevant risk free interest rate and an assumption regarding the Company's dividend policy in the future. If other assumptions are used, the value derived for the equity instruments could be significantly impacted.

### **Settlement of a Pre-Existing Relationship**

The Company has determined that the transactions entered into with Perrigo on February 28, 2014 have resulted in the re-acquisition of the rights to the development and commercialization of ELND005 previously licensed to Elan which in accordance with IFRS must be accounted for as a settlement of a pre-existing relationship (the collaboration agreement between Waratah and Elan). Accordingly, the company expensed \$3,096,186 in fiscal 2014 as the cost related to the settlement of the pre-existing relationship.

### **ACCOUNTING CHANGES**

The following accounting policies have been adopted effective July 1, 2014.

#### **IAS 36 – Impairment of Assets**

IAS 36 has been amended to include limited scope amendments to the impairment disclosures. The amendments are effective for annual periods beginning on or after January 1, 2014. The adoption of IAS 36 did not significantly impact the Company's interim consolidated financial statements;

#### **IFRS 2 – Share Based Payments**

IFRS 2 has been amended to clarify the definition of vesting conditions. The amendments are effective for annual periods beginning on or after July 1, 2014. The adoption of IFRS 2 did not significantly impact the Company's interim consolidated financial statements.

### **IFRS ISSUED BUT NOT YET ADOPTED**

#### **IAS 15 – Revenue from Contracts with Customers**

IFRS 15 specifies how and when to recognize revenue as well as requiring entities to provide users of financial statements with some informative, relevant disclosures. The standard supersedes IAS 18, Revenue, IAS 11, Construction Contracts, and a number of revenue-related interpretations. Application of the standard is mandatory for all IFRS reporters and it applies to nearly all contracts with customers: the main exceptions are leases, financial instruments and insurance contracts. IFRS 15 must be applied in an entity's first annual IFRS financial statements for periods beginning on or after January 1, 2017 and early adoption is permitted. Management is evaluating the standard and has not yet determined the impact on its consolidated financial statements.

### **INTERNAL CONTROLS OVER FINANCIAL REPORTING**

Internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

There have been no substantive changes in the Company's internal controls over financial reporting that have occurred during the most recent interim period beginning July 1, 2014 and ending September 30, 2014 that have materially affected, or are reasonably likely to materially affect, the Company's internal controls over financial reporting.

## LIQUIDITY AND CAPITAL RESOURCES

### Overview

The Company commenced operations in July 1998, and has devoted its resources primarily to fund its research and development programs. All revenue to date has been generated from milestone payments and licensing fees. The Company has incurred a cumulative deficit to September 30, 2014 of \$186,810,495. Losses are expected to continue for the next several years as the Company invests in research and development, preclinical studies, clinical trials, manufacturing and regulatory compliance.

Since inception, the Company has been financed primarily from public and private sales of equity, the exercise of warrants and stock options, interest earned on cash deposits and short term investments and revenues and reimbursements from partners.

The Company's cash and short term investments were \$45,855,591 at September 30, 2014 as compared to \$60,271,566 at June 30, 2014, resulting in a decrease of \$14,415,975. The Company's working capital position at September 30, 2014 decreased \$14,287,191 from \$54,777,871 at June 30, 2014 to \$40,490,680, at September 30, 2014.

The decrease in the Company's cash and short term investments as well as the decrease in working capital is primarily due to the expenditures incurred during the three month period ended September 30, 2014 which included a payment of US\$6 million to Lilly upon achieving the 20% patient enrollment milestone in the TT401 Phase 2 diabetes study.

The Company's current cash projection indicates that the current cash resources should enable the Company to execute its core business plan and meet its projected cash requirements beyond the next 12 months.

The success of the Company is dependent on its ability to bring its products to market, obtain the necessary regulatory approvals and achieve future profitable operations. The continuation of the research and development activities and the commercialization of its products are dependent on the Company's ability to successfully complete these activities and to obtain adequate financing through a combination of financing activities, operations, and partnerships. It is not possible to predict either the outcome of future research and development programs or the Company's ability to fund these programs going forward.

### Financial Instruments

Financial instruments of the Company consist mainly of cash, short term investments, accounts payable and accrued liabilities, and contingent consideration payable. Management's primary investment objective is to maintain safety of principal and provide adequate liquidity to meet all current payment obligations and future planned expenditures.

The Company is exposed to market risks related to volatility in interest rates for the Company's investment portfolio and foreign currency exchange rates related to investments and purchases of supplies and services made in U.S. dollars.

The Company is exposed to interest rate risk to the extent that the cash equivalents and short term investments are at a fixed rate of interest and their market value can vary with the change in market interest rates. The Company's maximum exposure to interest rate risk is based on the effective interest rate of the current carrying value of these assets. The Company does not speculate on interest rates and holds all deposits until their date of maturity.

## **Contractual Obligations**

Minimum payments under our contractual obligations are as follows:

	<b>Less than 1 Year</b>	<b>1 - 3 years</b>	<b>4 - 5 years</b>	<b>After 5 years</b>	<b>Total</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Lilly Phase 2	8,960,000	-	-	-	8,960,000
Operating leases	174,804	61,044	-	-	235,848
Collaboration Agreements	30,240	-	-	-	30,240
Clinical and toxicity study agreements	10,393,408	963,229	-	-	11,356,637
Manufacturing agreements	181,105	-	-	-	181,105
Contingent Consideration Payable	-	2,847,759	-	52,868,760	55,716,519
Other	121,170	-	-	-	121,170
<b>TOTAL</b>	<b>19,860,727</b>	<b>3,872,032</b>	<b>-</b>	<b>52,868,760</b>	<b>76,601,519</b>

Contractual obligations denominated in US dollars have been translated to Canadian dollars using the exchange rate at September 30, 2014.

## **PROPOSED TRANSACTIONS**

On July 19, 2013, the Company's shelf registration statement filed with the United States Securities and Exchange Commission on Form F-3 became effective. The shelf prospectus provides for the potential offering in the United States of up to an aggregate amount of US\$50 million of Transition's common shares, warrants, or a combination thereof, from time to time in one or more offerings until July 19, 2016. Utilization of the US shelf prospectus is dependent upon meeting certain market capitalization thresholds at the time of financing.

## **OUTSTANDING SHARE DATA**

### **Authorized**

The authorized share capital of the Company consists of an unlimited number of common shares.

### **Issued and Outstanding**

The following details the issued and outstanding equity securities of the Company:

#### ***Common Shares***

As at November 7, 2014, the Company has 35,307,083 common shares outstanding.

#### ***Stock Options***

As at November 7, 2014 the Company has 2,313,935 stock options outstanding with exercise prices ranging from \$2.09 to \$7.70 and various expiry dates extending to September 11, 2024. At November 7, 2014, on an if-converted basis, these stock options would result in the issuance of 2,313,935 common shares in the capital of the Company at an aggregate exercise price of \$9,124,680.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

## ***Warrants***

As at November 7, 2014, the Company has a total of 3,852,591 warrants outstanding. Details of the outstanding warrants are as follows.

- (i) on August 15, 2013, the Company issued 853,223 warrants with a purchase price of US\$4.60 and 1,050,118 warrants with a purchase price of US\$6.50; and
- (ii) on June 23, 2014, the Company issued 1,949,250 warrants with a purchase price of US\$7.10.

Each warrant entitles the holder, within two years of the issuance date, to purchase one additional common share in the capital of the Company.

## **RISKS AND UNCERTAINTIES**

The Company's risks and uncertainties are as described in the Company's annual MD&A, which can be found on SEDAR at [www.SEDAR.com](http://www.SEDAR.com).

# CONSOLIDATED INTERIM FINANCIAL STATEMENTS

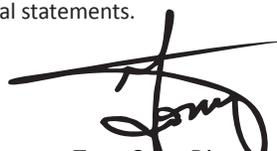
For the three months ended September 30, 2014 and 2013  
(Unaudited)

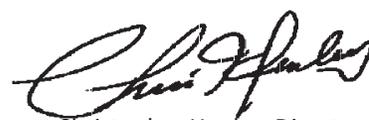
# CONSOLIDATED BALANCE SHEETS

(Unaudited)

<i>In Canadian Dollars</i>	Note	As at September 30, 2014 \$	As at June 30, 2014 \$
<b>Assets</b>			
<b>Current assets</b>			
Cash		42,782,040	57,212,004
Short term investments	6	3,073,551	3,059,562
Other receivables		204,208	220,514
Investment tax credits receivable		254,886	212,393
Prepaid expenses and deposits		326,084	36,656
		46,640,769	60,741,129
<b>Non-current assets</b>			
Property and equipment		183,222	158,926
Intangible assets	7	7,855,897	8,007,181
<b>Total assets</b>		<b>54,679,888</b>	<b>68,907,236</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	8	6,150,089	5,963,258
		6,150,089	5,963,258
<b>Non-current liabilities</b>			
Contingent consideration payable	9	4,207,774	3,838,286
Leasehold inducement		8,574	11,432
<b>Total liabilities</b>		<b>10,366,617</b>	<b>9,812,976</b>
<b>Equity attributable to owners of the Company</b>			
Share capital	11	207,383,967	207,374,493
Warrants	11	5,176,397	5,176,397
Contributed surplus	11	14,768,221	14,768,221
Share-based payment reserve	11	3,753,910	2,866,292
Accumulated other comprehensive income		41,451	24,028
Deficit		(186,810,495)	(171,115,171)
<b>Total equity</b>		<b>44,313,451</b>	<b>59,094,260</b>
<b>Total liabilities and equity</b>		<b>54,679,888</b>	<b>68,907,236</b>
Contingencies and commitments	14		
Subsequent event	18		

The notes are an integral part of these consolidated financial statements.

  
Tony Cruz, Director

  
Christopher Henley, Director

# CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS

For the three months ended September 30, 2014 and 2013  
(Unaudited)

<i>In Canadian Dollars, except per share data</i>	Note	September 30, 2014 \$	September 30, 2013 \$
<b>Expenses</b>			
Research and development	12	16,034,891	1,007,846
Selling, general and administrative expenses	12	1,305,832	947,360
<b>Operating Loss</b>			
Change in fair value of contingent consideration payable	9	(225,301)	-
Interest income		65,693	46,137
Foreign exchange gain (loss)		1,805,007	(422,117)
<b>Net loss for the period</b>		<b>(15,695,324)</b>	<b>(2,331,186)</b>
<b>Other comprehensive loss for the period</b>			
<b>Items that may be subsequently reclassified to net income:</b>			
Cumulative translation adjustment		17,423	-
<b>Comprehensive loss for the period</b>		<b>(15,677,901)</b>	<b>(2,331,186)</b>
<b>Basic and diluted net loss per common share</b>	13	<b>(0.45)</b>	<b>(0.08)</b>

The notes are an integral part of these consolidated financial statements.

# CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

For the three months ended September 30, 2014 and 2013

(Unaudited)

<i>In Canadian Dollars</i>	Note	Number of common shares #	Share capital \$
Balance, July 1, 2014		35,303,913	207,374,493
Net loss for the period		-	-
Cumulative translation adjustment		-	-
Share options exercised, expired or cancelled	11	2,270	9,474
Share-based payment compensation expense	11	-	-
Balance, September 30, 2014		35,306,183	207,383,967
Balance, July 1, 2013		26,930,634	165,367,524
Net loss and comprehensive loss for the period		-	-
Issued pursuant to a private placement, net	11	2,625,300	8,892,209
Share options exercised, expired or cancelled	11	63,522	234,713
Share-based payment compensation expense	11	-	-
Balance, September 30, 2013		29,619,456	174,494,446

The notes are an integral part of these consolidated financial statements.

**Attributable to equity holders of the company**

Warrants \$	Contributed surplus \$	Share-based payment reserve \$	Accumulated Other Comprehensive Income \$	Deficit \$	Total equity \$
5,176,397	14,768,221	2,866,292	24,028	(171,115,171)	59,094,260
-	-	-	-	(15,695,324)	(15,695,324)
-	-	-	17,423	-	17,423
-	-	(4,036)	-	-	5,438
-	-	891,654	-	-	891,654
5,176,397	14,768,221	3,753,910	41,451	(186,810,495)	44,313,451
-	14,768,002	2,352,002	-	(149,332,916)	33,154,612
-	-	-	-	(2,331,186)	(2,331,186)
2,025,839	-	-	-	-	10,918,048
-	-	(96,906)	-	-	137,807
-	-	351,697	-	-	351,697
2,025,839	14,768,002	2,606,793	-	(151,664,102)	42,230,978

# CONSOLIDATED STATEMENTS OF CASH FLOWS

For the three months ended September 30, 2014 and 2013

(Unaudited)

<i>In Canadian Dollars</i>	Note	September 30, 2014 \$	September 30, 2013 \$
<b>Cash flows used in operating activities</b>			
Net loss for the period		(15,695,324)	(2,331,186)
Adjustments for:			
Change in fair value of contingent consideration payable		225,301	-
Depreciation and amortization		161,596	268,190
Share-based payment compensation expense		891,654	351,697
Accrued interest		(13,989)	(22,501)
Unrealized foreign exchange (gain) loss		(1,944,564)	437,466
Change in working capital	15	(232,174)	(211,687)
<b>Net cash used in operating activities</b>		<b>(16,607,500)</b>	<b>(1,508,021)</b>
<b>Cash flows used in investing activities</b>			
Purchase of property and equipment		(37,466)	(4,861)
<b>Net cash used in investing activities</b>		<b>(37,466)</b>	<b>(4,861)</b>
<b>Cash flows from financing activities</b>			
Net proceeds from private placement		-	10,918,048
Proceeds from share options exercised	11	5,438	137,807
<b>Net cash from financing activities</b>		<b>5,438</b>	<b>11,055,855</b>
<b>Foreign exchange gains/(losses) on cash</b>		<b>2,209,564</b>	<b>(437,466)</b>
<b>Net increase (decrease) in cash</b>		<b>(14,429,964)</b>	<b>9,105,507</b>
Cash at beginning of period		57,212,004	23,067,937
<b>Cash at end of period</b>		<b>42,782,040</b>	<b>32,173,444</b>

The notes are an integral part of these consolidated financial statements.

# NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2014 *(Unaudited, in Canadian dollars)*

## 1. GENERAL INFORMATION AND NATURE OF OPERATIONS

Transition Therapeutics Inc. and its subsidiaries (together the Company or Transition) was incorporated by Articles of Incorporation under the Business Corporations Act (Ontario) on July 6, 1998. The Company is a public company with common shares listed on both the NASDAQ and Toronto Stock Exchange and is incorporated and domiciled in Canada. The address of its registered office is 101 College Street, Suite 220, Toronto, Ontario, Canada.

The Company is a product-focused biopharmaceutical company developing therapeutics for disease indications with large markets. The Company's lead technologies are focused on the treatment of Alzheimer's disease and diabetes.

The success of the Company is dependent on bringing its products to market, obtaining the necessary regulatory approvals and achieving future profitable operations. The continuation of the research and development activities and the commercialization of its products are dependent on the Company's ability to successfully complete these activities and to obtain adequate financing through a combination of financing activities and operations. It is not possible to predict either the outcome of future research and development programs or the Company's ability to fund these programs going forward.

## 2. BASIS OF PREPARATION

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board for interim financial statements, including IAS 34 Interim Financial Reporting. The consolidated financial statements have been prepared using the historical cost convention except for the revaluation of certain financial assets and financial liabilities to fair value, including the contingent consideration payable.

The preparation of financial statements in conformity with IFRS requires use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in the annual consolidated financial statements for the year ended June 30, 2014.

## 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Board of Directors approved the interim consolidated financial statements for issuance on November 7, 2014. The significant accounting policies that have been applied in the preparation of these interim consolidated financial statements are described in the Company's annual financial statements for the year ended June 30, 2014 and have been applied to all periods presented except the following accounting policies, which have been adopted effective July 1, 2014:

### IAS 36 – Impairment of Assets

IAS 36 has been amended to include limited scope amendments to the impairment disclosures. The amendments are effective for annual periods beginning on or after January 1, 2014. The adoption of IAS 36 did not significantly impact the Company's interim consolidated financial statements;

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2014 (Unaudited, in Canadian dollars)

### IFRS 2 – Share Based Payments

IFRS 2 has been amended to clarify the definition of vesting conditions. The amendments are effective for annual periods beginning on or after July 1, 2014. The adoption of IFRS 2 did not significantly impact the Company's interim consolidated financial statements.

### 4. GLOBAL COLLABORATION AGREEMENT WITH PERRIGO COMPANY PLC

On December 18, 2013, Perrigo Company plc (“Perrigo”) completed its acquisition of Elan and all its subsidiaries. With this acquisition, Perrigo acquired all the rights and obligations of Elan under the collaboration agreement with Waratah, a wholly owned subsidiary, for the development and commercialization of ELND005.

On February 28, 2014, through a series of transactions, the Company's newly obtained wholly owned Irish subsidiary, Transition Therapeutics Ireland Limited re-acquired all of the development and commercialization rights of the ELND005 drug candidate previously licensed to Elan. In addition, Perrigo is eligible to receive up to US\$40 million in approval and commercial milestone payments and 6.5% royalties on net sales of ELND005 products and sublicense fees received. The milestone payments meet the definition of a financial liability and accordingly, the Company has recorded the contingent consideration payable at fair value. The accounting for this transaction, in accordance with IFRS, required significant judgment. Based on management's review and assessment of the agreements entered into as well as the existing rights of the Company under the collaboration agreement with Elan, management determined that the transactions entered into resulted in the re-acquisition of the rights to the development and commercialization of ELND005 which in accordance with IFRS must be accounted for as a settlement of a pre-existing relationship (the collaboration agreement between Waratah and Elan). Accordingly, during the year ended June 30, 2014, the Company recognized a settlement on a pre-existing relationship in the amount of \$3,096,186 in the statement of income (loss).

In parallel with this acquisition, the Company issued 2,255,640 common shares for cash consideration of US\$15 million. The Company's Irish subsidiary will be responsible for all future development and commercialization activities of the ELND005 drug candidate.

### 5. FINANCIAL RISK MANAGEMENT

#### 5.1 Categories of financial assets and liabilities

All financial instruments are measured at amortized cost except for the contingent consideration payable which is at fair value. The following table outlines the Company's financial instruments, their classification, carrying value and fair value.

Financial Instruments as at September 30, 2014	Classification	Carrying Value \$	Fair Value \$
Cash	Loans and receivables	42,782,040	42,782,040
Short term investments	Loans and receivables	3,073,551	3,073,551
Accounts payable and accrued liabilities	Other liabilities	6,150,089	6,150,089
Contingent consideration payable	Fair value through profit and loss	4,207,774	4,207,774

Financial Instruments as at June 30, 2014	Classification	Carrying Value \$	Fair Value \$
Cash	Loans and receivables	57,212,004	57,212,004
Short term investments	Loans and receivables	3,059,562	3,059,562
Accounts payable and accrued liabilities	Other liabilities	5,963,258	5,963,258
Contingent consideration payable	Fair value through profit and loss	3,838,286	3,838,286

The Company has determined the estimated fair values of its financial instruments based on appropriate valuation methodologies; however, considerable judgment is required to develop these estimates. Fair value of cash equivalents and short term investments is determined based on a valuation model that uses daily pricing reports to determine the amount the holder would receive if the instrument were sold on that day. The carrying value of accounts payable and accrued liabilities approximates fair value due to the short-term nature of the financial instrument.

The contingent consideration is measured at fair value based on level 3 inputs. The contingent consideration is not based on observable inputs and is measured using a discounted cash flow analysis of expected payments in future periods. The significant estimates used in the fair value calculations are as follows:

- (a) Management has estimated the timing of the milestone payments based on current expectations and plans for the development of ELND005. The milestone payments are assigned a probability based on industry statistics for the successful development of pharmaceutical products. An increase of 10% applied to the probability assumptions, with all other variables held constant, will increase the contingent consideration payable by \$701,000. Conversely a decrease of 10% applied to the probability assumptions, with all other variables held constant, would decrease the contingent consideration payable by \$701,000;
- (b) The probability adjusted cash flows are discounted at a rate of 23% which is management's best estimate of the Company's cost of capital. An increase of 5% to the discount rate would decrease the contingent consideration payable by \$1,370,000. Conversely, a decrease of 5% to the discount rate would increase the contingent consideration payable by \$727,000.

## 5.2 Financial risk factors

The Company's activities expose it to a variety of financial risks: market risk (including foreign exchange and interest rate risks), credit risk and liquidity risk. Risk management is the responsibility of the Company's finance function which identifies, evaluates and where appropriate, mitigates financial risks.

- (a) Market risk
  - (i) Foreign exchange risk

The Company operates in Canada and has relationships with entities in other countries. Foreign exchange risk arises from purchase transactions, as well as recognized financial assets and liabilities denominated in foreign currencies, mainly the US dollar. The Company does not enter into hedging or other contracts to mitigate its exposure to foreign exchange risk and maintains sufficient US dollars to meet the Company's planned US dollar expenses.

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2014 (Unaudited, in Canadian dollars)

Financial instruments in foreign currencies at September 30, 2014 and June 30, 2014 are approximately:

	September 30, 2014 US\$	June 30, 2014 US\$
Cash and cash equivalents	34,657,583	48,722,203
Trade and other payables	(3,030,550)	(711,490)
	31,627,033	48,010,713

Fluctuations in the US dollar exchange rate could potentially have a significant impact on the Company's results. At September 30, 2014, if the Canadian dollar weakened 10% against the US dollar, with all other variables held constant, comprehensive loss for the three month period ended September 30, 2014 would have decreased by approximately \$3,400,000. Conversely, if the Canadian dollar strengthened 10% against the US dollar, with all other variables held constant, comprehensive loss for the three month period ended September 30, 2014 would have increased by approximately \$3,400,000.

### (ii) Interest rate risk

Interest rate risk is the risk that the future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company's cash and cash equivalents and short term investments which are at a fixed rate of interest and accordingly are not exposed to changes in market interest rates, however, their fair value can vary with the change in market interest rates.

Although the Company monitors market interest rates, the Company's investment policies are designed to maintain safety of principal and provide adequate liquidity to meet all current payment obligations and future planned expenditures. The Company does not speculate on interest rates and holds all deposits until their date of maturity.

Interest income from cash, cash equivalents and short term investments was \$65,693 for the three month ended period September 30, 2014 (three month period ended September 30, 2013 - \$46,137).

### (b) Credit risk

Credit risk is the risk of a financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligations.

The Company's exposure to credit risk at the period end is the carrying value of its cash and cash equivalents and short term investments.

The Company manages credit risk by maintaining bank accounts with financial institutions of high creditworthiness and investing in cash and cash equivalents with maturities less than 90 days and ratings of R-1 or higher. Short term investments consist of bankers' acceptances and other debentures maturing in less than 12 months and ratings of R-1 or higher.

### (c) Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its obligations as they become due.

The Company's investment policies are designed to maintain safety of principal and provide sufficient readily available cash in order to meet liquidity requirements. The Company manages its liquidity risk by forecasting cash flows from operations and anticipated investing and financing activities. All cash and cash equivalents and short term investments have maturities less than one year.

At September 30, 2014 the Company's financial liabilities which include trade and other payables are current and are expected to be repaid within 1 to 3 months of the period end date.

The contingent consideration payable is due upon achievement of milestone and is expected to be paid as follows:

Fiscal year ending June 30, 2016	\$2,847,759
Fiscal year ending June 30, 2020	\$11,200,000
Fiscal year ending June 30, 2021	\$20,597,096
Fiscal year ending June 30, 2022	\$21,071,664

### 5.3 Capital risk management

The Company's primary objective when managing capital is to ensure its ability to continue as a going concern in order to pursue the development of its drug candidates and the out-license of these drug candidates to pharmaceutical companies. The Company attempts to maximize return to shareholders by minimizing shareholder dilution and, when possible, utilizing non-dilutive funding arrangements such as interest income and collaborative partnership arrangements.

The Company includes equity comprised of issued share capital, warrants, contributed surplus and deficit in the definition of capital. The Company has financed its capital requirements primarily through share issuances since inception and collaborative partnership agreements.

The Company manages its capital structure and makes adjustments to it in light of changes in economic conditions and risk characteristics of the underlying assets. The Company monitors its cash requirements and market conditions to anticipate the timing of requiring additional capital to finance the development of its drug candidates. The Company is not subject to externally imposed capital requirements and there has been no change with respect to the overall capital management strategy during the three month period ended September 30, 2014 from the year ended June 30, 2014.

The Company's current cash projection indicates that the current cash resources should enable the Company to execute its core business plan and meet its projected cash requirements beyond the next 12 months. However, the Company's working capital may not be sufficient to meet its stated business objectives in the event of unforeseen circumstances or a change in the strategic direction of the Company. When, or if, the Company requires additional capital, there can be no assurance that the Company will be able to obtain further financing on favourable terms, if at all.

## 6. SHORT TERM INVESTMENTS

Short term investments consist of medium term note debentures totaling \$3,073,551 at September 30, 2014 [June 30, 2014 – \$3,059,562] with ratings of R1 or higher and maturity dates of October 23, 2014 and November 28, 2014. There were no gains or losses realized on the disposal of the short term investments during the three month period ended September 30, 2014 or in the year ended June 30, 2014 as all the financial assets were held to their redemption date. The maximum exposure to credit risk at the reporting date is the carrying amount of cash and cash equivalents and short term investments.

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2014 (Unaudited, in Canadian dollars)

### 7. INTANGIBLE ASSETS

Intangible assets consist of the following:

	ENI Technology acquired (ELND005) \$	Lilly Licenses acquired (TT401/402) \$	Total \$
<b>As at July 1, 2014</b>			
Cost	20,547,993	1,055,900	21,603,893
Accumulated amortization	(13,367,489)	(229,223)	(13,596,712)
Net book value July 1, 2014	7,180,504	826,677	8,007,181
<b>As at September 30, 2014</b>			
Cost	20,547,993	1,055,900	21,603,893
Accumulated amortization	(13,505,574)	(242,422)	(13,747,996)
Net book value September 30, 2014	7,042,419	813,478	7,855,897
<b>Period ended September 30, 2014</b>			
Opening net book value	7,180,504	826,677	8,007,181
Amortization charge	(138,085)	(13,199)	(151,284)
<b>Net book value September 30, 2014</b>	<b>7,042,419</b>	<b>813,478</b>	<b>7,855,897</b>
<b>As at July 1, 2013</b>			
Cost	20,547,993	1,055,900	21,603,893
Accumulated amortization	(12,488,792)	(176,427)	(12,665,219)
Net book value July 1, 2013	8,059,201	879,473	8,938,674
<b>As at June 30, 2014</b>			
Cost	20,547,993	1,055,900	21,603,893
Accumulated amortization	(13,367,489)	(229,223)	(13,596,712)
Net book value June 30, 2014	7,180,504	826,677	8,007,181
<b>Year ended June 30, 2014</b>			
Opening net book value	8,059,201	879,473	8,938,674
Amortization charge	(878,697)	(52,796)	(931,493)
<b>Net book value June 30, 2014</b>	<b>7,180,504</b>	<b>826,677</b>	<b>8,007,181</b>

The amortization of all intangible assets relates to the research and development efforts of the Company and has therefore been included in the “research and development” line in the consolidated statement of comprehensive income (loss).

## 8. TRADE AND OTHER PAYABLES

Trade and other payables consist of the following:

	September 30, 2014 US\$	June 30, 2014 US\$
Accounts payable	3,416,658	1,591,128
Accrued expenses	2,733,431	4,372,120
	<u>6,150,089</u>	<u>5,963,258</u>

## 9. CONTINGENT CONSIDERATION PAYABLE

- (a) Under the terms of the ENI step-acquisition agreement, the Company is committed to pay the former shareholders of ENI contingent clinical milestones potentially totaling \$10.9 million payable in cash or Transition common shares at the then market price and a royalty of up to 1% on net sales of the ELND005 product. The contingent consideration is required to be measured as a financial liability at fair value and re-measured at each reporting date. On February 28, 2014, the Company became responsible for the development of ELND005 and accordingly has re-evaluated the development program timelines and adjusted the estimate relating to the timing of the milestone payments. Accordingly, the Company has recognized a liability as at September 30, 2014 of \$1,090,385 (June 30, 2014 - \$1,030,775) which represents the fair value of the contingent consideration payable to the former shareholders of ENI.
- (b) Under the terms of the ELND005 milestone and royalty agreement, the Company is committed to pay Perrigo contingent approval and commercialization milestones potentially totaling US\$40 million and a royalty of up to 6.5% on net sales of the ELND005 product. The contingent consideration is required to be measured as a financial liability at fair value and re-measured at each reporting date. Accordingly, the Company has recognized a liability as at September 30, 2014 of \$3,117,389 (June 30, 2014 - \$2,807,511) which represents the fair value of the contingent consideration payable to Perrigo (note 4).

<b>Contingent Consideration Payable</b>	Payable to ENI \$	Payable to Perrigo \$	Total \$
<b>Balance at July 1, 2013</b>	3,756,331	-	3,756,331
Settlement of pre-existing relationship	-	3,096,186	3,096,186
Change in contingent consideration payable	(2,725,556)	(185,662)	(2,911,218)
Foreign exchange	-	(103,013)	(103,013)
<b>Balance at June 30, 2014</b>	1,030,775	2,807,511	3,838,286
Change in contingent consideration payable	59,610	165,691	225,301
Foreign exchange	-	144,187	144,187
<b>Balance at September 30, 2014</b>	<u>1,090,385</u>	<u>3,117,389</u>	<u>4,207,774</u>

Significant assumptions and the sensitivity of changes to these assumptions are discussed in Note 5.

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2014 (Unaudited, in Canadian dollars)

### 10. LICENSING AND COLLABORATION AGREEMENTS WITH ELI LILLY AND COMPANY

On March 3, 2010, Transition and Eli Lilly and Company (“Lilly”) entered into a licensing and collaboration agreement granting Transition the rights to a series of preclinical compounds in the area of diabetes. Under the licensing and collaboration agreement, Transition will receive exclusive worldwide rights to develop and potentially commercialize a class of compounds that, in preclinical models showed potential to provide glycemic control and other beneficial effects including weight loss.

Under the terms of the agreement, Lilly received an up-front payment of US\$1 million and retained the option to reacquire the rights to the compounds at a later date. The up-front payment of \$1,055,900 (US\$1 million) has been capitalized as a license acquired from Lilly and will be amortized over 20 years which represents the estimated remaining life of the underlying compounds and patents.

In June 2013, Lilly exercised their option and assumed all development and commercialization rights to type 2 diabetes drug candidate TT401. In conjunction with this assumption of rights, Transition received a milestone payment of \$7,118,300 (US\$7 million) which has been recognized as revenue during the year ended June 30, 2013. Lilly has assumed all costs and will perform all future development and commercialization activities of TT401, and Transition will pay US\$14 million to Lilly in three separate installments during the Phase 2 clinical study. In return, Transition is eligible to receive up to approximately US\$240 million in additional milestone payments and will also be eligible to receive a double-digit royalty on sales of TT401 products and a low single digit royalty on related compounds. During the three month period ended September 30, 2014, the Company paid Lilly the first instalment of US\$6 million and subsequent to September 30, 2014, the Company paid Lilly the second instalment of US\$4 million. (See note 18).

### 11. SHARE CAPITAL

#### [a] Authorized

At September 30, 2014, the authorized share capital of the Company consists of an unlimited number of no par value common shares. The common shares are voting and are entitled to dividends if, as and when declared by the Board of Directors.

#### [b] Common shares issued and outstanding during the period

At September 30, 2014, there were 35,306,183 common shares issued and outstanding [June 30, 2014 – 35,303,913].

#### Warrants

Details of whole warrants outstanding at September 30, 2014 and June 30, 2014 are as follows:

Warrants	#	Fair Value \$	Expiry Date
Balance at beginning of period	-	-	
US\$4.60 Warrants issued August 15, 2013	853,223	1,108,107	August 15, 2015
US\$6.50 Warrants issued August 15, 2013	1,050,118	917,732	August 15, 2015
US\$7.10 Warrants issued June 23, 2014	1,949,250	3,150,558	June 23, 2016
Warrants outstanding	3,852,591	5,176,397	

If and when all of the warrants are exercised, the Company may realize up to an additional US\$24.5 million in proceeds.

The warrants outstanding at September 30, 2014 have a total fair value of \$5,176,397 which was calculated using the Black-Scholes pricing model with the following assumptions:

<b>Warrants Issued:</b>	August 15, 2013	June 23, 2014
Risk free interest rate	1.18%	1.03%
Expected dividend yield	0%	0%
Stock price volatility	0.6348	0.6694
Expected life of warrants	2.0 years	2.0 years

### [c] Stock Options

<b>Stock options</b>	#	\$	Weighted Average Exercise Price \$
Stock options outstanding, July 1, 2014	2,305,589	2,866,292	3.91
Stock options issued [i]	30,000	-	7.70
Stock options exercised [ii]	(2,270)	(4,036)	2.52
Stock options forfeited or cancelled [iii]	(18,484)	-	5.58
Stock based compensation expense		891,654	-
Stock options outstanding, September 30, 2014	2,314,835	3,753,910	3.94

<b>Stock options</b>	#	\$	Weighted Average Exercise Price \$
Stock options outstanding, July 1, 2013	1,872,000	2,352,002	2.97
Stock options exercised [ii]	(63,522)	(96,906)	2.17
Stock options forfeited or cancelled [iii]	(2,917)	-	3.66
Stock based compensation expense		351,697	-
Stock options outstanding, September 30, 2013	1,805,561	2,606,793	3.00

- [i] The fair value of the 30,000 stock options issued during the three month period ended September 30, 2014 was \$171,210 [September 30, 2013 – nil options issued].
- [ii] During the three month period ended September 30, 2014, 2,270 stock options were exercised. These options had a fair value of \$4,036 and resulted in cash proceeds to the Company of \$5,438. During the three month period ended September 30, 2013, 63,522 options were exercised. These options had a fair value of \$96,906 and resulted in cash proceeds to the Company of \$137,807.
- [iii] During the three month period ended September 30, 2014, 18,484 stock options were forfeited. These options had a fair value of \$75,971 and were unvested at the time of forfeit. During the three month period ended September 30, 2013, 2,917 options were forfeited. These options had a fair value of \$7,701 and were unvested at the time of forfeit.

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2014 (*Unaudited, in Canadian dollars*)

[iv] The maximum possible cash proceeds to the Company from the exercise of the stock options outstanding at September 30, 2014 are \$9,126,570 [June 30, 2014 - \$9,005,578].

### 12. EXPENSES BY NATURE

	Three month period ended September 30, 2014 \$	Three month period ended September 30, 2013 \$
<b>Research and development</b>		
Clinical trials and manufacturing	14,314,818	245,777
Salaries and benefits	883,300	303,746
Stock compensation expense	509,889	142,034
Depreciation and amortization	155,344	265,276
Facility lease costs and utilities	85,380	44,445
Insurance	57,078	20,403
General laboratory supplies and materials	71,575	29,037
Ontario investment tax credits	(42,493)	(42,872)
	<b>16,034,891</b>	<b>1,007,846</b>
<b>Selling, general and administrative expenses</b>		
Salaries and benefits	416,961	360,501
Professional fees and services	198,468	115,973
Insurance	62,177	55,986
Stock compensation expense	381,765	209,663
Facility lease costs and utilities	38,119	37,948
Business development, corporate communication and investor relations	115,586	101,249
Regulatory and stock transfer fees	27,785	21,575
Office and related expenses	57,890	41,551
Depreciation and Amortization	7,081	2,914
	<b>1,305,832</b>	<b>947,360</b>

### 13. EARNINGS (LOSS) PER SHARE

Basic and diluted loss per share is calculated by dividing the profit attributable to equity holders of the Company by the weighted average number of common shares outstanding during the period. Outstanding options to purchase common shares of 2,314,835 [September 30, 2013 – 1,805,561] and warrants of 3,852,591 [September 30, 2013 – 1,903,341] are not included in the calculation of diluted earnings per share as the effect is anti-dilutive due to losses incurred in the three month periods ended September 30, 2014 and 2013.

For the three month periods ended September 30, 2014 and 2013, 79,908 contingently returnable common shares were excluded from the basic and diluted net loss per common share calculation. The contingently returnable common shares relate to employment contracts and will be released from escrow based on the achievement of certain corporate milestones.

	September 30, 2014	September 30, 2013
Loss attributable to equity holders of the Company	(15,695,324)	(\$2,331,186)
Weighted average number of common shares outstanding	35,226,053	28,200,909

### 14. CONTINGENCIES AND COMMITMENTS

At September 30, 2014, the Company is committed to aggregate expenditures of \$8,990,000 under its collaboration agreements [June 30, 2014 - \$14,976,000]. In addition, at September 30, 2014, the Company is committed to aggregate expenditures of approximately \$10,393,000 [June 30, 2014 - \$13,613,000] for clinical and toxicity studies to be completed during fiscals 2015 and 2016, approximately \$181,000 [June 30, 2014 - \$128,000] for manufacturing agreements and approximately \$121,000 [June 30, 2014 - \$482,000] for consulting and other agreements.

### 15. CHANGE IN WORKING CAPITAL

The change in working capital consists of the following:

	Three month period ended September 30, 2014 \$	Three month period ended September 30, 2013 \$
Other receivables	16,306	(9,089)
Investment tax credits receivable	(42,493)	(42,872)
Prepaid expenses and deposits	(289,428)	118,557
Trade and other payables	83,441	(278,283)
	(232,174)	(211,687)

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2014 (Unaudited, in Canadian dollars)

### 16. RELATED PARTY TRANSACTIONS

#### *Key management compensation*

Key management includes the Company's directors, and members of the senior management team. The compensation paid or payable to key management for employee services is show below:

	Three month period ended September 30, 2014 \$	Three month period ended September 30, 2013 \$
Salaries and other short-term employee benefits	516,097	386,272
Stock-compensation expenses	644,830	306,865
	1,160,927	693,137

### 17. SEGMENT DISCLOSURE

The Company operates in one operating segment, the research and development of therapeutic agents.

### 18. SUBSEQUENT EVENT

Under the terms of the Licensing and Collaboration Agreement with Lilly, Transition is required to pay US\$14 million in three separate installments to help fund the Phase 2 clinical study of diabetes drug candidate TT401. The second installment of US\$4 million is due when the clinical study achieves 50% patient enrollment. This clinical study milestone was achieved in October, 2014 and accordingly, the Company has paid Lilly US\$4 million subsequent to the three month period ended September 30, 2014.

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## **BOARD OF DIRECTORS**

**Michael R. D. Ashton:** Independent consultant to the pharmaceutical industry and former CEO of SkyePharma PLC

**Paul Baehr:** President, CEO and Chairman of IBEX Technologies Inc.

**Dr. Tony Cruz:** Chairman and CEO of Transition Therapeutics Inc.

**Christopher Henley:** President of Henley Capital Corporation

**Dr. Gary W. Pace:** Chairman and Founder of Sova Pharmaceuticals Inc., Founder, Director and former Chairman and CEO of QRxPharma Ltd.

## **CORPORATE INFORMATION**

### **Corporate Office**

220 - 101 College Street,  
Toronto, Ontario, Canada M5G 1L7  
Tel. 416-260-7770

### **Executive Officers**

**Dr. Tony Cruz,** Chairman and CEO

**Carl Damiani,** COO

**Nicole Rusaw,** CFO

**Dr. Aleksandra Pastrak,** VP Clinical Development and Medical Officer

**Dr. Bruce Connop,** VP Non-Clinical & Pharmaceutical Development

### **Auditors**

PricewaterhouseCoopers LLP  
Toronto, Ontario, Canada

### **Transfer Agents**

#### *Canada:*

Computershare Investor Services Inc.  
Tel. 800-564-6253

#### *USA:*

Computershare Trust Company, NA  
Tel. 303-262-0600

## **LEGAL COUNSEL**

### **Securities:**

#### *Canada:*

Michael J. Bennett, McCarthy Tétrault LLP

#### *USA:*

Brett Cooper, Orrick, Herrington & Sutcliffe LLP

## **CORPORATE SECRETARY**

Louis Alexopoulos, Sotos LLP

## **ANNUAL GENERAL MEETING**

December 9, 2014 @ 4:00 pm  
MaRS Center, South Tower  
101 College Street, Main floor, room CR3  
Toronto, Ontario, Canada