



## **Transition Therapeutics Announces Second Quarter Fiscal 2015 Financial Results**

**TORONTO, ON, February 9, 2015 – Transition Therapeutics Inc.** (“Transition” or the “Company”) (TSX: TTH; NASDAQ: TTHI), a biopharmaceutical development company advancing novel therapeutics for CNS and metabolic disease indications, today announced its financial results for the three and six month periods ended December 31, 2014. Investors are invited to participate in a conference call today at 4:30pm EST to discuss these results. Dial in information for the call is as follows: (800) 381-7839 (North America) and (212) 231-2900 (International). A replay of the conference call will be available on the Company’s website ([www.transitiontherapeutics.com](http://www.transitiontherapeutics.com)) for seven days following the call.

### **Selected Highlights**

Highlights for the Company during the six month period ended December 31, 2014 and up to the date of this press release include the following:

#### **ELND005:**

- ***January 2015 – Transition’s wholly owned subsidiary, Transition Therapeutics Ireland Limited (“TTIL”) revised the sample size of the Phase 2 study (Harmony AD Study) from 400 AD subjects to 320 AD subjects. After review of data from other recently released agitation and aggression studies, the TTIL clinical development team re-evaluated the sample size necessary for the Phase 2 study.*** The result of this analysis is that a sample size of 300-320 patients will provide sufficient statistical power to show treatment benefit of ELND005 over placebo. Accordingly, TTIL has informed the FDA of the revised sample size and enrolment is expected to be completed in February of 2015 with release of study results expected mid calendar 2015;
- ***November 24th, 2014 – Transition announced results from a thorough QT (tQT) study in which no QT effects were observed at supra-therapeutic single doses of neuropsychiatric drug candidate, ELND005.*** A tQT study is a specialized clinical trial required by the United States Food and Drug Administration (“FDA”) for the approval of most drugs in development. From a safety perspective, drugs that have no QT prolongation effects are particularly desirable for administration to an elderly Alzheimer’s disease (“AD”) population;
- ***November 20th, 2014 – Transition announced the results of a clinical study of neuropsychiatric drug candidate ELND005 in young adults with Down syndrome.*** TTIL completed this first study in Down syndrome subjects without dementia to allow optimal dose selection for future larger studies. The study enrolled 23 Down syndrome subjects in three study arms over a four-week treatment period. At the doses evaluated, ELND005 was determined to have an acceptable safety and tolerability profile and there were no serious adverse events reported;

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

ELND005 is an oral small molecule compound being investigated as a treatment for agitation and aggression in AD and as a therapy for Down syndrome.

#### **TT401 (LY2944876):**

- **Transition has paid all three installment payments totaling US\$14 million to diabetes drug candidate development partner Lilly.** Transition has no further financial obligations for the development and commercialization of TT401. In December, 2014, Lilly informed Transition that 70% of the planned 375 study subjects had been enrolled in the Phase 2 study of type 2 diabetic individuals.

TT401 (LY2944876) is an oxyntomodulin analogue that has dual agonist activity of the GLP-1 (Glucagon-Like Peptide-1) and glucagon receptors. A Phase 2 clinical trial of TT401 in type 2 diabetes subjects is being performed by Transition's development partner, Lilly. Results from this study are expected in calendar Q4 2015.

Transition is eligible to receive up to approximately US\$240 million in additional milestone payments plus double-digit royalties on sales of TT401 products and a low single digit royalty on sales of related compounds. Transition has no further funding obligations related to this clinical study.

#### **Corporate Developments:**

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

#### **Financial Liquidity**

At December 31, 2014, the Company had cash resources of \$26,756,324.

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 for the next 12 months.

#### **Financial Review**

For the three month period ended December 31, 2014, the Company recorded a net loss of \$16,910,139 (\$0.48 loss per common share) compared to a net loss of \$1,253,772 (\$0.04 loss per common share) for the three month period ended December 31, 2013.

For the six month period ended December 31, 2014, the Company recorded a net loss of \$32,605,463 (\$0.93 loss per common share) compared to a net loss of \$3,584,958 (\$0.12 loss per common share) for the six month period ended December 31, 2013.

## **Research and Development**

Research and development expenses increased by \$14,744,122 from \$1,160,767 for the three month period ended December 31, 2013 to \$15,904,889 for the three month period ended December 31, 2014. For the six month period ended December 31, 2014, research and development expenses increased \$29,771,167 to \$31,939,780 from \$2,168,613 for the same period in fiscal 2014.

The increases in research and development expenses for both the three and six month periods ended December 31, 2014 are primarily due to increases in clinical development costs related to ELND005. The increases are also attributed to increases in development costs associated with diabetes drug candidate TT401 as the Company has paid Lilly an aggregate of US\$14 million upon the achievement of all three patient enrollment milestones.

## **General and Administrative**

General and administrative expenses increased by \$229,730 from \$973,719 for the three month period ended December 31, 2013 to \$1,203,449 for the three month period ended December 31, 2014. For the six month period ended December 31, 2014, general and administrative expenses increased \$588,202 to \$2,509,281 from \$1,921,079 for the same period in fiscal 2014.

The increases in general and administrative expenses for both the three and six month periods ended December 31, 2014 are primarily due to increases in professional fees, compensation costs as well as overhead costs relating to the Company's premises in San Mateo, California.

## **About Transition**

Transition is a biopharmaceutical development company, advancing novel therapeutics for CNS and metabolic disease indications. The Company's wholly-owned subsidiary, Transition Therapeutics Ireland Limited is developing CNS drug candidate ELND005 for the treatment of Alzheimer's disease and Down syndrome. Transition's lead metabolic drug candidate is TT401 for the treatment of type 2 diabetes and accompanying obesity. The Company's shares are listed on the NASDAQ under the symbol "TTHI" and the Toronto Stock Exchange under the symbol "TTH".

For additional information about the Company, please visit [www.transitiontherapeutics.com](http://www.transitiontherapeutics.com).

Extracts of the Financial Statements to Follow:

**CONSOLIDATED BALANCE SHEETS**  
**(Unaudited)**

<i>In Canadian Dollars</i>	As at December 31, 2014	As at June 30, 2014
<b>Assets</b>		
<b>Current assets</b>		
Cash	26,756,324	57,212,004
Short term investments	-	3,059,562
Other receivables	1,387,856	220,514
Income tax and investment tax credits receivable	485,329	212,393
Prepaid expenses and deposits	241,058	36,656
	<b>28,870,567</b>	<b>60,741,129</b>
<b>Non-current assets</b>		
Property and equipment	242,674	158,926
Intangible assets	7,704,613	8,007,181
<b>Total assets</b>	<b>36,817,854</b>	<b>68,907,236</b>
<b>Liabilities</b>		
<b>Current liabilities</b>		
Trade and other payables	4,202,389	5,963,258
	<b>4,202,389</b>	<b>5,963,258</b>
<b>Non-current liabilities</b>		
Contingent consideration payable	4,569,179	3,838,286
Leasehold inducement	5,716	11,432
<b>Total liabilities</b>	<b>8,777,284</b>	<b>9,812,976</b>
<b>Equity attributable to owners of the Company</b>		
Share capital	207,419,257	207,374,493
Warrants	5,176,397	5,176,397
Contributed surplus	14,768,221	14,768,221
Share-based payment reserve	4,412,977	2,866,292
Accumulated other comprehensive income	(15,648)	24,028
Deficit	(203,720,634)	(171,115,171)
<b>Total equity</b>	<b>28,040,570</b>	<b>59,094,260</b>
<b>Total liabilities and equity</b>	<b>36,817,854</b>	<b>68,907,236</b>

**CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS**  
**For the six and three month periods ended December 31, 2014 and 2013**  
**(Unaudited)**

<i>In Canadian Dollars, except per share dat</i>	<b>Six month period ended December 31, 2014</b>	Six month period ended December 31, 2013	<b>Three month period ended December 31, 2014</b>	Three month period ended December 31, 2013
<b>Expenses</b>				
Research and development	<b>31,939,780</b>	2,168,613	<b>15,904,889</b>	1,160,767
Selling, general and administrative expenses	<b>2,509,281</b>	1,921,079	<b>1,203,449</b>	973,719
<b>Operating Loss</b>	<b>(34,449,061)</b>	(4,089,692)	<b>(17,108,338)</b>	(2,134,486)
Change in fair value of contingent consideration payable	<b>(470,959)</b>	-	<b>(245,658)</b>	-
Interest income	<b>112,247</b>	102,868	<b>46,554</b>	56,731
Foreign exchange gain	<b>2,202,310</b>	401,866	<b>397,303</b>	823,983
<b>Net loss for the period</b>	<b>(32,605,463)</b>	(3,584,958)	<b>(16,910,139)</b>	(1,253,772)
<b>Other Comprehensive loss for the period</b>				
<b>Items that may be subsequently reclassified to net income:</b>				
Cumulative translation adjustment	<b>(39,676)</b>	-	<b>(57,099)</b>	-
<b>Comprehensive loss for the period</b>	<b>(32,645,139)</b>	(3,584,958)	<b>(16,967,238)</b>	(1,253,772)
<b>Basic and diluted net loss per common share</b>	<b>(0.93)</b>	(0.12)	<b>(0.48)</b>	(0.04)

*Notice to Readers: Information contained in our press releases should be considered accurate only as of the date of this release and may be superseded by more recent information we have disclosed in later press releases, filings with the OSC, SEC or otherwise. Except for historical information, this press release may contain forward-looking statements, relating to expectations, plans or prospects for Transition, including conducting clinical trials. These statements are based upon the current expectations and beliefs of Transition's management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include factors beyond Transition's control and the risk factors and other cautionary statements discussed in Transition's quarterly and annual filings with the Canadian commissions and the U.S. Securities and Exchange Commission.*

For further information on Transition, visit [www.transitiontherapeutics.com](http://www.transitiontherapeutics.com), or contact:

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