

**TRANSITION THERAPEUTICS INC.  
2013 Second Quarter Financial Report**



# TO OUR SHAREHOLDERS

This fiscal quarter was highlighted by the commencement of a clinical study of our lead neurological drug candidate, ELND005, in Alzheimer's disease (AD) patients with agitation and aggression. This is the second Phase 2 study started by our licensing partner, Elan, adding to a Phase 2 clinical study of ELND005 in bipolar disorder which began in August 2012. In parallel, Transition has been performing a proof-of-concept clinical study of TT-401 in subjects with type 2 diabetes that is nearing completion.

## **PIPELINE REVIEW**

### *ELND005 - NEUROLOGICAL DISORDERS:*

Agitation/Aggression is a large unmet medical need as it is expected that approximately 60% of all AD patients will develop agitation/aggression over the course of their disease. These behavioral changes are very troubling and stressful for AD caregivers and patient families. The burdens of these behaviors are a leading cause in the decision to institutionalize AD patients. An effective therapy therefore would have the potential to reduce caregiver stress, prolong the time AD patients can remain with their caregivers and lower the institutional costs of AD care. There are currently no approved therapies to treat agitation and aggression in AD patients.

In November 2012, Elan announced the dosing of the first patient in a Phase 2 clinical study of ELND005 in approximately 400 moderate to severe AD patients that are experiencing moderate levels of agitation/aggression. The primary endpoint of the study is the change from baseline in agitation/aggression scores over a 12-week treatment period. The study is expected to be completed by the end of calendar 2013, with data available in early 2014. Elan has also begun a safety extension study of those subjects from the AD agitation/aggression trial to evaluate safety over 24 weeks exposure to ELND005.

The rationale for the agitation/aggression clinical study is derived from the completed Phase II clinical study of ELND005 in mild to moderate AD patients. While the primary endpoints of that completed study related to cognitive and functional outcomes, the study also followed changes in neuropsychiatric symptoms (NPS). In the completed study, ELND005 appeared to decrease the emergence and severity of specific NPS including agitation/aggression. The study also showed that the administration of ELND005 led to significant reductions in the brain levels of a molecule called myo-inositol. In some published clinical studies, reductions in myo-inositol have been correlated with the activity of lithium and valproic acid, two current leading therapies for mood disorders. Thus from both a clinical and scientific perspective, there are multiple lines of evidence supporting the symptomatic application of ELND005 for agitation/aggression in AD patients.

The agitation/aggression study is the second Phase II study commenced by Elan this year. A 400 patient Phase 2 study evaluating ELND005 in bipolar disorder type 1 patients is also underway. The bipolar disorder study will examine ELND005 as an adjunctive maintenance therapy to delay the time to occurrence of mood episodes.

### *TT-401 - TYPE 2 DIABETES:*

TT-401 is being developed as a next generation therapy for those individuals with type 2 diabetes. The data to date supports TT-401's product profile as a once-weekly administered peptide to effectively lower blood glucose levels of diabetes patients while also providing secondary benefits including weight loss and improvement of lipid profiles.

The single ascending dose Phase 1 study has been completed. In the study, TT-401 demonstrated an acceptable safety and tolerability profile in non-diabetic obese subjects. TT-401 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.

## TO OUR SHAREHOLDERS

Following receipt of these data, Transition together with its development partner Lilly jointly decided to advance TT-401 into a proof-of-concept clinical study. In this study, 60 obese or obese diabetic subjects receive TT-401 therapy or placebo for a treatment period of five weeks. The dosing phase of this study has been completed with only follow-up visits remaining. We expect data from this study to be announced in calendar Q2 2013.

### OUTLOOK

As we look ahead, there are upcoming clinical development milestones for all our therapeutic programs. For TT-401, the proof of concept clinical study has completed dosing and we look to report results in Q2 calendar 2013. This data could trigger a US\$7 million milestone payment from Lilly, should Lilly wish to retain their option for further development of TT-401. The development of ELND005 has broadened with two separate Phase II studies; a agitation/aggression clinical study in AD and a bipolar disorder clinical study. Both these studies are underway and will provide important efficacy data in the coming quarters. Finally, TT-301 is positioned to provide an opportunity for partnership or clinical studies in the near term.

We appreciate the continued support of shareholders and look forward to updating shareholders on the progress of these programs in the coming year.

A handwritten signature in black ink, appearing to read 'Tony Cruz', with a long horizontal stroke extending to the left.

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 and six month periods ended December 31, 2012 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, 2012, including the notes thereto, prepared in accordance with IFRS, and the annual fiscal 2012 Management Discussion and Analysis ("MD&A"). This MD&A provides a review of the performance of the Company for the three and six month periods ended December 31, 2012 as compared to the three and six month periods ended December 31, 2011. This review was performed by management with information available as of February 4, 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 2013 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 timing and manner of future clinical development of ELND005 performed by Elan Pharma International Limited ("Elan"); 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 potential clinical benefit of the anti-inflammatory compounds TT-301 and TT-302; the intention of the Company to seek a partnership for the development of TT-301 and TT-302; the development of TT-401 and the series of preclinical compounds in-licensed from Eli Lilly and Company ("Lilly") and their potential benefit in type 2 diabetes patients; 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 risk that the Company may not be able to capitalize on partnering and acquisition opportunities, (iii) the assumption

# MANAGEMENT'S DISCUSSION AND ANALYSIS

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" in this MD&A before making investment decisions with regard to the securities of the Company.

## OVERVIEW

Transition is a product-focused biopharmaceutical company, developing novel therapeutics for disease indications with large markets. The Company's lead product is ELND005 for the treatment of Alzheimer's disease and Bipolar Disorder. Transition has also in-licensed a series of compounds (TT-401/402) from Lilly in the area of diabetes. Transition also has an emerging pipeline of innovative preclinical and clinical drug candidates targeting anti-inflammatory and metabolic indications. TT-301 and TT-302 are small molecule anti-inflammatory compounds that have demonstrated efficacy in preclinical models of rheumatoid arthritis, Alzheimer's disease, intracerebral hemorrhage ("ICH") traumatic brain injury ("TBI") and neuropathic pain.

During fiscal 2013 and up to the date of this MD&A, the Company announced the following:

### ELND005:

- ***On November 28, 2012, Transition announced that their licensing partner Elan had enrolled the first patient in a Phase II study of ELND005 for the treatment of agitation/aggression in patients with moderate to severe Alzheimer's disease;***
- ***On August 30, 2012, Transition announced that their licensing partner Elan had dosed the first patient in a Phase II 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.

## **STRATEGIC COLLABORATIONS**

### **Elan Pharma International Limited**

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 will be 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. During the three-month period ended December 31, 2010, the Company recorded \$8,951,400 (US\$9,000,000) as revenue relating to the modification of the Agreement. The payment of US\$9 million was received in January, 2011.

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. The Company has recognized \$20,719,750 (US\$20,000,000) as revenue which represents the total of up-front and milestone payments received from Elan since the initiation of the agreement.

On August 29, 2012, Transition's licensing partner Elan announced dosing of the first patient in a Phase 2 trial of ELND005 in Bipolar 1 Disorder. Under the terms of the amended agreement, Transition received the US\$11 million payment that was due upon the commencement of the next ELND005 clinical trial. The payment was received on October 1, 2012 and was recognized as licensing fees during the three-month period ended September 30, 2012.

On November 27, 2012, Elan announced that they had enrolled the first patient in a Phase II 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.

### **Eli Lilly and Company**

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 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 will retain the option to reacquire the rights to the compounds at a later date. Lilly will retain this option up until the end of Phase II. If Lilly exercises these rights, Transition would be eligible to receive milestone payments up to US\$250 million and up to low double digit royalties on sales of products containing such compounds should such products be successfully commercialized. If Lilly does not exercise these rights, Lilly would be eligible for low single digit royalties from Transition on sales of products containing such compounds should such products be successfully commercialized.

The up-front payment of \$1,055,900 (US\$1 million) 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.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

## 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 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. In late stages of the disease, individuals need help with dressing, personal hygiene, eating and other basic functions. People with Alzheimer's disease die an average of eight years after first experiencing symptoms, but the duration of the disease can vary from three to 20 years.

The disease mainly affects individuals over age 65 and it is estimated over 18 million people are suffering from Alzheimer's disease worldwide. The likelihood of developing late-onset Alzheimer's approximately doubles every five years after age 65. By age 85, the risk reaches nearly 50 percent. 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 ("FDA") approved Alzheimer's disease medications may temporarily delay memory decline for some individuals, but none of the currently approved drugs is 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 patients neuropsychiatric symptoms and declines in cognitive ability.

In April 2007, Transition announced that the FDA granted Fast Track designation to ELND005. Under the FDA Modernization Act of 1997, Fast Track designation is intended to facilitate the development and expedite the review of a drug or biologic if it is intended for the treatment of a serious or life-threatening condition, and it demonstrates the potential to address unmet medical needs for such a condition.

On August 30, 2007, the Company announced the completion of Phase I clinical studies with ELND005. Transition and its development partner Elan have performed multiple Phase I studies evaluating the safety, tolerability and pharmacokinetic profile of ELND005 in healthy volunteers. Approximately 110 subjects have been exposed to ELND005 in multiple Phase I studies, including single and multiple ascending dosing; pharmacokinetic evaluation of levels in the brain; and cerebrospinal fluid ("CSF") and plasma studies. ELND005 was safe and well-tolerated at all doses and dosing regimens examined. There were no severe or serious adverse events observed. ELND005 was also shown to be orally bio-available, cross the blood-brain barrier and achieve levels in the human brain and CSF that were shown to be effective in animal models for Alzheimer's disease.

On April 23, 2009, Elan and Transition announced the receipt of a key patent for Alzheimer's disease treatment with ELND005. The United States Patent and Trademark Office issued US patent number 7,521,481 on April 21, 2009. The patent is entitled "Methods of Preventing, Treating and Diagnosing Disorders of Protein Aggregation," and generally claims methods for treating Alzheimer's disease comprising administering scyllo-inositol ELND005. The patent will expire in the year 2025 or later due to any patent term extensions.



On July 13, 2009, Elan and Transition announced Phase I data showing ELND005 achieves desired concentrations in brain tissue and cerebrospinal fluid when given orally. Preclinical data also were presented showing that ELND005 administration is associated with preservation of choline acetyltransferase (ChAT), reflecting preservation of nerve cells that are critical to memory function in the brain. These results were presented at the 2009 Alzheimer's Association International Conference on Alzheimer's Disease (ICAD 2009) in Vienna, Austria.

On December 15, 2009, Elan and Transition announced modifications to ELND005 Phase II clinical trials in Alzheimer's disease. Patients were withdrawn immediately from the study in the two higher dose groups (1000mg and 2000mg dosed twice daily). The study continued unchanged for patients who were assigned to the lower dose (250mg dosed twice daily) and placebo groups. The study was modified to dose patients only at 250mg twice daily. Greater rates of serious adverse events, including nine deaths, were observed among patients receiving the two highest doses. A direct relationship between ELND005 and these deaths has not been established. The Independent Safety Monitoring Committee ("ISMC") and both companies concur that the tolerability and safety data are acceptable among patients receiving the 250mg dose and that the blinded study should continue for this dose and the placebo group.

On August 9, 2010, Elan and Transition announced topline summary results of the Phase II study and plans for Phase III studies for ELND005. The AD201 study did not achieve significance on co-primary outcome measures (NTB and ADCS-ADL) in mild to moderate patients however; the study did identify a dose with acceptable safety and tolerability. The dose demonstrated a biological effect on amyloid-beta protein in the CSF and effects on clinical endpoints in an exploratory analysis. Based on the preponderance of evidence, and input from the experts in this field, the companies intend to advance ELND005 into Phase III studies.

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, 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 will be 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 will no longer fund the development or commercialization of ELND005 and has relinquished its 30% ownership of ELND005 to Elan.

On September 27, 2011, Transition announced that Phase II clinical study data of ELND005 in mild to moderate Alzheimer's disease has been published in the peer-reviewed journal, *Neurology*. The *Neurology* article was entitled "A Phase II randomized trial of ELND005, scyllo-inositol, in mild-moderate Alzheimer's disease". In addition, the embargo on the ELND005 Phase II data previously presented at the International Conference on Alzheimer's Disease (ICAD) in July 2011 was lifted.

On November 29, 2011, Elan provided an update on the development of ELND005. Elan reported that Lonza Group AG has been contracted to supply future active pharmaceutical ingredient. In addition, four oral presentations were presented at the 4th Annual Conference on Clinical Trials on Alzheimer's Disease ("CTAD") focusing on ELND005 treatment effects at earlier stages of AD and the use of validated "composite" cognitive endpoints. Elan also noted that ELND005's role in reducing neuropsychiatric symptoms in AD was highlighted at the CTAD meeting, and that ELND005 may have applications in additional psychiatric indications such as bipolar disorder.

On November 27, 2012, Elan announced that they had enrolled the first patient in a Phase II clinical trial of ELND005 for the treatment of agitation/aggression in patients with moderate to severe Alzheimer's disease. The objectives of

# MANAGEMENT'S DISCUSSION AND ANALYSIS

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.

## **ELND005 for 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.

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.

## ***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 and six month period ended December 31, 2012.

## **TT-401 / TT-402**

### ***Development of TT-401 and TT-402 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 1 diabetes develops when the body's immune system destroys pancreatic islet beta cells, the only cells in the body that make the hormone insulin that regulates blood glucose. To survive, people with type 1 diabetes must have insulin delivered by injection or pump. Type 1 diabetes accounts for 5-10% of all diagnosed cases of 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.

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 December 12, 2011, the Company announced that the first patient was dosed in a Phase I clinical study. TT-401 is a once-weekly administered peptide being studied for its potential to lower blood glucose levels in patients with type 2 diabetes and accompanying obesity.

On June 18, 2012, Transition announced the results of the Phase I clinical study of type 2 diabetes drug candidate, TT-401. 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 TT-401. TT-401 demonstrated an acceptable safety and tolerability profile in non-diabetic obese subjects in the study. TT-401 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. As the study results met expectations, Transition and its development partner Lilly jointly decided that the next development step will be a multiple ascending dose study of TT-401 in obese subjects with type 2 diabetes. This study commenced during the three month period ended September 30, 2012. In this study, 60 obese or obese diabetic subjects receive TT-401 therapy or placebo for a treatment period of five weeks. The dosing phase of this study has been completed with only follow-up visits remaining. Data from this study is expected to be announced by the end of fiscal 2013.

#### ***Expenditures for the TT-401/402 Program***

During the three and six month period ended December 31, 2012 and 2011, the Company incurred direct research and development costs for this program as follows:

<b>TT-401/402 Program<sup>(1)</sup></b>	<b>Three-month period ended December 31, 2012 \$</b>	<b>Three-month period ended December 31, 2011 \$</b>	<b>Six-month period ended December 31, 2012 \$</b>	<b>Six-month period ended December 31, 2011 \$</b>
Pre-clinical studies	231,124	142,641	484,273	457,529
Clinical studies	372,319	413,555	1,086,057	413,555
Manufacturing	501,193	138,215	581,299	457,374
Other direct research	48,878	42,674	98,251	55,894
<b>TOTAL</b>	<b>1,153,514</b>	<b>737,085</b>	<b>2,249,880</b>	<b>1,384,352</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 or an allocation of Company overhead.

#### **TT-301 / TT-302**

Pro-inflammatory cytokines are part of the body's natural defense mechanism against infection. However, the overproduction of these cytokines can play a harmful role in the progression of many different diseases. In the last decade there have been antibody and protein therapies approved (including Enbrel, Remicade and Humira) to inhibit the activity of pro-inflammatory cytokines. Each of these therapies has made a significant impact in the treatment regimen for hundreds of thousands of patients suffering from arthritis, Crohn's disease, and other autoimmune disorders and has annual sales in excess of US\$1.5 billion. The therapeutic and commercial success of these therapies provides a strong proof of concept for the approach of targeting pro-inflammatory cytokines. Unfortunately, an antibody or protein approach is not desirable for the treatment of CNS diseases for a variety of reasons including an inability to sufficiently cross the blood-brain-barrier.

# MANAGEMENT’S DISCUSSION AND ANALYSIS

To address this large unmet medical need, Transition is developing a class of small molecule compounds that are designed to cross the blood-brain-barrier and have been shown to have an inhibitory effect on pro-inflammatory cytokines. Animal model studies have been performed demonstrating that members of this class of compounds can have a therapeutic effect on diseases including arthritis, Alzheimer’s disease, Traumatic Brain Injury (“TBI”), Intracerebral Hemorrhage (“ICH”), and others.

### Development of TT-301 and TT-302

Transition’s lead drug candidates in development are TT-301 and TT-302. These novel drug candidates are derived from a diligent drug design program engineered to produce compounds optimized to target inhibiting pro-inflammatory cytokines in the brain and the periphery. Each compound is designed to cross the blood-brain-barrier and each has the flexibility to be administered by injection or orally. In preclinical studies, both TT-301/302 have shown a favorable safety profile and therapeutic window for efficacy.

Transition has completed a Phase I clinical study of intravenously administered TT-301. The study was a double blind, randomized, placebo controlled study in which healthy volunteers received placebo or escalating doses of TT-301.

Both TT-301 and TT-302 have been shown to suppress inflammatory cytokine production, reduce inflammation and improve outcomes in preclinical models of collagen-induced arthritis. The Company has also performed additional preclinical studies demonstrating the potential therapeutic application of TT-301 and TT-302 in the treatment of neuropathic pain. Transition may seek a partnership to access specialized expertise and resources to maximize the potential of these therapies.

### 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 must successfully complete clinical trials and achieve regulatory approval. The stages of development of the Company’s technologies are illustrated below:

### ELND005

	Preclinical	Phase I	Phase II	Phase III	Partner
Alzheimer’s Disease Agitation/Aggression	█	█	ONGOING	█	ELAN
Bipolar Disorder	█	█	ONGOING	█	
Alzheimer’s Disease Cognition	█	█	█	READY	

### TT401/TT401

Type 2 Diabetes/Obesity	█	ONGOING*	█	█	LILLY
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\* Proof-of-concept study in obese diabetics

### TT301/TT302

Arthritis	█	█	█	█	Partnership candidate
Alzheimer’s Disease	█	█	█	█	

## **RESULTS OF OPERATIONS**

For the three month period ended December 31, 2012, the Company recorded a net loss of \$2,754,534 (\$0.10 loss per common share) compared to net loss of \$3,790,421 (\$0.15 loss per common share) for the three month period ended December 31, 2011.

For the six month period ended December 31, 2012, the Company recorded a net income of \$4,981,512 (\$0.19 income per common share) compared to a net loss of \$6,661,178 (\$0.28 loss per common share) for the six-month period ended December 31, 2011.

Net loss decreased \$1,035,887 or 27% during the three month period ended December 31, 2012. The decrease in net loss during the three month period ended December 31, 2012 is mainly due to decreases in general and administrative expenses and increased foreign exchange gains. The decrease in net loss has been partially offset by increased research and development expenses.

Net loss decreased \$11,642,690 or 175% during the six month period ended December 31, 2012. The decrease in net loss for the six month period ended December 31, 2012 is largely attributed to the revenue recognized during the first quarter of fiscal 2013 resulting from the \$10,815,200 (US\$11 million) milestone payment received from Elan upon the commencement of the next ELND005 clinical trial. The decrease in net loss is also attributed to decreases in general and administrative expenses, research and development expenses and a loss on the disposal of property and equipment which has been offset by an increase in the foreign exchange loss recognized in the quarter.

### **Revenue**

Revenue is nil and \$10,815,200 in the three and six month periods ended December 31, 2012 respectively, compared to nil in both three and six month period ended December 31, 2011.

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 has recognized \$10,815,200 (US\$11,000,000) as revenue during the first quarter of fiscal 2013 which represents the milestone payment received from Elan upon their commencement of the next ELND005 clinical trial. The payment from Elan was received on October 1, 2012.

### **Research and Development**

Research and development expenses increased \$80,635 or 4% from \$2,060,622 for the three month period ended December 31, 2011 to \$2,141,257 for the three month period ended December 31, 2012. The increase is largely due to an increase in clinical development costs related to TT-401/402, which has been offset by decreases in clinical development costs related to TT-301/302 and salaries and related costs associated with headcount reductions.

For the six month period ended December 31, 2012, research and development expenses decreased \$118,543 or 3% to \$4,195,803 from \$4,314,346 for the same period in fiscal 2012. The decrease is primarily due to decreases in clinical development costs related to TT-301/302 and salaries and related costs associated with headcount reductions. The decrease is largely offset by increased clinical development costs related to TT-401/402.

The Company anticipates that research and development expenses will remain relatively consistent in the third quarter of fiscal 2013 as the Company continues to advance the development of TT-401/402.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

## General and Administrative

General and administrative expenses decreased by \$683,472 or 45% from \$1,532,912 for the three month period ended December 31, 2011 to \$849,440 for the three month period ended December 31, 2012. For the six month period ended December 31, 2012, general and administrative expenses decreased \$956,616 or 36% to \$1,666,342 from \$2,622,958 for the same period in fiscal 2012.

The decreases in general and administrative expenses for both the three and six month periods ended December 31, 2012 are due to decreases in legal consulting fees, facility lease costs, and investor relation and business development expenses, as well as decreased salaries and related costs resulting from headcount reductions as the comparative periods included severances relating to terminations.

The Company anticipates that general and administrative expenses will remain relatively consistent in the third quarter of fiscal 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 December 31, 2012.

	First Quarter \$	Second Quarter \$	Third Quarter \$	Fourth Quarter \$
<b>2013</b>				
Revenue	10,815,200	-		
Net income (loss) <sup>(1)</sup>	7,736,046	(2,754,534)		
Basic and diluted net income (loss) per common share	0.29	(0.10)		
<b>2012</b>				
Revenue	-	-	-	-
Net income (loss) <sup>(1)</sup>	(2,870,757)	(3,790,421)	(3,072,112)	(2,536,555)
Basic and diluted net income (loss) per common share	(0.12)	(0.15)	(0.11)	(0.10)
<b>2011</b>				
Revenue			-	-
Net income (loss) <sup>(1)</sup>			(3,219,529)	(4,131,394)
Basic and diluted net income (loss) per common share			(0.14)	(0.18)

<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 changes in activity levels of the clinical trials being performed by the Company, amortization of the technology relating to the assets acquired from Protana, ENI, and NeuroMedix, foreign exchange gains and losses, recognition of up-front and licensing fees relating to the Elan agreement, interest income and corporate development costs.

## **CRITICAL ACCOUNTING ESTIMATES**

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.

### **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 ranging from 15 to 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.

### **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 would increase the contingent consideration payable by \$258,000. Conversely a decrease of 10% applied to the probability assumptions would decrease the contingent consideration payable by \$258,000;
- (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 future 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.



# MANAGEMENT'S DISCUSSION AND ANALYSIS

## **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.

## **Recognition of Revenue**

As a result of the Company's amendment to the collaboration agreement with Elan, the Company has recognized as revenue all amounts that have been received under the contract. The recognition of revenue requires judgment in evaluating the contractual terms and assessing the Company's performance towards meeting the contractual obligations.

## **ACCOUNTING CHANGES**

There were no changes in accounting policies during the three and six month periods ended December 31, 2012.

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

### **IFRS 10 – Consolidated Financial Statements (“IFRS 10”)**

IFRS 10 requires an entity to consolidate an investee when it 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. Under existing IFRS, consolidation is required when an entity has the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities. IFRS 10 replaces SIC-12 Consolidation – Special Purpose Entities and parts of IAS 27 Consolidated and Separate Financial Statements.

### **IFRS 13 – Fair Value Measurement (“IFRS 13”)**

IFRS 13 is a comprehensive standard for the fair value measurement and disclosure requirements 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 an orderly transaction between market participants, at the measurement date. It also establishes disclosures about fair value measurement. Under existing IFRS, guidance on measuring and disclosing fair value is dispersed among the specific standards requiring fair value measurements and in many cases does not reflect a clear measurement basis or consistent disclosures.

IFRS 10 and IFRS 13 are effective for annual periods beginning on or after January 1, 2013 with early adoption permitted. The Company has not yet begun the process of assessing the impact that the new and amended standards will have on its consolidated financial statements or whether to early adopt either of these new standards.

## **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 October 1, 2012 and ending December 31, 2012 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 December 31, 2012 of \$144,374,701. 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 \$24,958,522 at December 31, 2012 as compared to \$19,012,345 at June 30, 2012. The increase of \$5,946,177 is primarily due to the US\$11 million milestone payment the Company received from Elan, partially offset by expenditures incurred during the six month period ended December 31, 2012.

The Company's working capital position at December 31, 2012 was \$22,617,738, as compared to \$16,113,952 at June 30, 2012. The increase in the Company's working capital position is due to the US\$11 million milestone payment received from Elan due to their commencement of the next ELND005 clinical trial in Bipolar Disorder, in August 2012. The increase is partially offset by expenditures incurred during the six month period ended December 31, 2012.

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 \$
Operating leases	79,333	290,429	-	-	369,762
Collaboration agreements	6,980	-	-	-	6,980
Clinical and toxicity study agreements	1,369,410	-	-	-	1,369,410
Manufacturing agreements	699,691	-	-	-	699,691
Contingent Consideration Payable	2,847,759	8,068,760	-	-	10,916,519
Other	10,750	-	-	-	10,750
<b>TOTAL</b>	<b>5,013,923</b>	<b>8,359,189</b>	<b>-</b>	<b>-</b>	<b>13,373,112</b>

## **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 February 4, 2013, the Company has 26,921,302 common shares outstanding.

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

As at February 4, 2013 the Company has 1,738,999 stock options outstanding with exercise prices ranging from \$2.09 to \$13.70 and various expiry dates extending to June 30, 2022. At February 4, 2013, on an if-converted basis, these stock options would result in the issuance of 1,738,999 common shares at an aggregate exercise price of \$6,778,034.

## **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).

Transition Therapeutics Inc.  
2013 Second Quarter Results

## **CONSOLIDATED INTERIM FINANCIAL STATEMENTS**

For the six and three month periods ended December 31, 2012 and 2011  
(Unaudited)

# CONSOLIDATED BALANCE SHEETS

(Unaudited, in Canadian dollars)

	Note	As at December 31, 2012 \$	As at June 30, 2012 \$
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents	6	18,955,854	12,955,081
Short term investments	6	6,002,668	6,057,264
Trade and other receivables		48,408	43,658
Investment tax credits receivable		370,289	241,951
Prepaid expenses and deposits		458,037	316,286
		25,835,256	19,614,240
<b>Non-current assets</b>			
Property and equipment		194,181	215,000
Intangible assets	7	16,374,143	17,263,790
<b>Total assets</b>		42,403,580	37,093,030
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables		896,145	1,178,915
Current portion of contingent consideration payable		2,321,373	2,321,373
		3,217,518	3,500,288
<b>Non-current liabilities</b>			
Contingent consideration payable		1,434,958	1,434,958
Leasehold inducement		28,579	34,295
		4,681,055	4,969,541
<b>Equity attributable to owners of the Company</b>			
Share capital	10	165,334,259	165,334,259
Contributed surplus	10	13,431,445	13,168,411
Share-based payment reserve	10	3,331,522	2,977,032
Deficit		(144,374,701)	(149,356,213)
		37,722,525	32,123,489
<b>Total liabilities and equity</b>		42,403,580	37,093,030

Contingencies and commitments

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*The 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 six and three month periods ended December 31, 2012 and 2011 (*Unaudited, in Canadian dollars*)

	Note	Six month period ended December 31, 2012 \$	Six month period ended December 31, 2011 \$	Three month period ended December 31, 2012 \$	Three month period ended December 31, 2011 \$
<b>Revenues</b>					
Licensing fees	8	10,815,200	-	-	-
<b>Expenses</b>					
Research and development	11	4,195,803	4,314,346	2,141,257	2,060,622
Selling, general and administrative expenses	11	1,666,342	2,622,958	849,440	1,532,912
Loss on disposal of property and equipment		-	118,623	-	38,709
<b>Operating income (loss)</b>		4,953,055	(7,055,927)	(2,990,697)	(3,632,243)
Interest income		68,489	80,339	34,872	40,412
Interest expense		-	(851)	-	(241)
Foreign exchange gain (loss)		(40,032)	315,261	201,291	(198,349)
<b>Net income (loss) and comprehensive income (loss) for the period</b>		4,981,512	(6,661,178)	(2,754,534)	(3,790,421)
<b>Basic and diluted net income (loss) per common share</b>	12	0.19	(0.28)	(0.10)	(0.15)

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

# CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

For the six month period ended December 31, 2012 and 2011

*(Unaudited, in Canadian dollars, except share data)*

	Note	Number of common shares #
Balance, July 1, 2012		26,921,302
Net income and comprehensive income for the period		-
Share options expired, forfeited or cancelled	10	-
Share-based payment compensation expense	10	-
Balance, December 31, 2012		26,921,302
Balance, July 1, 2011		23,217,599
Net loss and comprehensive loss for the period		-
Shares issued pursuant to a private placement		3,703,703
Share options expired, forfeited or cancelled	10	-
Share-based payment compensation expense	10	-
Balance, December 31, 2011		26,921,302

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

**Attributable to equity holders of the company**

Share capital \$	Contributed surplus \$	Share-based payment reserve \$	Deficit \$	Total equity \$
165,334,259	13,168,411	2,977,032	(149,356,213)	32,123,489
-	-	-	4,981,512	4,981,512
-	263,034	(263,034)	-	-
-	-	617,524	-	617,524
165,334,259	13,431,445	3,331,522	(144,374,701)	37,722,525
160,498,537	11,840,574	3,179,327	(137,086,368)	38,432,070
-	-	-	(6,661,178)	(6,661,178)
4,835,722	-	-	-	4,835,722
-	753,946	(753,946)	-	-
-	-	782,996	-	782,996
165,334,259	12,594,520	3,208,377	(143,747,546)	37,389,610

# CONSOLIDATED STATEMENTS OF CASH FLOWS

For the six and three month periods ended December 31, 2012 and 2011 *(Unaudited, in Canadian dollars)*

	Note	Six month period ended December 31, 2012 \$	Six month period ended December 31, 2011 \$	Three month period ended December 31, 2012 \$	Three month period ended December 31, 2011 \$
<b>Cash flows from operating activities</b>					
Net income (loss) for the period		4,981,512	(6,661,178)	(2,754,534)	(3,790,421)
Adjustments for:					
Depreciation and amortization		911,007	916,177	455,677	454,928
Share-based payment compensation expense		617,524	782,996	260,502	438,021
Loss on disposal of property and equipment		-	118,623	-	38,709
Accrued interest		31,233	(30,911)	47,366	(15,157)
Unrealized foreign exchange (gain) loss		282,571	(275,964)	(127,943)	254,318
Change in working capital	14	(557,609)	113,992	10,676,536	395,045
<b>Net cash provided by (used in) operating activities</b>		<b>6,266,238</b>	<b>(5,036,265)</b>	<b>8,557,604</b>	<b>(2,224,557)</b>
<b>Cash flows from investing activities</b>					
Maturity of short term investments		6,083,013	5,062,500	5,065,178	5,062,500
Purchase of short term investments		(6,063,747)	(5,000,000)	(6,063,747)	(5,000,000)
Purchase of property and equipment		(6,257)	(1,215)	(3,100)	-
<b>Net cash provided by (used in) investing activities</b>		<b>13,009</b>	<b>61,285</b>	<b>(1,001,669)</b>	<b>62,500</b>
<b>Cash flows from financing activities</b>					
Net proceeds from private placement		-	4,835,722	-	4,835,722
<b>Net cash provided by financing activities</b>		<b>-</b>	<b>4,835,722</b>	<b>-</b>	<b>4,835,722</b>
<b>Foreign exchange gains/(losses) on cash and cash equivalents</b>		<b>(278,474)</b>	<b>275,964</b>	<b>132,041</b>	<b>(254,318)</b>
<b>Net increase in cash and cash equivalents</b>		<b>6,000,773</b>	<b>136,706</b>	<b>7,687,976</b>	<b>2,419,347</b>
Cash and cash equivalents at beginning of period		12,955,081	17,422,364	11,267,878	15,139,723
<b>Cash and cash equivalents at end of period</b>	6	<b>18,955,854</b>	<b>17,559,070</b>	<b>18,955,854</b>	<b>17,559,070</b>

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



# NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

December 31, 2012 (*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) 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, 2012.

## 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The policies applied in these interim consolidated financial statements are based on IFRS issued and outstanding as of February 4, 2013, the date the Board of Directors approved the interim consolidated financial statements. Any subsequent changes to IFRS that are given effect in the Company's annual consolidated financial statements for the year ending June 30, 2013 could result in restatement of these interim consolidated financial statements.

The interim consolidated financial statements should be read in conjunction with the Company's annual financial statements for the year ended June 30, 2012 prepared in accordance with IFRS.

## 4. FINANCIAL RISK MANAGEMENT

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

December 31, 2012 (Unaudited, in Canadian dollars)

Balances in foreign currencies at December 31, 2012 and June 30, 2012 are approximately:

	December 31, 2012 US\$	June 30, 2012 US\$
Cash and cash equivalents	15,614,115	8,392,258
Short term investments	999,570	999,740
Trade and other payables	(482,360)	(724,901)
	16,131,325	8,667,097

Fluctuations in the US dollar exchange rate could potentially have a significant impact on the Company's results. At December 31, 2012, if the Canadian dollar weakened 10% against the US dollar, with all other variables held constant, comprehensive income for the three month period ended December 31, 2012 would have increased by approximately \$947,000. Conversely, if the Canadian dollar strengthened 10% against the US dollar, with all other variables held constant, comprehensive income for the three month period ended December 31, 2012 would have decreased by approximately \$947,000.

### 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, 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 six month period ended December 31, 2012 from the year ended June 30, 2012.

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. CASH AND CASH EQUIVALENTS AND SHORT TERM INVESTMENTS

The Company's cash equivalents are invested in bankers' acceptances and other short-term instruments with a rating of R1 or higher and maturities less than 90 days at the date of purchase.

Short term investments consist of medium term note debentures totaling \$6,002,668 at December 31, 2012 [June 30, 2012 – \$6,057,264] with maturity dates between January 28, 2013 and November 27, 2013 and have a rating of R1 or higher. There were no gains or losses realized on the disposal of the short term investments during the three and six month periods ended December 31, 2012 or in the year ended June 30, 2012 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.

Cash and cash equivalents consist of the following:

	December 31, 2012 \$	June 30, 2012 \$
Cash	18,955,854	11,955,426
Cash equivalents	-	999,655
	<u>18,955,854</u>	<u>12,955,081</u>

## 7. INTANGIBLE ASSETS

Intangible assets consist of the following:

	ENI Technology acquired (ELND005) \$	NMX Compounds acquired (TT-301/302) \$	Lilly Licenses acquired (TT-401/402) \$	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	9,046,672	7,284,849	932,269	17,263,790
<b>As at December 31, 2012</b>				
Cost	20,547,993	11,085,259	1,055,900	32,689,152
Accumulated amortization and impairment	(11,995,056)	(4,169,924)	(150,029)	(16,315,009)
Net book value December 31, 2012	8,552,937	6,915,335	905,871	16,374,143
<b>Period ended December 31, 2012</b>				
Opening net book value	9,046,672	7,284,849	932,269	17,263,790
Amortization charge	(493,735)	(369,514)	(26,398)	(889,647)
<b>Net book value December 31, 2012</b>	<b>8,552,937</b>	<b>6,915,335</b>	<b>905,871</b>	<b>16,374,143</b>

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

December 31, 2012 (Unaudited, in Canadian dollars)

	ENI Technology acquired (ELND005) \$	NMX Compounds acquired (TT-301/302) \$	Lilly Licenses acquired (TT-401/402) \$	Total \$
<b>As at July 1, 2011</b>				
Cost	20,547,993	11,085,259	1,055,900	32,689,152
Accumulated amortization and impairment	(10,513,849)	(3,061,382)	(70,835)	(13,646,066)
Net book value	10,034,144	8,023,877	985,065	19,043,086
<b>As at June 30, 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 June 30, 2012	9,046,672	7,284,849	932,269	17,263,790
<b>Period ended June 30, 2012</b>				
Opening net book value	10,034,144	8,023,877	985,065	19,043,086
Amortization charge	(987,472)	(739,028)	(52,796)	(1,779,296)
<b>Net book value June 30, 2012</b>	<b>9,046,672</b>	<b>7,284,849</b>	<b>932,269</b>	<b>17,263,790</b>

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. 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.

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 II clinical study of ELND005 in bipolar disorder. In light of this milestone being achieved, the Company recognized revenue of US\$11 million (CDN \$10,815,200) during the three month period ending September 30, 2012. The amount was received on October 1, 2012.

#### **9. LICENSING AND COLLABORATION AGREEMENT 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 will retain the option to reacquire the rights to the compounds at a later date. Lilly will retain this option up until the end of Phase II. If Lilly exercises these rights, Transition would be eligible to receive milestone payments of up to US\$250 million and up to low double digit royalties on sales of products containing such compounds should such products be successfully commercialized. If Lilly does not exercise these rights, Lilly would be eligible for low single digit royalties from Transition on sales of products containing such compounds should such products be successfully commercialized.

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.

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

December 31, 2012 (Unaudited, in Canadian dollars)

### 10. SHARE CAPITAL

#### Authorized

At December 31, 2012, 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

At December 31, 2012, there were 26,921,302 common shares issued and outstanding.

#### Stock Options

Stock options	#	\$	Weighed Average Exercise Price \$
Stock options outstanding, July 1, 2012	1,949,919	2,977,032	4.10
Stock options expired [ii]	(32,920)	(263,034)	15.31
Stock based compensation expense		617,524	-
Stock options outstanding, December 31, 2012	1,916,999	3,331,522	3.87

Stock options	#	\$	Weighed Average Exercise Price \$
Stock options outstanding, July 1, 2011	1,549,101	3,179,327	5.57
Stock options expired [ii]	(182,443)	(648,787)	5.94
Stock options forfeited or cancelled [iii]	(65,910)	(105,159)	6.02
Stock based compensation expense		782,996	-
Stock options outstanding, December 31, 2011	1,300,748	3,208,377	5.65

- [i] During the six month periods ended December 31, 2012 and 2011, no stock options were exercised.
- [ii] During the six month period ended December 31, 2012, 32,920 stock options expired unexercised. These stock options had a fair value of \$263,034 which has been reclassified to contributed surplus. During the six month period ended December 31, 2011, 182,443 stock options expired unexercised. These stock options had a fair value of \$648,787 which has been reclassified to contributed surplus.
- [iii] During the six month period ending December 31, 2012, no stock options were forfeited or cancelled. During the six month period ended December 31, 2011, 65,910 stock options were forfeited or cancelled. These options had a fair value of \$105,159 and at the date of forfeit, 17,547 were vested and 48,363 were unvested.
- [iv] The maximum possible cash proceeds to the Company from the exercise of the stock options outstanding at December 31, 2012 are \$7,418,672 [June 30, 2012 - \$7,991,811].

## 11. EXPENSES BY NATURE

	Six month period ended December 31, 2012 \$	Six month period ended December 31, 2011 \$	Three month period ended December 31, 2012 \$	Three month period ended December 31, 2011 \$
<b>Research and development</b>				
Clinical trials and manufacturing	2,459,322	2,400,175	1,241,573	1,122,355
Amortization	902,983	905,301	451,491	451,103
Salaries and benefits	615,996	790,455	325,841	404,171
Stock compensation expense	255,248	203,438	113,308	87,358
Facility lease costs and utilities	88,279	116,388	44,347	58,087
Insurance	46,894	44,820	23,447	22,410
General laboratory supplies and materials	37,521	14,493	12,224	3,792
Ontario investment tax credits	(210,440)	(160,724)	(70,974)	(88,654)
	4,195,803	4,314,346	2,141,257	2,060,622
<b>Selling, general and administrative expenses</b>				
Salaries and benefits	683,232	1,100,735	356,082	717,590
Professional fees and services	226,030	307,100	119,081	175,124
Insurance	129,012	135,958	64,506	67,979
Stock compensation expense	362,276	579,558	147,194	350,663
Facility lease costs and utilities	73,360	103,336	37,812	51,735
Business development, corporate communication and investor relations	95,935	263,564	87,073	112,368
Regulatory and stock transfer fees	22,407	26,281	1,358	7,703
Office and related expenses	66,066	95,049	32,148	45,925
Amortization	8,024	11,377	4,186	3,825
	1,666,342	2,622,958	849,440	1,532,912

## NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

December 31, 2012 (Unaudited, in Canadian dollars)

### 12. 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 1,916,999 [December 31, 2011 – 1,300,748] are not included in the calculation of diluted earnings per share as the effect is anti-dilutive due to the fact that the option exercise price exceeds the average market value of the Company's common shares at December 31, 2012. For the six month periods ended December 31, 2012 and 2011, 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.

	Six-month period ended December 31, 2012	Six-month period ended December 31, 2011	Three-month period ended December 31, 2012	Three-month period ended December 31, 2011
Income (loss) attributable to equity holders of the Company	\$4,981,512	(\$6,661,178)	(\$2,754,534)	(\$3,790,421)
Weighted average number of common shares outstanding	26,841,394	23,942,844	26,841,394	24,747,997

### 13. CONTINGENCIES AND COMMITMENTS

At December 31, 2012, the Company is committed to aggregate expenditures of \$7,000 under its collaboration agreements [June 30, 2012 – \$4,000]. In addition, at December 31, 2012, the Company is committed to aggregate expenditures of approximately \$1,369,000 [June 30, 2012 – \$2,654,000] for clinical and toxicity studies to be completed during fiscal 2013, approximately \$700,000 [June 30, 2012 – \$711,000] for manufacturing agreements and approximately \$11,000 [June 30, 2012 – \$8,000] for consulting and other agreements.

### 14. CHANGE IN WORKING CAPITAL

The change in working capital consists of the following:

	Six-month period ended December 31, 2012 \$	Six-month period ended December 31, 2011 \$	Three-month period ended December 31, 2012 \$	Three-month period ended December 31, 2011 \$
Due from Elan Pharma International Limited	-	-	10,815,200	-
Trade and other receivables	(4,750)	76,979	(3,448)	44,364
Investment tax credits receivable	(128,338)	(114,929)	(70,974)	(73,437)
Prepaid expenses and deposits	(141,751)	422,285	88,595	421,796
Trade and other payables	(282,770)	(270,343)	(152,837)	2,322
	(557,609)	113,992	10,676,536	395,045



## 15. 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:

	Six-month period ended December 31, 2012 \$	Six-month period ended December 31, 2011 \$	Three-month period ended December 31, 2012 \$	Three-month period ended December 31, 2011 \$
Salaries and other short-term employee benefits	724,682	779,077	383,378	400,628
Termination benefits	-	286,761	-	286,761
Stock-compensation expenses	527,103	726,076	221,698	416,001
	1,251,785	1,791,914	605,076	1,103,390

## 16. 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 six and three month periods ended December 31, 2012 are from one partner, Elan Pharma International Limited, a company based in Ireland.

## 17. COMPARATIVE CONSOLIDATED FINANCIAL STATEMENTS

The comparative financial statements have been reclassified from statements previously presented to conform to the presentation of the 2013 consolidated financial statements.

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