



## **Transition Therapeutics Announces Third Quarter Fiscal 2016 Financial Results**

**TORONTO, ON, May 11, 2016 – Transition Therapeutics Inc.** (“Transition” or the “Company”) (TSX: TTH; NASDAQ: TTHI), a biopharmaceutical development company advancing novel therapeutics for CNS, metabolic disease and androgen deficiency indications, today announced its financial results for the three and nine month periods ended March 31, 2016. 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) 698-9012 (North America) and (303) 223-4374 (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 nine month period ended March 31, 2016 and up to the date of this press release include the following:

#### **ELND005:**

ELND005 is an oral small molecule drug candidate with a proposed dual mechanism of action which includes  $\beta$ -amyloid anti-aggregation and regulation of brain myo-inositol levels. Transition’s subsidiary Transition Therapeutics Ireland (“TTIL”) owns all ELND005 development and commercialization rights.

- ***October 28, 2015 - Transition announced that data from the Phase 2/3 clinical study of ELND005 in Alzheimer’s disease patients with moderate and severe agitation and aggression was presented at the Clinical Trials in Alzheimer’s Disease (CTAD) meeting.*** A copy of the CTAD oral presentation is available on the Company website at [www.transitiontherapeutics.com](http://www.transitiontherapeutics.com);
- ***October 15, 2015 - Transition announced that its subsidiary, TTIL, has completed a thorough review of the data related to the Phase 2/3 study of ELND005 in AD patients with moderate or severe agitation and aggression.*** The analysis identified a significant clinical benefit of ELND005 in AD patients with severe agitation and aggression, and will serve as the basis for patient selection in a Phase 3 clinical study. The review was performed in consultation with a group of key opinion leaders in the field of neuropsychiatry.

#### **TT401:**

TT401 is an oxyntomodulin analogue that has dual agonist activity of the GLP-1 (Glucagon-Like Peptide-1) and glucagon receptors.



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- **April 18, 2016 – Transition announced that Lilly will not elect to advance diabetes drug candidate, TT401 into Phase 3 development.** Under the companies' collaboration agreement, all TT401 development and commercialization rights will be transferred to Transition. Transition is unencumbered to advance TT401 on its own or with a third party;
- **February 1, 2016 – Transition announced the results of a Phase 2 clinical study of drug candidate TT401 (LY2944876) for the treatment of type 2 diabetes.** TT401 development collaborator Eli Lilly and Company performed the Phase 2 study enrolling 420 type 2 diabetes subjects into a 24 week study consisting of a 12-week randomized blinded stage followed by a 12-week open-label stage. The study included 4 once-weekly dose arms of TT401 (10mg, 15mg, 30mg, 50mg), a placebo arm, and an active comparator arm (exenatide extended release – 2mg). TT401 demonstrated HbA1c improvements of up to -1.43% (similar to the exenatide arm). All TT401 dose arms and the exenatide arm were statistically significant relative to the placebo arm at Weeks 12 and 24. TT401 also produced dose dependent weight loss (up to -3.3 kg). The weight loss observed in the highest dose arm (50mg of TT401) was statistically significant relative to both the placebo and exenatide arms at weeks 12 and 24.

### TT701 SARM:

TT701 is an oral drug candidate that is a selective androgen receptor modulator (SARM). TTIL owns all TT701 development and commercialization rights. TT701 is in Phase 2 clinical development as a therapy to ameliorate the symptoms associated with androgen deficiency.

- **April 25, 2016 – Transition announced the dosing of the first patient of a Phase 2 study of selective androgen receptor modulator (SARM) drug candidate TT701.** Brigham and Women's Hospital (BWH) is conducting the investigator-led Phase 2 clinical study which is expected to enroll up to 125 subjects at selected specialized clinical sites including BWH. The principal investigator for the Phase 2 study is Dr. Shalender Bhasin, Director of the Research Program in Men's Health: Aging and Metabolism at BWH and an internationally recognized endocrinologist with expertise in testosterone biology and men's aging;
- **October 29, 2015 – Transition announced that its subsidiary, TTIL, has entered into an agreement with BWH for an investigator-led clinical study of drug candidate TT701.** TTIL will support a Phase 2 study to evaluate SARM drug candidate TT701 as a therapy to improve the symptoms of androgen deficiency in men with prostate cancer that have undergone a radical prostatectomy procedure.



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### **Financial Liquidity**

At March 31, 2016, the Company had cash resources of \$24,768,772 and a working capital of \$23,095,324.

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 three month period ended March 31, 2016, the Company recorded a net loss of \$4,177,942 (\$0.11 loss per common share) compared to a net loss of \$4,748,096 (\$0.13 loss per common share) for the three month period ended March 31, 2015.

For the nine month period ended March 31, 2016, the Company recorded a net loss of \$10,675,178 (\$0.28 loss per common share) compared to a net loss of \$37,353,559 (\$1.04 loss per common share) for the nine month period ended March 31, 2015.

### **Research and Development**

Research and development expenses decreased by \$3,309,363 from \$4,888,272 for the three month period ended March 31, 2015 to \$1,578,909 for the three month period ended March 31, 2016. For the nine month period ended March 31, 2016, research and development expenses decreased \$28,860,717 to \$7,967,335 from \$36,828,052 for the same period in fiscal 2015.

The decreases in research and development expenses for both the three and nine month periods ended March 31, 2016 are primarily due to a decrease in clinical development costs related to ELND005 and reduced salary and related expenses which resulted from cost cutting efforts. The decrease in research and development expenses for the nine month period ended March 31, 2016 is also due to a decrease in funding obligations relating to TT401 as the Company paid US\$14 million in milestone payments to Lilly during the comparative nine month period.

### **General and Administrative**

General and administrative expenses decreased by \$69,073 from \$1,268,531 for the three month period ended March 31, 2015 to \$1,199,458 for the three month period ended March 31, 2016. For the nine month period ended March 31, 2016, general and administrative expenses increased \$40,848 to \$3,818,660 from \$3,777,812 for the same period in fiscal 2015.



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The decrease in general and administrative expenses for the three month period ended March 31, 2016 are primarily due to reduced professional fees which have been partially offset by inflationary increases in compensation costs.

The increase in general and administrative expenses for the nine month period ended March 31, 2016 are primarily due to business taxes paid for the Company's US subsidiary and inflationary increases in compensation costs which have been partially offset by reduced professional fees.

### **About Transition**

Transition is a biopharmaceutical development company, advancing novel therapeutics for CNS, metabolic disease and androgen deficiency 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 as well as drug candidate TT701, a selective androgen receptor molecule. 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 (Unaudited)

<i>In Canadian Dollars</i>	As At March 31, 2016	As at June 30, 2015
<b>Assets</b>		
<b>Current assets</b>		
Cash	24,768,772	40,510,758
Other receivables	53,348	265,189
Income tax and investment tax credits receivable	424,355	399,668
Prepaid expenses and deposits	157,126	259,143
	<b>25,403,601</b>	41,434,758
<b>Non-current assets</b>		
Property and equipment	133,351	191,944
Intangible assets	7,554,259	8,022,383
<b>Total assets</b>	<b>33,091,211</b>	49,649,085
<b>Liabilities</b>		
<b>Current liabilities</b>		
Trade and other payables	1,406,388	8,549,895
Contingent consideration payable	901,889	858,257
	<b>2,308,277</b>	9,408,152
<b>Non-current liabilities</b>		
Contingent consideration payable	3,804,036	3,503,344
<b>Total liabilities</b>	<b>6,112,313</b>	12,911,496
<b>Equity attributable to owners of the Company</b>		
Share capital	233,623,544	233,633,493
Warrants	3,150,558	5,176,397
Contributed surplus	17,458,649	14,771,907
Share-based payment reserve	6,519,525	5,892,305
Accumulated other comprehensive income	(643,501)	(281,814)
Deficit	(233,129,877)	(222,454,699)
<b>Total equity</b>	<b>26,978,898</b>	36,737,589
<b>Total liabilities and equity</b>	<b>33,091,211</b>	49,649,085



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### CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS

For the nine and three months periods ended March 31, 2016 and 2015

(Unaudited)

<i>In Canadian Dollars, except per share data</i>	<b>Nine month period ended March 31, 2016</b>	Nine month period ended March 31, 2015	<b>Three month period ended March 31, 2016</b>	Three month period ended March 31, 2015
<b>Expenses</b>				
Research and development	<b>7,967,335</b>	36,828,052	<b>1,578,909</b>	4,888,272
Selling, general and administrative expenses	<b>3,818,660</b>	3,777,812	<b>1,199,458</b>	1,268,531
<b>Operating Loss</b>	<b>(11,785,995)</b>	(40,605,864)	<b>(2,778,367)</b>	(6,156,803)
Change in fair value of contingent consideration payable	<b>(232,427)</b>	(747,698)	<b>(2,005)</b>	(276,739)
Interest income	<b>97,923</b>	146,551	<b>34,204</b>	34,304
Foreign exchange gain (loss)	<b>1,247,393</b>	3,930,317	<b>(1,429,702)</b>	1,728,007
Loss on disposal of property and equipment	<b>(2,072)</b>	(76,865)	<b>(2,072)</b>	(76,865)
<b>Net loss for the period</b>	<b>(10,675,178)</b>	(37,353,559)	<b>(4,177,942)</b>	(4,748,096)
<b>Other Comprehensive loss for the period</b>				
<b>Items that may be subsequently reclassified to net income:</b>				
Cumulative translation adjustment	<b>(361,687)</b>	35,596	<b>19,247</b>	75,272
<b>Comprehensive loss for the period</b>	<b>(11,036,865)</b>	(37,317,963)	<b>(4,158,695)</b>	(4,672,824)
<b>Basic and diluted net loss per common share</b>	<b>(0.28)</b>	(1.04)	<b>(0.11)</b>	(0.13)



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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:

Dr. Tony Cruz  
Chairman & Chief Executive Officer  
Transition Therapeutics Inc.  
Phone: (416) 260-7770, x.223  
[tcruz@transitiontherapeutics.com](mailto:tcruz@transitiontherapeutics.com)

Nicole Rusaw  
Chief Financial Officer  
Transition Therapeutics Inc.  
Phone: (416) 260-7770, x.202  
[nrusaw@transitiontherapeutics.com](mailto:nrusaw@transitiontherapeutics.com)