



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

**TORONTO, ON, September 15, 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 year ended June 30, 2015. 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) 750-5849 (North America) and (416) 981-9035 (International). A live webcast can be accessed via Transition’s website [www.transitiontherapeutics.com](http://www.transitiontherapeutics.com), with a replay available for seven days following the call.

### **Selected Highlights**

Highlights for the Company during the year ended June 30, 2015 and up to the date of this press release include the following:

#### **ELND005:**

- ***June 24, 2015 – Transition announced results of Clinical Study of ELND005 in Agitation and Aggression in Patients with Alzheimer’s Disease.*** The Phase 2/3 clinical study of neuropsychiatric drug candidate ELND005 did not meet its primary efficacy endpoint. In the study, both the treatment and placebo groups showed a significant, but similar, reduction in agitation and aggression relative to baseline. There was a greater than expected reduction in agitation and aggression observed in the placebo group as measured in weeks 4, 8 and 12 in the study. The safety and tolerability profile of ELND005 was consistent with previous studies in AD at the 250mg bid dose;
- ***March 26, 2015 – Transition announced results from two phase 1 clinical studies of neuropsychiatric drug candidate ELND005.*** These studies, an absorption-metabolism-excretion (“AME”) study and a renal clearance study, are specialized clinical pharmacology trials that are required by the United States Food and Drug Administration (“FDA”) for the approval of most drugs in development;
- ***November 24, 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 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 AD population;



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- *November 20, 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.

### **TT401:**

- *In February, 2015, development partner Lilly informed Transition that 420 type 2 diabetic subjects have been enrolled in the current Phase 2 study thereby completing the enrollment phase of the study;*
- *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.

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.

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.

### **Corporate Developments:**

- *June 16, 2015 - Transition announced that Carl Damiani has been appointed as President and Chief Operating Officer of Transition;*



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- ***May 6, 2015 – Transition announced its wholly-owned subsidiary, TTIL has exclusively licensed worldwide rights to a novel small molecule drug candidate (“TT701”) from Eli Lilly and Company.*** Under the terms of the agreement, TTIL has acquired rights to develop and commercialize TT701. Lilly will receive upfront consideration of up to US\$1 million. In addition, Lilly is eligible to receive up to US\$100 million in commercial milestones and a mid-single digit royalty on sales of TT701 products should such products be successfully commercialized. TT701 is a selective androgen receptor modulator that has been shown in a Phase 2 study to significantly increase lean body mass and a measurement of muscle strength in male subjects. This completed 12-week, Phase 2 study of 350 subjects also demonstrated additional beneficial effects, including significant fat mass reduction with no significant change in prostate specific antigen (PSA) levels. TTIL is evaluating multiple development paths for TT701, including as a new therapeutic option for patients with androgen deficiency. TTIL is engaged with potential collaborators to rapidly commence a Phase 2 clinical study;
- ***February 18, 2015 – Transition announced the closing of a public offering of US\$23 million of common shares equivalent to an aggregate of 3,538,461 common shares at a price to the public of US\$6.50 per share, including 461,538 common shares issued upon the exercise of the underwriters’ over-allotment option.*** Cowen and Company, LLC was the sole book-running manager and Canaccord Genuity Inc., H.C. Wainwright & Co., LLC, and LifeSci Capital LLC were the co-managers for the offering.

### **Financial Liquidity**

At June 30, 2015, the Company had cash resources of \$40,510,758 and a working capital of \$32,026,606.

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

### **Financial Review**

During the year ended June 30, 2015, the Company recorded a net loss of \$51,339,528 (\$1.41 loss per common share) compared to a net loss of \$21,782,255 (\$0.72 loss per common share) for the year ended June 30, 2014.



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### **Research and Development**

Research and development expenses increased \$31,842,318 or 183% from \$17,367,385 for the fiscal year ended June 30, 2014 to \$49,209,703 for the fiscal year ended June 30, 2015.

The increases in research and development expenses are primarily due to increases in development costs related to ELND005. The increases are also attributed to increases in development costs associated with diabetes drug candidate TT401 as during fiscal 2015 the Company paid Lilly an aggregate of US\$14 million upon the achievement of all three patient enrollment milestones. The increase in research and development costs have been partially offset by decreases in clinical development costs associated with the costs related to the TT601 program.

### **General and Administrative**

General and administrative expenses increased by \$787,698 or 17% from \$4,726,574 for the fiscal year ended June 30, 2014 to \$5,514,272 for the fiscal year ended June 30, 2015.

The increases in general and administrative expenses are primarily due to increases in compensation and 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:*



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### CONSOLIDATED BALANCE SHEETS

<i>In Canadian Dollars</i>	<b>June 30, 2015</b>	June 30, 2014
<b>Assets</b>		
<b>Current assets</b>		
Cash	<b>40,510,758</b>	57,212,004
Short term investments	-	3,059,562
Other receivables	<b>265,189</b>	220,514
Income tax and investment tax credits receivable	<b>399,668</b>	212,393
Prepaid expenses and deposits	<b>259,143</b>	36,656
	<b>41,434,758</b>	60,741,129
<b>Non-current assets</b>		
Property and equipment	<b>191,944</b>	158,926
Intangible assets	<b>8,022,383</b>	8,007,181
<b>Total assets</b>	<b>49,649,085</b>	68,907,236
<b>Liabilities</b>		
<b>Current liabilities</b>		
Trade and other payables	<b>8,549,895</b>	5,963,258
Contingent consideration payable	<b>858,257</b>	-
	<b>9,408,152</b>	5,963,258
<b>Non-current liabilities</b>		
Contingent consideration payable	<b>3,503,344</b>	3,838,286
Leasehold inducement	-	11,432
<b>Total liabilities</b>	<b>12,911,496</b>	9,812,976
<b>Equity attributable to owners of the Company</b>		
Share capital	<b>233,633,493</b>	207,374,493
Warrants	<b>5,176,397</b>	5,176,397
Contributed surplus	<b>14,771,907</b>	14,768,221
Share-based payment reserve	<b>5,892,305</b>	2,866,292
Accumulated other comprehensive income	<b>(281,814)</b>	24,028
Deficit	<b>(222,454,699)</b>	(171,115,171)
<b>Total equity</b>	<b>36,737,589</b>	59,094,260
<b>Total liabilities and equity</b>	<b>49,649,085</b>	68,907,236



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### CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS

For the years ended June 30, 2015 and 2014

<i>In Canadian Dollars</i>	<b>2015</b>	2014
<b>Expenses</b>		
Research and development	<b>49,209,703</b>	17,367,385
Selling, general and administrative expenses	<b>5,514,272</b>	4,726,574
Change in fair value of contingent consideration payable	<b>65,787</b>	(2,911,218)
Settlement of pre-existing relationship	-	3,096,186
<b>Operating loss</b>	<b>(54,789,762)</b>	(22,278,927)
Interest income	<b>196,073</b>	220,119
Foreign exchange gain	<b>3,331,026</b>	284,523
Loss on disposal of property and equipment	<b>(76,865)</b>	(7,970)
<b>Net loss for the year</b>	<b>(51,339,528)</b>	(21,782,255)
<b>Other comprehensive income (loss) for the year</b>		
<b>Items that may be subsequently reclassified to net income:</b>		
Cumulative translation adjustment	<b>(305,842)</b>	24,028
<b>Comprehensive loss for the year</b>	<b>(51,645,370)</b>	(21,758,227)
<b>Basic and diluted net loss per common share</b>	<b>(1.41)</b>	(0.72)



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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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