

TORONTO, Sept. 11, 2013 /PRNewswire/ - **Transition Therapeutics Inc.** ("Transition" or the "Company") (TSX: TTH; NASDAQ:

[TTHI](#)

), a product-focused biopharmaceutical company developing therapeutics for disease indications with large markets, today announced its financial results for the year ended June 30, 2013

Selected Highlights

During fiscal 2013 and up to the date of this press release, the Company announced the following:

ELND005:

- **September 4, 2013 - Transition announced that their licensing partner Elan had dosed the first patient in a Phase 2a clinical study of ELND005 in Down Syndrome;**
- **July 17, 2013 - Transition announced that the US Food and Drug Administration (FDA) has granted Fast Track Designation to the development program for ELND005 which was submitted for the treatment of Neuropsychiatric Symptoms (NPS) in Alzheimer's disease (AD).** The FDA concluded that the development program for ELND005 for the treatment of NPS in AD meets their criteria for Fast Track Designation. Transition's licensing partner, Elan is responsible for all development and commercialization activities and costs of ELND005;
- **November 28, 2012 - Transition announced that their licensing partner Elan had**

enrolled the first patient in a Phase 2 study of ELND005 for the treatment of agitation/aggression in patients with moderate to severe Alzheimer's disease

;

- ***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.

TT-401:

- ***June 17, 2013 - Transition announced that Lilly has exercised its option to assume all development and commercialization rights to type 2 diabetes drug candidate TT-401. In conjunction with this assumption of rights, Transition received a US\$7 million milestone payment***

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- ***April 30, 2013 - Transition announced the results of a five-week proof of concept clinical study of TT-401 in type 2 diabetic and obese non-diabetic subjects.***

In the study, TT-401, a once-weekly administered peptide, demonstrated significant improvements in glycemic control and reductions in body weight.

TT-601:

- ***July 23, 2013 - Transition announced the exclusive licensing of worldwide rights to a novel small molecule transcriptional regulator ("TT-601") from Lilly for the treatment of osteoarthritis ("OA") pain.***

TT-601 is a potent and selective ligand for a novel nuclear receptor target. Modulating the activity of this novel target in patients with osteoarthritis may provide pain relief to a large segment of OA patients who do not have adequate response to therapy with NSAIDs (non-steroidal anti-inflammatory drugs). TT-601 has completed preclinical development to date and Transition anticipates can enter the clinic in the first half of calendar 2014.

Corporate Developments:

- August 15, 2013 - Transition announced the closing of the private placement involving Jack W. Schuler, Larry N. Feinberg, Oracle Investment Management, certain Transition Board members, management and other existing shareholders of 1 million US\$1 by purchasing 2,625,300 units of the Company at a price of US\$4.19 per common share

Financial Liquidity

The Company's cash and cash equivalents and short term investments were \$28,125,639 at June 30, 2013

Subsequent to June 30, 2013, the Company announced the issuance of 2,625,300 units in a private placement to existing shareholders, board members and management which resulted in gross proceeds of \$US11 million. Each unit consisted of (i) one common share, (ii) 0.325 Common Share purchase warrant with a purchase price of US\$4.60 per whole warrant and (iii) 0.4 Common Share purchase warrant with a purchase price of US\$6.50 per whole warrant. Each whole warrant will entitle the holder, within two years, to purchase one additional common share in the capital of the Company. If and when all of the warrants are exercised, the Company will realize an additional US\$10.7 million in proceeds.

In light of the recent private placement, 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.

Transition Therapeutics Announces Fiscal 2013 Year End Financial Results

Written by Australian Business

Financial Review

During the year ended June 30, 2013, the Company recorded a net income of \$23,297 (\$0.00 income per common share) compared to a net loss of \$12,269,845 (\$0.48 loss per common share) for the year ended June 30, 2012.

In fiscal 2013, the Company recognized \$17,933,500 as revenue which represents the milestone payment of \$10,815,200 (US\$1,000,000) received from Elan upon their commencement of the next ELND005 clinical trial and the milestone payment of \$7,118,300 (US\$7,000,000) received from Lilly upon exercising its option to assume all development and commercialization rights to type 2 diabetes drug candidate TT-401.

Revenue is \$17,933,500 in the year ended June 30, 2013 compared to nil in the year ended June 30, 2012.

Research and development expenses increased \$664,147 or 8% from \$8,198,725 for the fiscal year ended June 30, 2012 to \$8,862,872 for the fiscal year ended June 30, 2013.

The increase in research and development expenses is primarily due to an increase in clinical development costs related to TT-401/TT-402 which has been partially offset by a decrease in clinical development costs related to TT-301/302.

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General and administrative expenses decreased by \$849,488 or 19% from \$4,407,280 for the fiscal year ended

June 30, 2012

to

\$3,557,792

for the fiscal year ended

June 30, 2013

. The decreases in general and administrative expenses during the fiscal year ended

June 30, 2013

are due to decreases in legal consulting fees 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 decrease in general and administrative expenses has been partially offset by increased investor relation expenses.

Impairment of intangible assets is \$6,545,821 for the year ended June 30, 2013 compared to nil for the year ended

June 30, 2012

. During the year ended

June 30, 2013

, the Company decided to no longer develop TT-301 and TT-302, the compounds acquired from NMX. Accordingly, the Company has recognized an impairment loss of \$6,545,821

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About Transition

Transition is a biopharmaceutical company, developing novel therapeutics for disease indications with large markets. The Company's lead CNS drug candidate is ELND005 for the treatment of Alzheimer's disease and bipolar disorder. Transition's lead metabolic drug candidate is TT-401 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:

CONSOLIDATED BALANCE SHEETS

Transition Therapeutics Announces Fiscal 2013 Year End Financial Results

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As at

<i>In Canadian Dollars</i>	June 30, 2013	June 30, 2012
Assets		
Current assets		
Cash and cash equivalents	23,067,937	12,955,081
Short term investments	5,057,702	6,057,264
Other receivables	35,792	43,658
Investment tax credits receivable	180,652	241,951
Prepaid expenses and deposits	359,164	316,286
	28,701,247	19,614,240
Non-current assets		
Property and equipment	168,034	215,000
Intangible assets	8,938,674	17,263,790
Total assets	37,807,955	37,093,030
Liabilities		
Current liabilities		
Trade and other payables	874,149	1,178,915
Current portion of contingent consideration payable	2,321,373	2,321,373
	3,195,522	3,500,288
Non-current liabilities		
Contingent consideration payable	1,434,958	1,434,958
Leasehold inducement	22,863	34,295
	4,653,343	4,969,541
Equity attributable to owners of the Company		
Share capital	165,367,524	165,334,259
Contributed surplus	14,768,002	13,168,411
Share-based payment reserve	2,352,002	2,977,032
Deficit	(149,332,916)	(149,356,213)
	33,154,612	32,123,489
Total liabilities and equity	37,807,955	37,093,030

CONSOLIDATED STATEMENTS OF INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS) For the year ended June 30, 2013 and 2012

<i>In Canadian Dollars</i>	2013	2012
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Revenues

Licensing fees	17,933,500	-
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Expenses

Research and development	8,862,872	8,198,725
Selling, general and administrative expenses	3,557,792	4,407,280
Impairment of intangible assets	6,545,821	-
Loss on disposal of property and equipment	-	125,748
	18,966,485	12,731,753

Operating loss	(1,032,985)	(12,731,753)
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Interest income	146,209	165,070
Interest expense	-	(851)
Foreign exchange gain	910,073	297,689

Net income (loss) and comprehensive income (loss) for the year	28,297	(12,269,845)
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Basic and diluted net income (loss) per common share	0.00	(0.48)
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Notice to Readers: Information contained in our press releases should be considered accurate only as of the date of the 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.

SOURCE Transition Therapeutics Inc.