

# TRANSITION THERAPEUTICS INC.

First Quarter Results  
2004



## TO OUR SHAREHOLDERS

During the first quarter of fiscal 2004, Transition continued to build shareholder value by securing additional financing, advancing our products through clinical development and building partnerships. In addition, subsequent to the end of the quarter, Transition signed an agreement granting Novo Nordisk A/S (“Novo Nordisk”) an exclusive option to license our Islet Neogenesis Therapy (“I.N.T.™”).

### Agreement with Novo Nordisk

Under the agreement, Novo Nordisk will provide up to US\$500,000 to Transition for the further development of the I.N.T.™ technology. Following the review of research data from the ongoing development program, which Transition expects to occur in the third quarter of calendar 2004, Novo Nordisk must exercise its exclusive option or the option will expire.

If the option is exercised, Novo Nordisk will execute a licensing agreement with an upfront payment and equity investment (at then market prices) of approximately US\$5 million and development milestone payments potentially worth up to an additional US\$51.5 million. In addition, Transition will be entitled to receive commercial milestone payments and royalty payments on sales.

### Developing Products for Growth

Transition has completed a Phase I clinical trial for our interferon enhancer, EMZ701. During this trial, all dose levels were well tolerated and no adverse events occurred. We are now preparing to initiate a Phase II clinical trial, in patients with multiple sclerosis. We expect to commence this Phase II trial during fiscal 2004.

Transition has also completed a Phase I clinical trial for our I.N.T.™ technology. During this trial, the two I.N.T.™ compounds were administered separately and examined for safety. Based on the positive results, we are now preparing to initiate an extended Phase I clinical trial for I.N.T.™ where the two compounds will be administered in combination. We expect to commence this trial before the end of calendar 2003.

Finally, the compounds that we select as our lead restenosis inhibitors are expected to enter final validation studies in animal models early in calendar 2004. This will position Transition to pursue partnership opportunities to co-develop local delivery formulations.

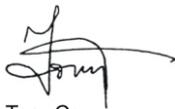
### Financial Strength

In July 2003, Transition raised gross proceeds of \$500,000 through the issuance of 1,111,111 common shares to Novo Nordisk. Transition believes that it has adequate financing for anticipated expenditures until the second quarter of fiscal 2005.

### Outlook

Transition is focused on continuing to build shareholder value by advancing our products through the clinic and we believe that Novo Nordisk will be a great partner through this process. We are also currently in negotiations with potential corporate partners to establish licensing, co-development and other opportunities for our interferon enhancing technology and our restenosis inhibitors.

I would like to express my thanks, on behalf of the Board of Directors, to our shareholders and employees for their continued support. I am convinced that we will continue to make great strides forward and I look forward to reporting on our progress.



Tony Cruz  
Chairman and CEO  
Transition Therapeutics Inc.

## MANAGEMENT'S DISCUSSION & ANALYSIS

The following information should be read in conjunction with the Company's unaudited interim financial statements included herein as well as the June 30, 2003 audited consolidated financial statements and the related notes, which are prepared in accordance with Canadian generally accepted accounting principles. Except for historical information, the following report includes statements which are forward looking. Readers are cautioned that the actual results may differ materially from the results projected in any forward looking statements.

### Overview

Transition Therapeutics Inc. (the "Company") is a Canadian biopharmaceutical company, engaged in the business of developing novel approaches and therapeutics with the potential for enhancing the quality of life of patients with such debilitating diseases as diabetes, multiple sclerosis and restenosis. The Company commenced operations in July 1998, and has devoted its resources primarily to fund its research and development programs. All revenue to date has been generated from interest income on surplus funds and the sale of reagents. The Company has incurred a cumulative deficit to September 30, 2003 of \$23,951,227. Losses are expected to continue for the next several years as the Company invests in research and development, pre-clinical studies, clinical trials and regulatory compliance. The success of the Company is dependent on bringing its products to market, obtaining necessary regulatory approvals and achieving future profitable operations.

The Company's cash and cash equivalents were \$6,395,128 at September 30, 2003, and the net working capital position was \$5,971,394. The Company believes that it has adequate financing for anticipated expenditures until the end of the second quarter of fiscal 2005.

### Financing activities

On July 24, 2003, the Company sold 1,111,111 common shares to Novo Nordisk A/S ["Novo Nordisk"] at a purchase price of \$0.45 per common share through a private placement for a total amount of \$500,000. The cash proceeds of the private placement, net of expenses, were \$474,325. In addition, the Company also granted Novo Nordisk a non-transferable right to acquire up to an additional 10,101,010 common shares of the Company at a price of \$0.495 per share which right expired on October 1, 2003.

### Results of operations

For the three months ended September 30, 2003, the Company recorded a net loss of \$2,292,926 (\$0.03 per common and Class B share) compared to a net loss of \$3,111,760 (\$0.07 per common and Class B share) for the three months ended September 30, 2002. The decrease in the loss is primarily due to a temporary decrease in research and development expenditures, as the Company prepares for an extended Phase I clinical trial and a Phase II clinical trial, partially offset by an increase in amortization due to the technology acquired from Stem Cell Therapeutics Inc., and a decrease in the recovery of future income taxes.

### Interest income

Interest income for the three months ended September 30, 2003, was \$44,456 as compared to \$14,560 for the three months ended September 30, 2002. The increase in interest income resulted from an increase in cash and cash equivalents and short-term investments between the periods of \$3,962,304, which resulted from the Company completing several private placements late in fiscal 2003 and one private placement in the first quarter of fiscal 2004. Interest income is expected to decline during the second quarter of fiscal 2004 due to lower cash balances resulting from ongoing expenditures.

### Research and development

Research and development expenses decreased to \$423,433 for the three months ended September 30, 2003 from \$1,637,651 for the same period in 2003. This decrease resulted primarily from a temporary decrease in clinical and toxicity study expenses while the Company prepares for the next stage of clinical trials. The Company anticipates that research and development expenses will increase during the second quarter of fiscal 2004, as it commences an extended Phase I clinical trial for its Islet Neogenesis Therapy ("I.N.T.<sup>TM</sup>"), prepares for a Phase II clinical trial for its Interferon Enhancing Therapy ("I.E.T.") and commences additional pre-clinical and toxicity studies for its technologies.

### General and administrative expenses

General and administrative expenses decreased to \$363,943 for the three months ended September 30, 2003 from \$379,258 for the three months ended September 30, 2002. This small decrease resulted from savings realized from management's decision to close the Waratah Pharmaceuticals Inc. facility in Woburn, MA, partially offset by an increase in accounting fees. The Company anticipates that general and administrative expenses will increase for the second quarter of fiscal 2004 as the Company incurs costs related to changes in its management team.

### Liquidity and capital resources

The Company's cash and cash equivalents and the Company's working capital position were \$6,395,128 and \$5,971,394, respectively at September 30, 2003 down from June 30, 2003 balances of \$6,857,576 and \$6,343,029, respectively. The decrease is the net result of the private placement completed during July 2003 and expenditures incurred during the three months ended September 30, 2003.

The Company believes that it has adequate financing for anticipated expenditures until the end of the second quarter of fiscal 2005.

### Capital expenditures

During the three months ended September 30, 2003, the Company's capital expenditures were \$4,135, as compared to \$605 for the three months ended September 30, 2002. The expenditure during the first quarter of fiscal 2004 was for computer equipment. The Company does not anticipate any significant capital expenditures during the second quarter of fiscal 2004.

### Subsequent event

In November 2003, the Company signed an agreement granting Novo Nordisk an exclusive option to license the Company's I.N.T.<sup>TM</sup> technology. Under the agreement, Novo Nordisk will provide up to US\$500,000 to the Company for the further development of the I.N.T.<sup>TM</sup> technology. Following the review of research data from the ongoing development program, which the

Company expects to occur in the third quarter of calendar 2004, Novo Nordisk must exercise its exclusive option or the option will expire.

If the option is exercised, Novo Nordisk will execute a licensing agreement with an upfront payment and equity investment (at then market prices) of approximately US\$5 million and development milestone payments potentially worth up to an additional US\$51.5 million. In addition, the Company will be entitled to receive commercial milestone payments and royalty payments on sales.

### **Risks and uncertainties**

Prospects for companies in the biopharmaceutical industry generally may be regarded as uncertain given the nature of the industry and, accordingly, investments in such companies should be regarded as highly speculative. The Company's technologies are currently in either the research and development stage or early in the clinical development stage, which are both risky stages for a company in the biopharmaceutical industry. It is not possible to predict, based upon studies in animals and early clinical data, whether a new therapeutic or device will prove to be safe and effective in humans. To date, the Company has not introduced a product into the market and there is no assurance that research and development programs conducted by the Company will result in any commercially viable products.

The Company has incurred losses and anticipates that it will continue to incur losses as it continues its research and development and clinical trials and eventually seeks regulatory approval for the sale of its products. If a product is approved for sale, there is no assurance that the Company will generate adequate funds to continue development or will ever achieve profitable operations. There are many factors such as competition, proprietary rights, patent protection and the regulatory environment that can influence the Company's ability to be profitable.

From time to time, the Company will seek additional funding through public or private placements, corporate collaborations or partnership arrangements. The Company's ability to access the capital markets or to enlist partners is mainly dependent on the progress of its research and development and regulatory approval of its products. There is no assurance that additional funding will be available on acceptable terms, if at all.

To continue the Company's research and development programs and to conduct future clinical trials, the Company will rely upon employees, collaborators and other third party relationships. There is no assurance that the Company will be able to maintain or establish these relationships as required.

Market prices for securities of biotechnology companies may be highly volatile and subject to significant fluctuation and may not necessarily be related to the operating or other performances of such companies.

### **Outlook**

The Company continues to be focused on driving shareholder value by advancing its products through clinical trials. During fiscal 2004, the Company intends to commence a Phase II clinical trial for its I.E.T. technology in patients with MS, complete an extended Phase I clinical trial for I.N.T.<sup>™</sup>, and select lead restenosis inhibitors to enter final validation studies. As a result of the Company's option agreement with Novo Nordisk, and the additional studies that are going to be performed, the Company is currently revising its Phase II timelines for I.N.T.<sup>™</sup>.

The Company is currently in negotiations with potential corporate partners to establish licensing, co-development and other opportunities for its I.E.T and restenosis inhibitor technologies.

## CONSOLIDATED BALANCE SHEETS

	Unaudited September 30, 2003 \$	Audited June 30, 2003 \$
<b>ASSETS</b>		
<b>Current</b>		
Cash and cash equivalents	6,395,128	6,857,576
Receivables	46,590	93,208
Investment tax credits receivable	468,400	458,400
Research inventory	377,561	379,956
Prepaid expenses and other assets	130,887	84,089
Future tax asset	30,315	66,250
<b>Total current assets</b>	<b>7,448,881</b>	<b>7,939,479</b>
Long-term deposits	145,587	148,202
Long-term research inventory	295,386	303,239
Capital assets, net	448,743	469,110
Technology <i>[note 2]</i>	28,879,374	31,020,940
	<b>37,217,971</b>	<b>39,880,970</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current</b>		
Accounts payable and accrued liabilities	1,457,778	1,576,741
Current portion of leasehold inducement	3,698	3,698
Current portion of obligation under capital leases	16,011	16,011
<b>Total current liabilities</b>	<b>1,477,487</b>	<b>1,596,450</b>
Leasehold inducement	20,654	21,578
Obligation under capital leases	29,163	36,261
Provision for facility closure	398,876	470,769
Future tax liability	3,611,570	4,257,090
<b>Total liabilities</b>	<b>5,537,750</b>	<b>6,382,148</b>
Research commitments <i>[note 5]</i>		
Subsequent event <i>[note 7]</i>		
<b>Shareholders' equity</b>		
Common shares <i>[note 3[b]]</i>	48,889,758	48,415,433
Class B shares <i>[note 3[b]]</i>	2,276,120	2,276,120
Contributed surplus <i>[notes 3[c] and [d]]</i>	2,461,769	2,461,769
Stock options <i>[note 3[d]]</i>	814,871	814,871
Warrants <i>[note 3[c]]</i>	1,188,930	1,188,930
Deficit	(23,951,227)	(21,658,301)
<b>Total shareholders' equity</b>	<b>31,680,221</b>	<b>33,498,822</b>
	<b>37,217,971</b>	<b>39,880,970</b>

See accompanying notes

## CONSOLIDATED STATEMENTS OF LOSS AND DEFICIT

(Unaudited)

	Three-month period ended September 30, 2003 \$	Three-month period ended September 30, 2002 \$
<b>EXPENSES</b>		
Research and development, net	423,433	1,637,651
General and administrative	363,943	379,258
Amortization	2,162,789	2,026,465
Foreign exchange gain	(3,198)	(6,884)
	<b>2,946,967</b>	<b>4,036,490</b>
Loss before the following	<b>(2,946,967)</b>	<b>(4,036,490)</b>
Interest income, net	44,456	14,560
Loss before income taxes	<b>(2,902,511)</b>	<b>(4,021,930)</b>
Recovery of (provision for) income taxes		
Current	-	(10,000)
Future	609,585	920,170
<b>Net loss for the period</b>	<b>(2,292,926)</b>	<b>(3,111,760)</b>
Deficit, beginning of period	<b>(21,658,301)</b>	<b>(10,074,955)</b>
<b>Deficit, end of period</b>	<b>(23,951,227)</b>	<b>(13,186,715)</b>
<b>Basic net loss per common and Class B share</b> <i>[note 3[b][ii]]</i>	<b>\$(0.03)</b>	<b>\$(0.07)</b>

See accompanying notes

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three-month period ended September 30, 2003 \$	Three-month period ended September 30, 2002 \$
<b>OPERATING ACTIVITIES</b>		
Net loss for the period	<b>(2,292,926)</b>	<b>(3,111,760)</b>
Add (deduct) items not involving cash		
Amortization	2,166,068	2,030,304
Amortization of leasehold inducement	(924)	(924)
Recovery of income taxes - future	(609,585)	(920,170)
	<b>(737,367)</b>	<b>(2,002,550)</b>
Net change in non-cash working capital balances related to operations <i>[note 4]</i>	<b>(188,173)</b>	33,842
<b>Cash used in operating activities</b>	<b>(925,540)</b>	<b>(1,968,708)</b>
<b>INVESTING ACTIVITIES</b>		
Purchase of capital assets	<b>(4,135)</b>	(605)
<b>Cash used in investing activities</b>	<b>(4,135)</b>	(605)
<b>FINANCING ACTIVITIES</b>		
Repayment of obligation under capital leases	<b>(7,098)</b>	(8,865)
Proceeds from issuance of common shares, net <i>[note 3[b][i]]</i>	<b>474,325</b>	-
<b>Cash provided by (used in) financing activities</b>	<b>467,227</b>	<b>(8,865)</b>
<b>Net decrease in cash and cash equivalents during the period</b>	<b>(462,448)</b>	<b>(1,978,178)</b>
Cash and cash equivalents, beginning of period	<b>6,857,576</b>	2,894,277
<b>Cash and cash equivalents, end of period</b>	<b>6,395,128</b>	916,099

See accompanying notes

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

## 1. NATURE OF OPERATIONS

Transition Therapeutics Inc. [the "Company"] is a biopharmaceutical company, incorporated on July 6, 1998 under the Business Corporations Act (Ontario). The Company is engaged in the business of developing novel approaches and therapeutics with the potential for enhancing the quality of life of patients with such debilitating diseases as diabetes, multiple sclerosis and restenosis.

The success of the Company is dependent on bringing its products to market, obtaining the necessary regulatory approvals and achieving future profitable operations. The continuation of the research and development activities and the commercialization of its products are dependent on the Company's ability to successfully complete these activities and to obtain adequate financing through a combination of financing activities and operations. It is not possible to predict either the outcome of future research and development programs or the Company's ability to fund these programs going forward.

These consolidated financial statements have been prepared using the same accounting principles used in the audited consolidated financial statements for the period ended June 30, 2003.

## 2. TECHNOLOGY

Technology consists of the following:

	September 30, 2003		
	Cost \$	Accumulated amortization \$	Net book value \$
Acquired on acquisition of Waratah Pharmaceuticals Inc.	39,799,917	13,598,305	26,201,612
Acquired from Biogenesys, Inc.	137,000	50,227	86,773
Acquired on acquisition of Stem Cell Therapeutics Inc.	3,055,560	464,571	2,590,989
	<b>42,992,477</b>	<b>14,113,103</b>	<b>28,879,374</b>

The amortization to be taken on the technology by fiscal year is as follows:

	\$
2004	8,584,266
2005	8,584,266
2006	8,584,266
2007	4,919,962
2008	348,180
	<b>31,020,940</b>

### 3. SHARE CAPITAL

#### [a] Authorized

Unlimited common shares

Unlimited Class B shares, which are convertible on a one to one basis into common shares without additional consideration

#### [b] Issued and outstanding and changes during the period

Common shares	#	\$
Balance, June 30, 2003	72,460,056	48,415,433
Issued pursuant to private placement, net [i]	1,111,111	474,325
Balance, September 30, 2003	73,571,167	48,889,758
Class B shares	#	\$
Balance, June 30, 2003 and September 30, 2003	8,129,000	2,276,120
<b>Total common and Class B shares, September 30, 2003</b>	<b>81,700,167</b>	<b>51,165,878</b>

[i] On July 24, 2003, the Company sold 1,111,111 common shares to Novo Nordisk A/S ["Novo Nordisk"] at a purchase price of \$0.45 per common share through a private placement for a total amount of \$500,000. The cash proceeds from the private placement, net of expenses, were \$474,325. In addition, the Company also granted Novo Nordisk a non-transferable right to acquire up to an additional 10,101,010 common shares of the Company at \$0.495 per common share which right expired on October 1, 2003.

[ii] The weighted average number of shares used in the computation of basic loss per common and Class B share for the three-month period ended September 30, 2003 is 80,412,878 (three-month period ended September 30, 2002 - 45,022,697).

For the three-month period ended September 30, 2003, 1,009,511 (three-month period ended September 30, 2002 - 1,009,511) contingently returnable common shares were excluded from the basic loss per common and Class B share calculation.

#### [c] Share purchase warrants and Agents' Warrants

Share purchase warrants	#	\$
Share purchase warrants outstanding, June 30, 2003 and September 30, 2003	7,245,098	859,616
Agents' Warrants	#	\$
Agents' Warrants outstanding, June 30, 2003 and September 30, 2003	1,431,800	329,314
<b>Total warrants, September 30, 2003</b>	<b>8,676,898</b>	<b>1,188,930</b>

### 3. SHARE CAPITAL (continued)

#### [d] Stock options

Stock options	#	\$
<b>Stock options outstanding, June 30, 2003 and September 30, 2003</b>	<b>3,830,197</b>	<b>814,871</b>

The pro forma information below, regarding net loss and net loss per common and Class B share, has been determined as if the Company had accounted for stock options granted to employees, officers and directors on or after July 1, 2002 under the fair value based method of accounting for stock-based compensation.

		Three-month period ended September 30, 2003 \$	Three-month period ended September 30, 2002 \$
Net loss	As reported	2,292,926	3,111,760
	Pro-forma	2,293,676	3,111,760
Net loss per common and Class B share	As reported	\$0.03	\$0.07
	Pro-forma	\$0.03	\$0.07

### 4. CONSOLIDATED STATEMENTS OF CASH FLOWS

The net change in non-cash working capital balances related to operations consists of the following:

		Three-month period ended September 30, 2003 \$	Three-month period ended September 30, 2002 \$
Receivables		46,618	(22,987)
Investment tax credits receivable		(10,000)	(24,000)
Research inventory		10,248	598
Deposits on collaborations		-	254,083
Prepaid expenses and other assets		(46,798)	45,929
Long-term deposits		2,615	(7,655)
Accounts payable and accrued liabilities		(118,963)	(212,126)
Provision for facility closure		(71,893)	-
		<b>(188,173)</b>	<b>33,842</b>
<b>Supplemental cash flow information</b>			
Interest paid		2,959	4,075
Taxes paid		26,642	-

## 5. RESEARCH COMMITMENTS

As at September 30, 2003, the Company is committed to aggregate expenditures of \$215,665 [June 30, 2003 - \$115,250] under its collaboration agreements. In addition, at September 30, 2003, the Company is committed to aggregate expenditures of approximately \$292,942 [June 30, 2003 - \$41,773] for clinical and toxicity studies to be completed during fiscal 2004 and approximately nil [June 30, 2003 - nil] for manufacturing agreements.

## 6. SEGMENTED INFORMATION

The Company considers itself to be in one business segment, that is the research and development of therapeutic agents. Following the acquisition of Waratah Pharmaceuticals Inc., the Company's operations are conducted in Canada and the United States. Geographic segment information is as follows:

	Canada \$	United States \$
Net loss:		
Three-months ended September 30, 2003	2,270,773	22,153
Three-months ended September 30, 2002	2,729,704	382,056
Amortization of capital assets:		
Three-months ended September 30, 2003	21,217	3,285
Three-months ended September 30, 2002	14,162	20,298
Interest income (expense):		
Three-months ended September 30, 2003	44,800	(344)
Three-months ended September 30, 2002	16,929	(2,369)
Income taxes:		
Three-months ended September 30, 2003	-	-
Three-months ended September 30, 2002	-	10,000
Recovery of income taxes - future:		
Three-months ended September 30, 2003	609,585	-
Three-months ended September 30, 2002	920,170	-
Capital assets:		
September 30, 2003	386,322	62,421
June 30, 2003	403,404	65,706

## 7. SUBSEQUENT EVENT

In November 2003, the Company signed an agreement granting Novo Nordisk an exclusive option to license the Company's Islet Neogenesis Therapy ("I.N.T.<sup>TM</sup>"). Under the agreement, Novo Nordisk will provide up to US\$500,000 to the Company for the further development of the I.N.T.<sup>TM</sup> technology. Following the review of research data from the ongoing development program, which the Company expects to occur in the third quarter of calendar 2004, Novo Nordisk must exercise its exclusive option or the option will expire.

If the option is exercised, Novo Nordisk will execute a licensing agreement with an upfront payment and equity investment (at then market prices) of approximately US\$5 million and development milestone payments potentially worth up to an additional US\$51.5 million. In addition, the Company will be entitled to receive commercial milestone payments and royalty payments on sales.



*Stock symbol:* **TTH**

*Exchange:* **TSX Venture**

*Fiscal year end:* **JUNE 30**

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