

**TRANSITION THERAPEUTICS INC.**

**2014 First Quarter Financial Report**

# TO OUR SHAREHOLDERS

This fiscal quarter was highlighted by important milestones in the advancement of our development candidates and the addition of a new program through a collaboration with Lilly. Our lead neuropsychiatric drug candidate, ELND005, received FDA “Fast Track” designation for the treatment of agitation and aggression in Alzheimer’s disease and an additional Phase 2A study was commenced evaluating ELND005 in Down syndrome. For TT401, our partner Lilly has assumed all development activities as they prepare for a large Phase 2 efficacy study. The Company also broadened its pipeline with the new osteoarthritis drug candidate TT601 and raised US\$11 million in a private placement financing.

## **PIPELINE REVIEW**

### ***ELND005 – Neurological Disorders:***

Since the commencement of the bipolar clinical study of ELND005 in August 2012, our licensing partner Elan Pharmaceuticals has made a significant financial commitment to the development of ELND005 for neuropsychiatric disorders. Elan is performing two large Phase 2 studies of ELND005, each to enroll approximately 400 subjects. The first is a 400 patient study to evaluate ELND005 as an adjunctive maintenance therapy for bipolar disorder. The second is a 400 patient study to treat agitation and aggression in moderate to severe Alzheimer’s disease patients. Each of these studies has engaged more than 60 clinical sites worldwide to identify and enroll patients. With positive outcomes, these large studies will generate robust data sets that can provide important clinical evidence to advance ELND005 toward approval.

The neuropsychiatric disease indications of bipolar disorder and agitation and aggression in AD can be very disruptive conditions for patients, their families and their caregivers. Neuropsychiatric symptoms are a large problem as it is estimated that 60% of all AD patients will experience agitation and aggression during the course of their disease. As well, there are approximately 3.5 million people with bipolar disorder in the US and EU alone. An effective treatment for the neuropsychiatric effects of these diseases could provide clinicians with a tool to help patients maintain a more stable behavioral state. Development of ELND005 was granted “Fast Track” status by the FDA in July 2013 as the ELND005 program met the agency’s criteria of a therapy to treat a serious condition and fill an unmet clinical need.

Building on the clinical development of ELND005, Elan also announced a third clinical study. A Phase 2A study in 24 young adults with Down syndrome to evaluate the safety and pharmacokinetics of ELND005 and follow selected cognitive and behavioral measures. As people with Down syndrome have similar amyloid pathology to AD patients, and have an overproduction of a chemical called myo-inositol, ELND005 through its dual mechanism of anti-amyloid aggregation and myo-inositol lowering activity may have the potential to improve outcomes for people with Down Syndrome.

We also note that Perrigo Company has entered into a definitive agreement to acquire Elan Pharmaceuticals, our ELND005 licensing partner. As the results are generated from these ELND005 Phase 2 clinical studies in the coming quarters, we look forward to working closely with Perrigo to support all development efforts of ELND005.

### ***TT401 – Type 2 Diabetes:***

The problem of diabetes continues to grow as estimates of the future prevalence of the disease increase. The clinical and pharmaceutical communities are working to identify tools and strategies to address this mounting health-care challenge. One strategy that is gaining momentum is to find approaches to reduce obesity, a key cause of diabetes. This overall approach aligns well with the potential therapeutic application of TT401, as the drug candidate was shown to significantly reduce both body weight and fasting plasma glucose levels in a recently completed proof-of-concept study.

More specifically, the Company performed a proof-of-concept study where type 2 diabetes subjects received TT401 or placebo once weekly over a five week period. TT401-treated patients in the three highest dose groups experienced

## TO OUR SHAREHOLDERS

statistically significant reductions in mean fasting plasma glucose relative to placebo. Statistically significant mean body weight reduction relative to baseline also occurred in the three highest dose groups. In addition, TT401 demonstrated an acceptable safety and tolerability profile at all doses evaluated in diabetic and non-diabetic obese subjects.

At the completion of this study, our partner Lilly exercised their option to assume all development and commercialization activities. Transition has been interacting closely with Lilly to facilitate transfer of the program to their development team. Lilly is working diligently with preparations for a Phase 2 efficacy study in type 2 diabetes patients.

### ***TT601 – Osteoarthritis:***

During the quarter, Transition licensed a new program from Lilly for the treatment of osteoarthritis. The acquisition of TT601 continues the Company strategy of broadening our development pipeline with new opportunities for growth and value creation. As with our current development programs for AD, bipolar disorder and diabetes, TT601 aims to provide an important new therapeutic alternative for a large disease indication.

Osteoarthritis (OA) is a chronic form of arthritis which affects approximately 27 million Americans. The disease is characterized by the breakdown of cartilage, the part of the joint that cushions the ends of the bones and allows easy movement. This breakdown leads to stiffness, pain and loss of movement in the joint. There is currently no cure for OA. Available therapeutics focus on pain relief and include acetaminophen, NSAIDs, and opioids.

The TT601 drug candidate is a potent and selective ligand for a novel nuclear receptor target. Modulating the activity of this novel target in patients with osteoarthritis may provide pain relief to a large segment of OA patients who do not have adequate response to therapy with NSAIDs (non-steroidal anti-inflammatory drugs). TT601 is an orally administered small molecule that has completed preclinical development to date and Transition anticipates can enter the clinic in the first half of 2014.

### **OUTLOOK**

As we look ahead, there are upcoming clinical development milestones for our key therapeutic programs. For ELND005, both Phase 2 studies in agitation and aggression for AD and bipolar disorder, are actively enrolling patients across multiple clinical sites. Efficacy data from these completed trials is expected in the coming quarters and will be integral to the next steps in the development of ELND005. For TT401, Lilly is preparing to advance this drug candidate into a Phase 2 efficacy study in type 2 diabetes patients in the near future. Internally, the Transition development team is advancing the TT601 drug candidate toward clinical studies in the first half of calendar 2014. Building on our pipeline, Transition is also pursuing additional potential programs to expand the number of product opportunities in development.

We appreciate the continued support of our shareholders and look forward to providing an update on the progress of these programs in the coming year.



Tony Cruz  
Chairman and Chief Executive Officer  
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, 2013 and the related notes, which are prepared in accordance with International Financial Reporting Standards (IFRS) for interim financial statements, as well as the audited consolidated financial statements for the year ended June 30, 2013, including the notes thereto, prepared in accordance with IFRS, and the annual fiscal 2013 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, 2013 as compared to the three-month period ended September 30, 2012. This review was performed by management with information available as of November 8, 2013.

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 2014 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 an adjunctive maintenance treatment in patients with Bipolar Disorder; 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 performed by Elan Pharma International Limited ("Elan") or its successors; 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 and agitation in Alzheimer's disease; the demand for a product that can reduce the occurrence of mood episodes in patients with Bipolar Disorder; the potential clinical benefit of ELND005 in the treatment of bipolar disorder or 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; the timing and manner of future clinical development of TT401 performed by Lilly; the potential clinical development of TT601 for the treatment of osteoarthritis pain; the engagement of third party manufacturers to produce the Company's drug substances and products; 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

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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 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, 2013.

## OVERVIEW

Transition is a product-focused biopharmaceutical company, developing novel therapeutics for disease indications with large markets. The Company's lead CNS drug candidate is ELND005 for the treatment of Alzheimer's disease, Bipolar Disorder and Down syndrome. Transition's lead metabolic drug candidate is TT401 for the treatment of type 2 diabetes and accompanying obesity. Transition has also in-licensed a lead drug candidate from Lilly in the area of osteoarthritis pain (TT601).

During the three month period ended September 30, 2013 and up to the date of this MD&A, the Company announced the following:

### ELND005:

- **September 4, 2013 - Transition announced that their licensing partner Elan had dosed the first patient in a Phase 2a clinical study of ELND005 in Down syndrome;**
- **July 17, 2013 - Transition announced that the US Food and Drug Administration ("FDA") has granted Fast Track Designation to the development program for ELND005 which was submitted for the treatment of Neuropsychiatric Symptoms ("NPS") in Alzheimer's disease ("AD").** The FDA concluded that the development program for ELND005 for the treatment of NPS in AD meets their criteria for Fast Track Designation. Transition's licensing partner, Elan is responsible for all development and commercialization activities and costs of ELND005;

### TT601:

- **July 23, 2013 - Transition announced the exclusive licensing of worldwide rights to a novel small molecule transcriptional regulator ("TT601") from Lilly for the treatment of osteoarthritis ("OA") pain.** TT601 is a potent and selective ligand for a novel nuclear receptor target. Modulating the activity of this novel target in patients with osteoarthritis may provide pain relief to a large segment of OA patients who do not have adequate response to therapy with NSAIDs (non-steroidal anti-inflammatory drugs). TT601 has completed preclinical development to date and Transition anticipates can enter the clinic in the first half of calendar 2014.

### Corporate Developments:

- **August 15, 2013 - Transition announced the closing of the private placement involving Jack W. Schuler, Larry N. Feinberg, Oracle Investment Management, certain Transition Board members, management and other existing shareholders of US\$11 million by purchasing 2,625,300 units of the Company at a price of US\$4.19 per unit.**

## **STRATEGIC COLLABORATIONS**

### **Elan Pharma International Limited**

Transition has exclusively licensed the ELND005 technology to Elan for worldwide development and commercialization. Under the current agreement, Elan is responsible for performing and funding all development and commercialization activities. Transition is eligible to receive from Elan up to US\$93 million regulatory and commercial launch related milestone payments plus tiered royalties ranging from 8% to 15% based on net sales of ELND005 should the drug receive the necessary regulatory approvals for commercialization. To date, Transition has received US\$40 million from Elan in upfront and achieved milestone payments.

Currently, Elan is performing three clinical studies with ELND005. In August 2012, Elan announced the dosing of the first patient in a Phase 2 clinical study evaluating ELND005 as an adjunctive maintenance therapy in 400 bipolar disorder patients. In November, Elan enrolled the first patient in a Phase 2 study of ELND005 to treat aggression and agitation in 400 moderate to severe Alzheimer's disease patients. In September, 2013, Elan announced the first patient was dosed in a Down syndrome Phase 2a study of ELND005.

### **Eli Lilly and Company**

#### **(i) 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 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. In return, 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.

#### **(ii) Osteoarthritis Pain**

On July 23, 2013, Transition announced the exclusive licensing of worldwide rights to a novel small molecule transcriptional regulator ("TT601") from Lilly for the treatment of osteoarthritis pain. TT601 is a potent and selective ligand for a novel nuclear receptor target. Modulating the activity of this novel target in patients with osteoarthritis may provide pain relief to a large segment of OA patients who do not have adequate response to therapy with NSAIDs (non-steroidal anti-inflammatory drugs).

Under the terms of the agreement, Transition has acquired the rights to develop and potentially commercialize TT601. Lilly retains an option to reacquire all rights to TT601 following review of clinical proof-of-concept study results. If Lilly exercises this option right, Transition would be eligible to receive milestone payments of approximately US\$130 million and a high single-digit royalty on sales of products containing TT601 should such products be successfully

# MANAGEMENT'S DISCUSSION AND ANALYSIS

commercialized. If Lilly does not exercise this option right, Lilly would be eligible for a low single-digit royalty from Transition on sales of products containing TT601 should such products be successfully commercialized.

## 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:

### ELND005 for Neuropsychiatric Diseases

#### **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.

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.

#### **Bipolar Disorder:**

Bipolar I Disorder is a severe form of Bipolar Disorder, also commonly known as manic depressive illness. It is a psychiatric disorder characterized by excessive swings in a person's mood and energy affecting their ability to function. Bipolar Disorder is a lifetime recurrent disorder with cycles of dramatic mood swings of highs and lows, often with periods of normal moods in between. The periods of highs and lows are called episodes of mania and depression. Bipolar Disorder is also associated with increased cardiovascular morbidity and suicide risk. The U.S. and European Union population of Bipolar Disorder patients is estimated at approximately 3.5 million.

#### **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 of ELND005:**

ELND005, scyllo-inositol, 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, Transition's licensing partner, Elan is performing and funding three Phase 2 clinical studies of ELND005:

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

On November 27, 2012, Elan announced that they had enrolled the first patient in a Phase 2 clinical trial of ELND005 for the treatment of agitation/aggression in patients with moderate 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 moderate to severe AD, who are experiencing at least moderate levels of agitation/aggression. The study is expected to enroll approximately 400 patients at multiple sites in the US, Canada and potentially other selected regions.

##### **(b) Bipolar Disorder**

On August 30, 2012, Transition announced that their licensing partner Elan had dosed the first patient in a Phase 2 clinical study of ELND005 in Bipolar Disorder. The study is a placebo-controlled, safety and efficacy study of oral ELND005 as an adjunctive maintenance treatment in patients with Bipolar 1 Disorder to delay the time to occurrence of mood episodes. As the first patient has been dosed in the study, Transition received a milestone payment of US\$11 million from Elan on October 1, 2012.

##### **(c) Down Syndrome**

On September 4, 2013, Transition announced the first patient was dosed in a Phase 2a study of ELND005 in Down syndrome. Study ELND005-DS201 will evaluate the safety and pharmacokinetics of two doses of ELND005 and placebo in young adults with Down syndrome without dementia, and will also include select cognitive and behavioural measures.

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 December 27, 2010, Elan and Transition announced the mutual agreement to modify their collaboration agreement for the development and commercialization of ELND005. Under the terms of the modification, as the agreement is now a royalty arrangement, Transition will no longer fund the development or commercialization of ELND005. Accordingly, Transition did not incur any expenditures relating to the program during the three-month periods ended September 30, 2013 and 2012.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

## **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.

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**

On March 3, 2010, Transition announced that it had acquired the rights to a series of preclinical compounds from Lilly in the area of diabetes. Under this licensing and collaboration agreement with Lilly, Transition will receive exclusive worldwide rights to develop and potentially commercialize a class of compounds that, in preclinical diabetes models showed potential to provide glycemic control and other beneficial effects including weight loss. The unique properties of these compounds have the potential to provide important therapeutic benefits to type 2 diabetes patients and could represent the next generation of diabetes therapies to be advanced in clinical development.

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.

Data from the study support a clear development path forward to a larger Phase 2 efficacy study of TT401.

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. Transition will contribute payment of US\$14 million to Lilly in three separate installments during the Phase 2 clinical study.

#### ***Expenditures for the TT401/402 Program***

During the three month periods ended September 30, 2013 and 2012, the Company incurred direct research and development costs for this program as follows:

<b>TT401/402 Program<sup>(1)</sup></b>	<b>Three month period ended September 30, 2013 \$</b>	<b>Three month period ended September 30, 2012 \$</b>
Pre-clinical studies	7,488	253,149
Clinical studies	87,567	713,738
Manufacturing	(37,444 )	80,106
Other direct research	18,108	49,373
<b>TOTAL</b>	<b>75,719</b>	<b>1,096,366</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.

#### **TT601 for Osteoarthritis Pain**

Osteoarthritis is the most common form of arthritis and is a chronic condition characterized by the breakdown of the joint's cartilage. Cartilage is the part of the joint that cushions the ends of the bones and allows easy movement of joints. The breakdown of cartilage causes the bones to rub against each other, causing stiffness, pain and loss of movement in the joint. The joints most commonly affected are the knees, hips, and those in the hands and spine.

An estimated 27 million Americans live with OA, with almost one third of people over the age of 65 affected by OA. Key risk factors for OA include age, obesity, injury or overuse and genetics. There is currently no cure for OA. Available therapeutics focus on pain relief and include acetaminophen, NSAIDs, and opioids.

#### ***Clinical Development of TT601***

TT601 has completed preclinical development to date and Transition anticipates can enter the clinic in the first half of calendar 2014.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

## ***Expenditures for the TT601 Program***

During the three month periods ended September 30, 2013 and 2012, the Company incurred direct research and development costs for this program as follows:

<b>TT601 Program<sup>(1)</sup></b>	<b>Three month period ended September 30, 2013</b> \$	<b>Three month period ended September 30, 2012</b> \$
Pre-clinical studies	8,964	-
Clinical studies	-	-
Manufacturing	84,492	-
Other direct research	24,406	-
<b>TOTAL</b>	<b>117,862</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.

## **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:



## **RESULTS OF OPERATIONS**

For the three month period ended September 30, 2013, the Company recorded a net loss of \$2,331,186 (\$0.08 loss per common share) compared to net income of \$7,736,046 (\$0.29 income per common share) for the three month period ended September 30, 2012.

Revenue during the three month period ended September 30, 2013 was nil, compared \$10,815,200 (US\$11,000,000) in the comparative three month period ended September 30, 2012 relating to the milestone payment received from Elan upon their commencement of the next ELND005 clinical trial. In light of this, the Company reported an increase in net loss of \$10,067,232 for the three month period ended September 30, 2013 compared to the three month period ended September 30, 2012. The increase in net loss is also attributed to an increased foreign exchange loss as well as increased general and administrative expenses, which has been offset by a decrease in research and development expenses.

### **Revenue**

Revenue is nil in the three month period ended September 30, 2013 compared to \$10,815,200 (US\$11,000,000) in the three month period ended September 30, 2012.

In August 2012, Elan dosed the first patient in a Phase 2 clinical study of ELND005 in Bipolar Disorder. In light of the amendments to the Elan agreement, the Company recognized \$10,815,200 (US\$11,000,000) as revenue during the three month period ended September 30, 2012 which represents the milestone payment received from Elan upon their commencement of the next ELND005 clinical trial.

### **Research and Development**

Research and development expenses decreased to \$1,007,846 for the three month period ended September 30, 2013 from \$2,054,546 for the three month period ended September 30, 2012. The decrease in research and development expenses is primarily due to decreases in clinical development costs related to diabetes drug candidate TT401/TT402 which has been partially offset by an increase in clinical development costs related to TT601.

The Company anticipates that research and development expenses will increase during the second quarter of fiscal 2014 as the Company advances the development of TT601 for the treatment of osteoarthritis pain.

### **General and Administrative**

General and administrative expenses increased to \$947,360 for the three month period ended September 30, 2013 from \$816,902 for the three month period ended September 30, 2012. The increase in general and administrative expenses is primarily due to increased business and corporate development activities.

The Company anticipates that general and administrative expenses will remain relatively consistent in the second quarter of fiscal 2014 as the Company continues with on-going business and corporate development initiatives.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

## 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, 2013.

	First Quarter \$	Second Quarter \$	Third Quarter \$	Fourth Quarter \$
<b>2014</b>				
Revenue	-			
Net income (loss) <sup>(1)</sup>	(2,331,186)			
Basic and diluted net income (loss) per common share	(0.08)			
<b>2013</b>				
Revenue	10,815,200	-	-	7,118,300
Net income (loss) <sup>(1)</sup>	7,736,046	(2,754,534)	(2,903,331)	(2,054,884)
Basic and diluted net income (loss) per common share	0.29	(0.10)	(0.11)	(0.08)
<b>2012</b>				
Revenue		-	-	-
Net income (loss) <sup>(1)</sup>		(3,790,421)	(3,072,112)	(2,536,555)
Basic and diluted net income (loss) per common share		(0.15)	(0.11)	(0.10)

<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 Elan and 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; head count reductions and corporate development costs.

## 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 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. 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. An impairment loss of \$6,545,821 was recognized in the fourth quarter of fiscal 2013 to write off the intangible asset related to TT301 as a result of management's decision to terminate the program.

#### **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. An increase of 10% applied to the probability assumptions, with all other variables held constant, would increase the contingent consideration payable by \$698,000. Conversely a decrease of 10% applied to the probability assumptions, with all other variables held constant, would decrease the contingent consideration payable by \$698,000;
- (b) The probability adjusted cash flows are discounted at a rate of 24% 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 \$211,913. Conversely, a decrease of 5% to the discount rate would increase the contingent consideration payable by \$235,888.

#### **Valuation Allowance for Deferred Income Tax Assets**

The Company has not recognized certain deferred tax assets primarily related to the carry forward of operating losses and qualifying research and development expenses. The Company has determined that it is not probable that these carry forward amounts will be realized based on historical results and estimated future taxable income. The generation of future taxable income or the implementation of tax planning strategies could result in the realization of some or all of the carry forward amounts, which could result in a material change in our net income (loss) through the recovery of deferred income taxes. However, there is no assurance that the Company will be able to record deferred income tax recoveries in the future.

#### **Share Based Payments**

When the Company issues stock options, 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.

#### **(b) Judgments**

##### **Recognition of Revenue**

The Company has recognized as revenue all amounts that have been received under the contracts with Elan and Lilly. The recognition of revenue requires judgment in evaluating the contractual terms and assessing the Company's performance towards meeting the contractual obligations.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

## ACCOUNTING CHANGES

The following accounting policies have been adopted effective July 1, 2013.

**IFRS 10 – Consolidated Financial Statement**, requires an entity to consolidate an investee when it has power over the investee, is exposed, or has rights to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. IFRS 10 replaced SIC-12, Consolidation – Special Purpose Entities, and parts of IAS 27, Consolidated and Separate Financial Statements. The adoption of IFRS 10 did not impact the Company's interim consolidated financial statements;

**IFRS 12 – Disclosure of Interests in Other Entities** establishes disclosure requirements for interests in other entities, such as subsidiaries, joint arrangements, associates and unconsolidated structured entities. The standard carries forward existing disclosures and also introduces significant additional disclosure that address the nature of, and risks associated with, an entity's interest in other entities. The adoption of this IFRS will require additional disclosures in the annual consolidated financial statements;

**IFRS 13 – Fair Value Measurement** is a comprehensive standard for fair value measurement and disclosure for use across all IFRS standards. The new standard clarifies that fair value is the price that would be received to sell an asset, or paid to transfer a liability in a transaction between market participants, at the measurement date. The adoption of IFRS 13 did not require any adjustments to the valuation techniques used by the Company to measure fair value and did not result in any adjustments as at July 1, 2013.

## IFS ISSUED BUT NOT YET ADOPTED

### IAS 36 – Impairment of Assets (“IAS 36”)

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 Company has not determined the impact of the adoption of this IFRS on the Company's 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.

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, 2013 and ending September 30, 2013 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 interest income on surplus funds, milestone payments, and licensing fees. The Company has incurred a cumulative deficit to September 30, 2013 of \$151,664,102. 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, cash equivalents and short term investments were \$37,253,647 at September 30, 2013 as compared to \$28,125,639 at June 30, 2013, resulting in an increase of \$9,128,008. The Company's working capital position at September 30, 2013 increased \$9,339,695 from \$25,505,725 at June 30, 2013 to \$34,845,420, at September 30, 2013.

The increase in the Company's cash, cash equivalents and short term investments as well as the increase in working capital is primarily due to the net proceeds of \$10.9 million received from the private placement equity financing which closed on August 15, 2013 whereby the Company issued 2,625,300 units of the Company to existing shareholders, board members and management at a price of US\$4.19 per unit. Each unit consisted of (i) one common share, (ii) 0.325 Common Share purchase warrant with a purchase price of US\$4.60 per whole warrant and (iii) 0.4 Common Share purchase warrant with a purchase price of US\$6.50 per whole warrant. Each whole warrant will entitle the holder, within two years of the closing date, to purchase one additional common share in the capital of the Company. If and when all of the warrants are exercised, the Company may realize up to an additional SU\$10.7 million in proceeds.

The increase in the Company's cash, cash equivalents and short term investments as well as the increase in working capital is partially offset by expenditures incurred during the three month period ended September 30, 2013.

In light of the recent private placement, 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 well 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 and cash equivalents, 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.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

## Contractual Obligations

Minimum payments under our contractual obligations are as follows:

	Less than 1 year \$	1 - 3 years \$	4 - 5 years \$	After 5 years \$	Total \$
Lilly Phase 2	6,181,800	8,242,400	-	-	14,424,200
Operating leases	123,129	142,776	1,377	-	267,282
Collaboration agreements	7,121	-	-	-	7,121
Clinical and toxicity study agreements	45,340	-	-	-	45,340
Manufacturing agreements	394,635	-	-	-	394,635
Contingent Consideration Payable	2,847,759	8,068,760	-	-	10,916,519
Other	18,349	-	-	-	18,349
<b>TOTAL</b>	<b>9,618,133</b>	<b>16,453,936</b>	<b>1,377</b>	<b>-</b>	<b>26,073,446</b>

## **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 8, 2013, the Company has 29,619,456 common shares outstanding.

#### **Stock Options**

As at November 8, 2013 the Company has 1,805,561 stock options outstanding with exercise prices ranging from \$2.09 to \$4.29 and various expiry dates extending to June 30, 2023. At November 8, 2013, on an if-converted basis, these stock options would result in the issuance of 1,805,561 common shares at an aggregate exercise price of \$5,415,253.

## **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, 2013 and 2012  
(Unaudited)

# CONSOLIDATED BALANCE SHEETS

(Unaudited, in Canadian dollars)

	Note	As at September 30, 2013 \$	As at June 30, 2013 \$
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents		32,173,444	23,067,937
Short term investments	6	5,080,203	5,057,702
Other receivables		44,881	35,792
Investment tax credits receivable		223,524	180,652
Prepaid expenses and deposits		240,607	359,164
		37,762,659	28,701,247
<b>Non-current assets</b>			
Property and equipment		161,917	168,034
Intangible assets	7	8,678,604	8,938,674
<b>Total assets</b>		46,603,180	37,807,955
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables		595,866	874,149
Current portion of contingent consideration payable	8	2,321,373	2,321,373
		2,917,239	3,195,522
<b>Non-current liabilities</b>			
Contingent consideration payable	8	1,434,958	1,434,958
Leasehold inducement		20,005	22,863
		4,372,202	4,653,343
<b>Equity attributable to owners of the Company</b>			
Share capital	11	174,494,446	165,367,524
Warrants	11	2,025,839	-
Contributed surplus	11	14,768,002	14,768,002
Share-based payment reserve	11	2,606,793	2,352,002
Deficit		(151,664,102)	(149,332,916)
		42,230,978	33,154,612
<b>Total liabilities and equity</b>		46,603,180	37,807,955

Contingencies and commitments 14

*These notes are an integral part of these consolidated financial statements.*

On behalf of the Board:

  
Tony Cruz, Director

  
Christopher Henley, Director

## CONSOLIDATED STATEMENTS OF INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)

For the three months ended September 30, 2013 and 2012 (*Unaudited, in Canadian dollars, except per share data*)

	Note	September 30, 2013 \$	September 30, 2012 \$
<b>Revenues</b>			
Licensing fees	9	-	10,815,200
<b>Expenses</b>			
Research and development	12	1,007,846	2,054,546
Selling, general and administrative expenses	12	947,360	816,902
<b>Operating Income (loss)</b>		(1,955,206)	7,943,752
Interest income		46,137	33,617
Foreign exchange gain (loss)		(422,117)	(241,323)
<b>Net income (loss) and comprehensive income (loss) for the period</b>		(2,331,186)	7,736,046
<b>Basic and diluted net income (loss) per common share</b>	13	(0.08)	0.29

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

# CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

For the three months ended September 30, 2013 and 2012 (Unaudited, in Canadian dollars)

	Note	Number of common shares #	Share capital \$
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
Balance, July 1, 2012		26,921,302	165,334,259
Net income and comprehensive income for the period		-	-
Share-based payment compensation expense	11	-	-
Balance, September 30, 2012		26,921,302	165,334,259

*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 \$	Deficit \$	Total equity \$
-	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
-	13,168,411	2,977,032	(149,356,213)	32,123,489
-	-	-	7,736,046	7,736,046
-	-	357,022	-	357,022
-	13,168,411	3,334,054	(141,620,167)	40,216,557

# CONSOLIDATED STATEMENTS OF CASH FLOWS

For the three months ended September 30, 2013 and 2012 (Unaudited, in Canadian dollars)

	Note	September 30, 2013 \$	September 30, 2012 \$
<b>Cash flows from operating activities</b>			
Net income (loss) for the period		(2,331,186)	7,736,046
Adjustments for:			
Depreciation and amortization		268,190	455,330
Share-based payment compensation expense		351,697	357,022
Accrued interest		(22,501)	(16,133)
Unrealized foreign exchange loss		437,466	267,845
Change in working capital	15	(211,687)	(11,234,146)
<b>Net cash used in operating activities</b>		<b>(1,508,021)</b>	<b>(2,434,036)</b>
<b>Cash flows from investing activities</b>			
Maturity of short term investments		-	1,017,835
Purchase of property and equipment		(4,861)	(3,157)
<b>Net cash (used in) provided by investing activities</b>		<b>(4,861)</b>	<b>1,014,678</b>
<b>Cash flows from financing activities</b>			
Net proceeds from private placement	11	10,918,048	-
Proceeds from share options exercised	11	137,807	-
<b>Net cash from financing activities</b>		<b>11,055,855</b>	<b>-</b>
<b>Foreign exchange losses on cash and cash equivalents</b>		<b>(437,466)</b>	<b>(267,845)</b>
<b>Net increase (decrease) in cash and cash equivalents</b>		<b>9,105,507</b>	<b>(1,687,203)</b>
Cash and cash equivalents at beginning of period		23,067,937	12,955,081
<b>Cash and cash equivalents at end of period</b>		<b>32,173,444</b>	<b>11,267,878</b>

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

# NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2013 (*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 CNS drug candidate is ELND005 for the treatment of Alzheimer's disease, Bipolar Disorder and Down syndrome. Transition's lead metabolic drug candidate is TT401 for the treatment of type 2 diabetes and accompanying obesity.

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) 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, 2013.

## 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Board of Directors approved the interim consolidated financial statements for issuance on November 8, 2013. 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, 2013 and have been applied to all periods presented except the following accounting policy, which has been adopted effective July 1, 2013:

*IFRS 10* – Consolidated Financial Statement, requires an entity to consolidate an investee when it has power over the investee, is exposed, or has rights to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. IFRS 10 replaced SIC-12, Consolidation – Special Purpose Entities, and parts of IAS 27, Consolidated and Separate Financial Statements. The adoption of IFRS 10 did not impact the Company's interim consolidated financial statements;

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2013 (Unaudited, in Canadian dollars)

*IFRS 12* – Disclosure of Interests in Other Entities establishes disclosure requirements for interests in other entities, such as subsidiaries, joint arrangements, associates and unconsolidated structured entities. The standard carries forward existing disclosures and also introduces significant additional disclosure that address the nature of, and risks associated with, an entity’s interest in other entities. The adoption of this IFRS will require additional disclosures in the annual consolidated financial statements;

*IFRS 13* – Fair Value Measurement is a comprehensive standard for fair value measurement and disclosure for use across all IFRS standards. The new standard clarifies that fair value is the price that would be received to sell an asset, or paid to transfer a liability in a transaction between market participants, at the measurement date. The adoption of IFRS 13 did not require any adjustments to the valuation techniques used by the Company to measure fair value and did not result in any adjustments as at July 1, 2013.

### 4. FINANCIAL RISK MANAGEMENT

#### 4.1 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, 2013	Classification	Carrying Value \$	Fair Value \$
Cash	Loans and receivables	32,173,444	32,173,444
Short term investments	Loans and receivables	5,080,203	5,080,202
Accounts payable and accrued liabilities	Other liabilities	595,868	595,868
Contingent consideration payable	Fair value through profit and loss	3,756,331	3,756,331

Financial Instruments as at June 30, 2012	Classification	Carrying Value \$	Fair Value \$
Cash	Loans and receivables	23,067,937	23,067,937
Short term investments	Loans and receivables	5,057,702	5,057,212
Accounts payable and accrued liabilities	Other liabilities	874,149	874,149
Contingent consideration payable	Fair value through profit and loss	3,756,331	3,756,331

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 the 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 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, would increase the contingent consideration payable by \$698,000. Conversely a decrease of 10% applied to the probability assumptions, with all other variables held constant, would decrease the contingent consideration payable by \$698,000

- (b) The probability adjusted cash flows are discounted at a rate of 24% 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 \$211,913. Conversely, a decrease of 5% to the discount rate would increase the contingent consideration payable by \$235,888.

#### 4.2 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.

Balances in foreign currencies at September 30, 2013 and June 30, 2013 are approximately:

	September 30, 2013 US\$	September 30, 2012 US\$
Cash and cash equivalents	25,181,130	15,953,520
Trade and other payables	(103,585)	(336,561)
	<u>25,077,545</u>	<u>15,616,959</u>

Fluctuations in the US dollar exchange rate could potentially have a significant impact on the Company's results. At September 30, 2013, 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, 2013 would have decreased by approximately \$1,960,000. 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, 2013 would have increased by approximately \$1,960,000.

#### 5. 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

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2013 (Unaudited, in Canadian dollars)

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, 2013 from the year ended June 30, 2013.

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 \$5,080,203 at September 30, 2013 [June 30, 2013 – \$5,057,702] with ratings of R1 or higher and maturity dates between October 21, 2013 and April 8, 2014. There were no gains or losses realized on the disposal of the short term investments during the three month period ended September 30, 2013 or in the year ended June 30, 2013 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.

### 7. INTANGIBLE ASSETS

Intangible assets consist of the following:

	ENI Technology acquired (ELND005) \$	Lilly Licenses acquired (TT401/402) \$	Total \$
<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 September 30, 2013</b>			
Cost	20,547,993	1,055,900	21,603,893
Accumulated amortization	(12,735,663)	(189,626)	(12,895,289)
Net book value September 30, 2013	7,812,330	866,274	8,678,604
<b>Period ended September 30, 2013</b>			
Opening net book value	8,059,201	879,473	8,938,674
Amortization charge	(246,871)	(13,199)	(260,070)
<b>Net book value September 30, 2013</b>	<b>7,812,330</b>	<b>866,274</b>	<b>8,678,604</b>

	Technology acquired (ELND005) \$	NMX Compounds acquired (TT301/302) \$	Lilly Licenses acquired (TT401/402) \$	Total \$
<b>As at July 1, 2012</b>				
Cost	20,547,993	11,085,259	1,055,900	32,689,152
Accumulated amortization and impairment	(11,501,321)	(3,800,410)	(123,631)	(15,425,362)
Net book value July 1, 2012	9,046,672	7,284,849	932,269	17,263,790
<b>As at June 30, 2013</b>				
Cost	20,547,993	11,085,259	1,055,900	32,689,152
Accumulated amortization and impairment	(12,488,792)	(11,085,259)	(176,427)	(23,750,478)
Net book value June 30, 2013	8,059,201	-	879,473	8,938,674
<b>Year ended June 30, 2013</b>				
Opening net book value	9,046,672	7,284,849	932,269	17,263,790
Amortization charge	(987,471)	(739,028)	(52,796)	(1,779,295)
Impairment charge	-	(6,545,821)	-	(6,545,821)
Net book value June 30, 2013	8,059,201	-	879,473	8,938,674

The amortization and impairment charges 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. CONTINGENT CONSIDERATION PAYABLE

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. Accordingly, the Company has recognized a liability as at September 30, 2013 of \$3,756,311 (June 30, 2013 - \$3,756,311) which represents the fair value of the contingent consideration payable.

## 9. GLOBAL COLLABORATION AGREEMENT WITH ELAN PHARMA INTERNATIONAL LIMITED

On September 25, 2006, Elan and the Company entered into an exclusive, worldwide collaboration agreement for the joint development and commercialization of the Company’s novel therapeutic agent, ELND005, for the treatment of Alzheimer’s disease.

Under the terms of the agreement, the Company received up-front payments of US\$15 million: US\$7.5 million in calendar 2006 and the remaining US\$7.5 million in calendar 2007. In addition, the Company was eligible to receive milestone payments of up to US\$185 million of which US\$5 million was received during fiscal 2008.

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2013 *(Unaudited, in Canadian dollars)*

On December 27, 2010, Transition and Elan mutually agreed to modify their collaboration agreement for the development and commercialization of ELND005. Under the terms of the modification, in lieu of the contractually required initiation of Phase III milestone payment of US\$15 million, Transition received from Elan a payment of US\$9 million and was eligible to receive a US\$11 million payment upon the commencement of the next ELND005 clinical trial. As per the terms of the original agreement, Transition is also eligible to receive up to an aggregate of US\$93 million in additional regulatory and commercial launch related milestone payments plus tiered royalties ranging from 8% to 15% based on net sales of ELND005 should the drug receive the necessary regulatory approvals for commercialization.

As the agreement is now a royalty arrangement, Transition is no longer obligated to fund the development or commercialization of ELND005 and has relinquished its 30% ownership of ELND005 to Elan. In light of the amendments to the collaboration agreement, the Company no longer has any funding obligations to Elan for the development of ELND005.

During the three month period ended September 30, 2012, Elan dosed the first patient in a Phase 2 clinical study of ELND005 in bipolar disorder. In light of this milestone being achieved, the Company recognized revenue of \$10,815,200 (US\$11 million) during that period.

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

- (a) 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 will assume all costs and 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.

- (b) On July 23, 2013, the Company entered into an exclusive licensing agreement with Lilly for the worldwide rights to a novel small molecule transcriptional regulator (“TT601”) for the treatment of osteoarthritis pain.

Under the terms of the agreement, Transition has acquired the rights to develop and potentially commercialize TT601. As part of this development, Transition plans to file an Investigational New Drug (“IND”) application with the Food and Drug Administration to seek clearance for clinical development of TT601. Following the IND filing, Transition has an option to continue development into clinical studies. Should Transition proceed with development following the IND filing, Transition shall pay Lilly US\$1 million.

Also as part of the agreement, Lilly retains an option to reacquire all rights to TT601 following review of clinical proof-of-concept study results. If Lilly exercises this option right, Transition would be eligible to receive milestone payments of approximately US\$130 million and a high single-digit royalty on sales of products containing TT601 should such products be successfully commercialized. If Lilly does not exercise this option right, Lilly would be eligible for a low single-digit royalty from Transition on sales of products containing TT601 should such products be successfully commercialized.

## **11. SHARE CAPITAL**

### **Authorized**

At September 30, 2013, 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.

### **Common shares issued and outstanding during the period**

On August 15, 2013, the Company announced the closing of its private placement financing issuing 2,625,300 units of the Company to existing shareholders, board members and management at a price of US\$4.19 per unit, raising gross proceeds of \$11,439,000 (US\$11.0 million). Each unit consists of (i) one common share, (ii) 0.325 Common Share purchase warrant with a purchase price of US\$4.60 per whole warrant and (iii) 0.4 Common Share purchase warrant with a purchase price of US\$6.50 per whole warrant. The Company incurred total share issuance costs of \$521,000, resulting in net cash proceeds of approximately \$10,918,000.

At September 30, 2013, there were 29,619,456 common shares issued and outstanding.

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2013 (Unaudited, in Canadian dollars)

### Warrants

In connection with the Company's private placement, on August 15, 2013, the Company issued 853,223 full warrants with a purchase price of US\$4.60 and 1,050,118 full warrants with a purchase price of US\$6.50. Each whole warrant will entitle the holder, within two years of the closing date, to purchase one additional common share in the capital of the Company.

The warrants have a total fair value of \$2,025,839 which was calculated using the Black-Scholes pricing model with the following assumptions:

Risk free interest rate	1.18%
Expected dividend yield	0%
Stock price volatility	0.6348
Expected life of warrants	2.0 years

If and when all of the warrants are exercised, the Company may realize up to an additional US\$10.7 million in proceeds. All unexercised warrants will expire on August 15, 2015.

### Stock Options

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

Stock options	#	\$	Weighted Average Exercise Price
			\$
Stock options outstanding, July 1, 2012	1,949,919	2,977,032	4.10
Stock based compensation expense		357,022	-
Stock options outstanding, September 30, 2012	1,949,919	3,334,054	4.10

[i] During the three month period ended September 30, 2013, 63,522 stock options were exercised. These options had a fair value of \$96,906 and resulted in cash proceeds to the Company of \$137,807. There were no options exercised in the comparative period ended September 30, 2012.

[ii] During the three month period ended September 30, 2013, 2,917 stock options were forfeited. These options had a fair value of \$7,701 and were unvested at the time of forfeit. There were no options forfeited or cancelled during the comparative period ended September 30, 2012.

[iii] The maximum possible cash proceeds to the Company from the exercise of the stock options outstanding at September 30, 2013 are \$5,415,253 [June 30, 2013 - \$5,563,736].

## 12. EXPENSES BY NATURE

	Three month period ended September 30, 2013 \$	Three month period ended September 30, 2012 \$
<b>Research and development</b>		
Clinical trials and manufacturing	245,777	1,217,749
Amortization	265,276	451,492
Salaries and benefits	303,746	290,155
Stock compensation expense	142,034	141,940
Facility lease costs and utilities	44,445	43,932
Insurance	20,403	23,447
General laboratory supplies and materials	29,037	25,297
Ontario investment tax credits	(42,872)	(139,466)
	1,007,846	2,054,546
<b>Selling, general and administrative expenses</b>		
Salaries and benefits	360,501	327,150
Professional fees and services	115,973	106,949
Insurance	55,986	64,506
Stock compensation expense	209,663	215,082
Facility lease costs and utilities	37,948	35,548
Business development, corporate communication and investor relations	101,249	8,862
Regulatory and stock transfer fees	21,575	21,049
Office and related expenses	41,551	33,918
Amortization	2,914	3,838
	947,360	816,902

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

September 30, 2013 (Unaudited, in Canadian dollars)

### 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 year. Outstanding options to purchase common shares of 1,805,561 [June 30, 2013 – 1,872,000] 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 period ended September 30, 2013 and also due to the fact that the option exercise price exceeds the average market value of the Company's common shares for the three month period ended September 30, 2013. For the three month periods ended September 30, 2013 and 2012, 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, 2013	September 30, 2012
Income (loss) attributable to equity holders of the Company	(\$2,331,186)	\$7,736,046
Weighted average number of common shares outstanding	28,200,909	26,841,394

### 14. CONTINGENCIES AND COMMITMENTS

At September 30, 2013, the Company is committed to aggregate expenditures of \$14,431,000 under its collaboration agreements [June 30, 2013 - \$14,007,000]. In addition, at September 30, 2013, the Company is committed to aggregate expenditures of approximately \$45,000 [June 30, 2013 - \$187,000] for clinical and toxicity studies to be completed during fiscal 2014, approximately \$395,000 [June 30, 2013 - \$244,000] for manufacturing agreements and approximately \$20,000 [June 30, 2013- \$11,000] for consulting and other agreements.

### 15. CHANGE IN WORKING CAPITAL

The change in working capital consists of the following:

	For the three month period ended September 30, 2013 \$	For the three month period ended September 30, 2012 \$
Due from Elan Pharma International Limited	-	(10,815,200)
Trade and other receivables	(9,089)	(1,302)
Investment tax credits receivable	(42,872)	(57,364)
Prepaid expenses and deposits	118,557	(230,346)
Trade and other payables	(278,283)	(129,934)
	(211,687)	(11,234,146)

## 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:

	For the three month period ended September 30, 2013 \$	For the three month period ended September 30, 2012 \$
Salaries and other short-term employee benefits	386,272	341,304
Stock-compensation expenses	306,865	305,405
	693,137	646,709

## 17. SEGMENT DISCLOSURE

The Company operates in one operating segment, the research and development of therapeutic agents, and operates in Canada. All revenues recognized during the comparative three month period ended September 30, 2012 are from one partner, Elan Pharma International Limited, a company based in Ireland.

## **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

**Nicole Rusaw,** CFO

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

**Carl Damiani,** VP Business Development

**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, Norton Rose Fulbright LLP

*USA:*

Brett Cooper, Orrick, Herrington & Sutcliffe LLP

## **CORPORATE SECRETARY**

Louis Alexopoulos, Sotos LLP

## **ANNUAL GENERAL MEETING**

December 13, 2013 @ 4:00 pm  
MaRS Center, South Tower  
101 College Street, Main floor, room CR3  
Toronto, Ontario, Canada