



Transition Therapeutics Announces Third Quarter Fiscal 2015 Financial Results

TORONTO, ON, May 12, 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 nine month periods ended March 31, 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) 931-5132 (North America) and (212) 271-4651 (International). A live webcast can be accessed via Transition’s website www.transitiontherapeutics.com, with a replay available for seven days following the call.

Selected Highlights

Highlights for the Company during the nine month period ended March 31, 2015 and up to the date of this press release include the following:

ENLD005

- ***March 26, 2015 – Transition announced results from two phase I 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;***
- ***March 2, 2015 – Transition announced that its wholly owned subsidiary, TTIL completed enrolment of 350 patients in the Phase 2 clinical study evaluating neuropsychiatric drug candidate ELND005 as a treatment for agitation and aggression in patients with Alzheimer’s disease (“AD”).*** The objectives of the Phase 2 clinical study (“Harmony AD Study”) are to evaluate the efficacy, safety and tolerability of ELND005 over 12 weeks of treatment in patients with mild to severe AD, who are experiencing at least moderate levels of agitation/aggression. The randomized, double-blind, placebo-controlled study has enrolled 350 AD patients at 69 clinical sites in the United States, Canada, Spain and the United Kingdom. The primary efficacy endpoint of the study is the change from baseline in the Neuropsychiatric Inventory – Clinician (“NPI-C”) scale of agitation and aggression. It is anticipated that the top-line data from the Harmony AD Study will be announced early summer 2015;
- ***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 Alzheimer’s disease (“AD”) population;



Transition Therapeutics Announces Third Quarter Fiscal 2015 Financial Results

- **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. In December, 2014, Lilly informed Transition that the 70% enrollment milestone had been achieved.

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:

- **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.



Transition Therapeutics Announces Third Quarter Fiscal 2015 Financial Results

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

Financial Liquidity

At March 31, 2015, the Company had cash resources of \$50,248,469.

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 for the next 12 months.

Financial Review

For the three month period ended March 31, 2015, the Company recorded a net loss of \$4,748,096 (\$0.13 loss per common share) compared to a net loss of \$5,067,292 (\$0.17 loss per common share) for the three month period ended March 31, 2014.

For the nine month period ended March 31, 2015, the Company recorded a net loss of \$37,353,559 (\$1.04 loss per common share) compared to a net loss of \$8,652,250 (\$0.29 loss per common share) for the nine month period ended March 31, 2014.



Transition Therapeutics Announces Third Quarter Fiscal 2015 Financial Results

Research and Development

Research and development expenses increased by \$153,984 from \$4,734,288 for the three month period ended March 31, 2014 to \$4,888,272 for the three month period ended March 31, 2015. For the nine month period ended March 31, 2015, research and development expenses increased \$29,925,151 to \$36,828,052 from \$6,902,901 for the same period in fiscal 2014.

The increases in research and development expenses for both the three and nine month periods ended March 31, 2015 are primarily due to increases in development costs related to ELND005. The increase for the nine month period is 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. 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 \$136,652 from \$1,131,879 for the three month period ended March 31, 2014 to \$1,268,531 for the three month period ended March 31, 2015. For the nine month period ended March 31, 2015, general and administrative expenses increased \$724,854 to \$3,777,812 from \$3,052,958 for the same period in fiscal 2014.

The increases in general and administrative expenses for both the three and nine month periods ended March 31, 2015 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.

Extracts of the Financial Statements to Follow:



Transition Therapeutics Announces Third Quarter Fiscal 2015 Financial Results

CONSOLIDATED BALANCE SHEETS

(Unaudited)

<i>In Canadian Dollars</i>	As at March 31, 2015	As at June 30, 2014
Assets		
Current assets		
Cash	50,248,469	57,212,004
Short term investments	-	3,059,562
Other receivables	1,303,013	220,514
Income tax and investment tax credits receivable	399,668	212,393
Prepaid expenses and deposits	162,651	36,656
	52,113,801	60,741,129
Non-current assets		
Property and equipment	199,774	158,926
Intangible assets	7,553,329	8,007,181
Total assets	59,866,904	68,907,236
Liabilities		
Current liabilities		
Trade and other payables	4,740,024	5,963,258
	4,740,024	5,963,258
Non-current liabilities		
Contingent consideration payable	5,165,122	3,838,286
Leasehold inducement	2,858	11,432
Total liabilities	9,908,004	9,812,976
Equity attributable to owners of the Company		
Share capital	233,518,538	207,374,493
Warrants	5,176,397	5,176,397
Contributed surplus	14,771,907	14,768,221
Share-based payment reserve	4,901,164	2,866,292
Accumulated other comprehensive income	59,624	24,028
Deficit	(208,468,730)	(171,115,171)
Total equity	49,958,900	59,094,260
Total liabilities and equity	59,866,904	68,907,236



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CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS

For the nine and three month periods ended March 31, 2015 and 2014

(Unaudited)

<i>In Canadian Dollars, except per share data</i>	Nine month period ended March 31, 2015	Nine month period ended March 31, 2014	Three month period ended March 31, 2015	Three month period ended March 31, 2014
Expenses				
Research and development	36,828,052	6,902,901	4,888,272	4,734,288
Selling, general and administrative expenses	3,777,812	3,052,958	1,268,531	1,131,879
Settlement of a pre-existing relationship	-	3,101,507	-	3,101,507
Change in fair value of contingent consideration payable	747,698	(2,781,907)	276,739	(2,781,907)
Operating Loss	(41,353,562)	(10,275,459)	(6,433,542)	(6,185,767)
Interest income	146,551	163,869	34,304	61,001
Foreign exchange gain	3,930,317	1,467,310	1,728,007	1,065,444
Loss on disposal of property and equipment	(76,865)	(7,970)	(76,865)	(7,970)
Net loss for the period	(37,353,559)	(8,652,250)	(4,748,096)	(5,067,292)
Other Comprehensive loss for the period				
Items that may be subsequently reclassified to net income:				
Cumulative translation adjustment	35,596	-	75,272	-
Leasehold inducement	(37,317,963)	(8,652,250)	(4,672,824)	(5,067,292)
Total liabilities	(1.04)	(0.29)	(0.13)	(0.17)



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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 or contact:

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