

STEM CELL  

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THERAPEUTICS

**Stem Cell Therapeutics Corp.**

Management Discussion and Analysis  
For the fiscal year ended June 30, 2009

Dated: August 25, 2009

Dated August 25, 2009

The following information should be read in conjunction with the Company's unaudited financial statements as at and for the six months ended June 30, 2008 and 2009, and should also be read in conjunction with the audited financial statements and Management's Discussion and Analysis ("MD&A") for the year ended December 31, 2008.

The financial statements have been prepared in accordance with Canadian generally accepted accounting principles ("GAAP").

Where "we", "us", "our", "SCT", "Company" or the "Corporation" is used, it is referring to Stem Cell Therapeutics Corp. unless otherwise indicated.

All amounts are in Canadian dollars, unless otherwise indicated.

Additional information relating to the Company including the Company's Annual Information Form can be found on SEDAR at [www.sedar.com](http://www.sedar.com).

Certain information contained in this report constitutes forward-looking statements. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements.

This management's discussion and analysis ("MD&A") has been prepared in accordance with the requirements of National Instrument 51-102 and covers the period from January 1, 2009 to August 25, 2009 unless otherwise noted.

## **Overview**

Stem Cell Therapeutics Corp. is a biotechnology company focused on the development and commercialization of drug-based therapies to treat central nervous system ("CNS") disorders. SCT is a leader in the development of therapies that utilize drugs to stimulate a patient's own resident autologous stem cells. The Company's programs aim to repair neurological functions lost due to disease or injury. SCT's stem cell regenerative therapeutic approach was founded on the work of Dr. Samuel Weiss, Director of the Hotchkiss Brain Institute at the University of Calgary, who was awarded the Gairdner Award in April 2008 for this work on neural stem cells. SCT's lead product, NTx®-265, targets the treatment of stroke by repurposing approved and clinically well defined drugs. The Company's extensive patent portfolio supports the potential expansion into future clinical programs in numerous other neurological diseases such as traumatic brain injury and multiple sclerosis.

SCT's primary program, NTx®-265, is a therapeutic regimen of two approved and clinically well-defined drugs, human Chorionic Gonadotropin ("hCG") and Erythropoietin ("EPO"), targeting the treatment of stroke. The twin objectives of the regimen are to stimulate the growth and differentiation of new neurons to replace the brain cells that were lost or damaged by the stroke, and importantly, to direct motor, visual and cognitive recovery after acute ischemic stroke. Animal studies have shown a significant recovery in motor function after receiving the NTx®-265 regimen 24-48 hours post stroke. Encouraging final clinical results from SCT's completed BETAS (Beta-hCG + Erythropoietin in Acute Stroke) Phase IIa stroke trial were presented at the International Stroke Conference in February 2009, showing clinically relevant recovery in 12 of 12 patients who received the complete regimen. In May of 2008, SCT began recruiting patients

for its multi-centre, double-blind, placebo-controlled REGENESIS (a Phase II prospective, randomized, double-blind, placebo controlled study of NTx®-265: hCG and epoetin alfa in acute ischemic stroke patients) Phase IIb stroke study for NTx®-265 with primary endpoints of safety and efficacy.

Due to an unrelated German clinical study, the REGENESIS Phase IIb clinical trial was officially placed on clinical hold in September 2008 at the request of Health Canada and the U.S. Food and Drug Administration (“FDA”). The clinical hold was formally lifted by FDA on May 14, 2009. Health Canada approved the modified REGENESIS Phase IIb stroke trial on July 20<sup>th</sup> and the Drug Controller General of India (“DCGI”) followed shortly thereafter on July 21<sup>st</sup> issuing the Company a No Objection Letter (“NOL”) for the same protocol. This trial is co-Led by two principle investigators: Dr. Steven C. Cramer from the University of California, Irvine and Dr. Michael D. Hill of Foothills Hospital at the University of Calgary. The recruitment target for this study is to enroll 128 patients. The Indian, U.S., and Canadian protocols share similar design, as well as safety and efficacy endpoints.

On August 11, 2009, the Company announced the enrollment of its first patient in the dose response designed modified REGENESIS Phase IIb stroke trial. It is expected that the Company will complete recruiting by the end of 2009 in the modified REGENESIS phase IIb stroke trial using NTx®-265. A top-line read of the data is anticipated to be available Q1 2010.

## **2009 Objectives**

- ✓ Receive FDA approval to proceed with modified REGENESIS Phase IIb stroke trial; completed
- ✓ Initiate and enrol patients in modified REGENESIS Phase IIb stroke trial; commenced
- Complete recruiting for modified REGENESIS Phase IIb clinical stroke trial; Q4 09
- Top-line read of modified REGENESIS Phase IIb stroke trial data; Q1 2010
- Initiate and enrol patients in a Phase IIa clinical study for traumatic brain injury; H2 09
- Initiate clinical Proof-of-Concept study for multiple sclerosis; H2 09
- Partnership/Co-Development deal in advanced stage for at least one indication

## **Operating results for the period April 1, 2009 to August 25, 2009**

On April 30, 2009, Dr. Alan Moore, President and CEO, was invited to present at EDC’s 8<sup>th</sup> Annual Life Science Conference in Miami, Florida. Dr. Moore discussed SCT’s unique regenerative stem cell therapy and how it will be the frontier of personalized healthcare specifically in the key areas of stroke, traumatic brain injury and multiple sclerosis.

On May 14, 2009, SCT received verbal confirmation from the FDA that the clinical hold was lifted and then shortly thereafter on May 16, 2009, SCT received a formal letter from the FDA confirming immediate removal of the clinical hold placed on the Phase IIb stroke trial, September 18, 2008. This allowed SCT to commence the recruitment of patients under an amended protocol using NTx®-265 for the Company’s Phase IIb clinical trial treating acute ischemic stroke.

On May 19, 2009, the Company was issued United States Patent No. 7,534,765, entitled “Pregnancy Induced Oligodendrocyte Precursor Cell Proliferation Regulated by Prolactin”. This patent covers methods of using prolactin for enhancing the formation of oligodendrocytes *in vivo*, which is valuable to treat diseases associated with loss of myelin-producing oligodendrocytes (white matter diseases).

“This patent bolsters our intellectual property position around the use of prolactin for treating demyelinating neurodegenerative diseases such as multiple sclerosis (“MS”) in which the myelin sheath surrounding the axon of neurons is damaged. The finding that prolactin enhances oligodendrocyte production and remyelination is what stimulated the development of our NTx®-488 program for MS, with preclinical studies being completed in preparation for Phase II clinical trials.” Stated Dr. Alan Moore, President and CEO, “Importantly, as covered by other SCT patents, prolactin also stimulates neural stem cell proliferation and neurogenesis. Prolactin is therefore expected to repair both the myelin damage and the neuronal damage in MS, which is necessary for full functional recovery, and makes prolactin a unique MS drug candidate.”

On June 22, 2009, SCT announced that Dr. Samuel Weiss, Director of the Hotchkiss Brain Institute at the University of Calgary, provided the keynote address and Dr. Allen Davidoff, VP Product Development at SCT, was a member of a response panel at the Alberta Council of Technologies hosted event in Calgary, June 23, 2009, at the Alberta Research Council. Dr Weiss’ work founded SCT, and he remains a key member of SCT’s Scientific Advisory Board.

On July 9, 2009, the Company was issued two patents in India: Indian Patent No. 229684 entitled, “Combined Regulation of Neural Cell Production” and Indian Patent No. 229924 entitled, “A Composition for Increasing Neural Stem Cell Number and In Vitro Method of Using the Same”. Together, these patents cover pharmaceutical compositions for increasing neural stem cell number or for producing specialized neural stem cell progeny, with the compositions comprising prolactin in combination with other neural stem cell proliferating agents or differentiating agents, such as EPO. Methods for using prolactin and other such agents in neural stem cell culture are also covered, with the resulting cells being useful, for example, in regenerative transplant therapy.

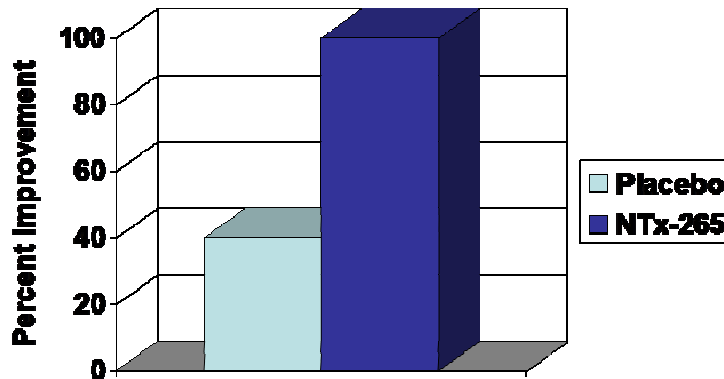
On July 20, 2009, SCT received a No Objection Letter (“NOL”) from Health Canada for the modified REGENESIS protocol using NTx®-265 for a Phase IIb clinical trial treating acute ischemic stroke.

On July 21, 2009, SCT received an NOL from the Drug Controller General of India (“DCGI”) to initiate the Phase IIb acute ischemic stroke trial. This investigational new drug (“IND”) opening study is a double-blind, randomized, placebo-controlled clinical trial of its lead program, NTx®-265, for the treatment of acute ischemic stroke. The DCGI response allowed initiation of the modified REGENESIS protocol for the Phase IIb clinical trial in acute ischemic stroke, which is co-Led by two principle investigators: Dr. Steven C. Cramer from the University of California, Irvine and Dr. Michael D. Hill of the Foothills Hospital at the University of Calgary.

On July 27, 2009, the Company provided an update on key corporate developments and strategies. SCT conducted a meta-analysis of the combined BETAS Phase IIa clinical stroke trial data and REGENESIS Phase IIb clinical stroke trial data. At the time the clinical hold was placed on the REGENESIS Phase IIb trial, seven patients had been recruited, and subsequently they completed their 90-day evaluation period. Because this trial was placebo controlled, patients received either placebo or NTx®-265 and so could be combined with patient data from the non-placebo controlled BETAS Phase IIa trial where patients only received NTx®-265. By performing this type of statistical analysis, the Company was able to compare the combined data from 19 patients: 14 of which received drug (12 from BETAS Phase IIa and 2 from REGENESIS Phase IIb) and 5 patients who received placebo (all from REGENESIS Phase IIb). A decrease in the National Institute of Health Stroke Score (“NIHSS”) represents an improvement in a patient’s functionality, and importantly for a recovering patient, a decrease of 4 units in the NIHSS scale is considered a clinically relevant improvement. Of the 5 patients who received placebo, the average NIHSS actually increased by +0.7 points and out of the 14 patients who received NTx®-265, the

NIHSS decreased by 8.1 points. The p-value from this meta-analysis was  $< 0.0001$ , statistically significant.

For both the BETAS Phase IIa trial and REGENESIS Phase IIb trial, a patient that showed a decrease of 4 NIHSS points or greater was considered a responder. Hence the meta-analysis, when expressed as percentage responders, stated that the placebo group showed a 40% response (2 out of 5) whereas the NTx®-265 treated group showed a 100% response (14 out of 14) resulting in a p-value of  $p < 0.01$ , again statistically significant. The diagram below summarizes the improvement of patients in both the placebo group and NTx®-265 treated group.



“In parallel with re-initiating the Phase IIb stroke trial, we continue to work on two additional programs, traumatic brain injury (“TBI”) and multiple sclerosis (“MS”), both of which should also reach clinical milestones towards the second half of this calendar year. We will provide updates on the progress of these efforts as they reach fruition during the next few months,” stated Dr. Alan Moore, President and CEO. “Concurrently, we are also in discussions with potential partners for all programs.”

On July 30, 2009, SCT announced the acceptance and publication of the paper entitled “Open labeled, uncontrolled pharmacokinetic study of single intramuscular hCG dose in healthy male volunteers” by the International Journal of Clinical Pharmacology and Therapeutics, Vol. 47, August 2009. This paper was authored by Drs. Alan Moore, President & CEO, Allen Davidoff, VP Product Development and Yan Yang, Clinical Research Associate, all of SCT; Dr. Michael D. Hill of Foothills Hospital at the University of Calgary, and Dr. Steven C. Cramer, from the University of California, Irvine.

On August 4, 2009, the Company announced a presentation by Dr. Alan Moore, President and CEO, at the Advanced Technology Applications for Combat Casualty Care (“ATACCC”) 2009 conference which is the U.S. Department of Defense’s premier scientific meeting. Dr. Moore discussed patient recovery from brain injury by pharmacological (‘drug-induced’) activation of endogenous neural adult stem cells in traumatic brain injury (“TBI”) and stroke. This discussion of recovery was supported by SCT’s Phase IIa and Phase IIb clinical data in acute ischemic stroke patients and SCT’s preclinical data from animal models of TBI.

On August 11, 2009, SCT announced enrollment of the first patient in its modified REGENESIS Phase IIb acute ischemic stroke trial. The modified REGENESIS trial is a double-blind, randomized, placebo-controlled Phase IIb clinical trial for SCT’s lead program, NTx®-265, for the treatment of acute ischemic stroke. This first patient was enrolled by the clinical team of Dr.

Vijaya Pamidimukkala from the Lalitha Super Specialties Hospital Pvt Ltd in Guntur, Hyderabad, A.P.

## **Development Programs**

### *Stroke*

The primary focus of SCT's development activities is aimed at rapidly advancing NTx®-265 for the treatment of acute ischemic stroke. Stroke was chosen as the lead program because it represents both a large, attractive market opportunity with few competitors and a key first application for our neuro-regeneration technology platform.

A human stroke can be compared to a heart attack but located in the brain, and occurs due to a reduction in blood flow to certain regions due to a blockage, or rupture of a blood vessel's wall. This interrupted blood flow causes a reduction in oxygen available to affected regions of the brain, and cells located there subsequently die. After an acute ischemic injury (stroke), brain tissue dies quickly in the absence of gas and nutrient exchange and has a limited capacity to spontaneously repair, regenerate or regain lost functionality. For this reason, injury due to stroke is frequently irreversible, recovery is insufficient and extensive recovery periods that range from months to years accompanied by intensive physiotherapy are required. Moderate to severe acute ischemic stroke is accompanied by the loss of a large number of neural cells within a patient's brain. Loss of brain matter is accompanied by a varied array of symptoms including loss of cognitive function, loss of motor control to one side or both sides of the body, loss of visual and other symptoms that create a syndrome from which patient, family and medical practitioners must address. It is generally accepted that improved prognosis is directly related to maintenance of brain matter. Thus, this therapeutic approach using NTx®-265 for increasing regeneration of new, functional brain matter represents a novel approach that may directly influence a patient's prognosis and the degree of improvement of a stroke patient's symptoms. A final benefit that results from improved speed and robustness of recovery is decreased dependence of recovering patients on family and the medical system.

SCT announced enrollment of the first patient in its original REGENESIS Phase Iib stroke trial on May 28, 2008. Enrollment in the U.S. Phase Iib study was expected to begin in Q4 2008 and finish in Q2 2009. At the time the clinical hold occurred on the REGENESIS Phase Iib stroke trial, 7 patients had been enrolled in the study. On May 15, 2009 the Company announced that the FDA had formally lifted its clinical hold, allowing the company to proceed with a modified REGENESIS Phase Iib stroke trial.

On May 21, 2009 the Company announced encouraging results from the original 7 patients enrolled in the trial prior to the clinical hold. The results of the Phase Iib trial from the 7 patients indicated an improvement in the treated group as compared to the placebo group. Of the 7 patients enrolled, 5 received placebo and 2 were treated with NTx®-265: A decrease in the NIHSS score represents an improvement in a patient's functionality. A change of 4 units in the NIHSS scale is considered clinically significant. The placebo patients score decreased by an average of 1.4 units, which did not attain this level of clinical significance. The treated patients, however, showed an average decrease of 9 units, exceeding the level for clinical significance. While the results of this study were not statistically significant due to the small number of patients enrolled before the study was halted, the large numerical difference in response to drug regimen versus placebo is encouraging.

The next step in the clinical development for NTx®-265 is completion of the modified REGENESIS Phase Iib double-blind, randomized, placebo-controlled clinical stroke trial focused

on functional outcome measures. This will involve approximately 128 stroke patients in a number of different centers in India, Canada and the U.S. Dr. Steven C. Cramer at the University of California, Irvine and Dr. Michael D. Hill at the University of Calgary, Calgary Health Region, are serving as co-Principal Investigators for this Phase IIb clinical stroke program.

The Company is currently recruiting patients for the modified REGENESIS Phase IIb stroke trial and expects to complete all patient recruitment by the end of 2009. Given that the protocol has a 90 day end-point, we anticipate a top-line data read by the end of Q1 2010.

### *Traumatic Brain Injury*

Stem Cell Therapeutic Corp. has completed a preclinical comparator study designed to characterize the neuroregenerative effects of stem cell proliferative agents plus EPO in an animal model of traumatic brain injury ("TBI"). This study represents a promising new program launch that builds upon intellectual property held by SCT and supported by fundamental findings from the laboratory of Dr. Samuel Weiss at the University of Calgary. Acute traumatic injury to the head resulting from automobile accidents, concussive explosions or serious athletic impact to the head represents serious events that cause loss of independence and demand intense medical intervention with recovery periods that often persist for months or years. A therapy that induces improved neurological recovery or functional recovery after an acute injury, would increase patient independence, decrease rehabilitation time and cost, represents a new important scientific advancement and medical development.

The preclinical comparator study mentioned previously was sponsored by SCT and was designed to characterize the ability of either hCG or prolactin followed by EPO to promote recovery of the brain following moderate-to-serious acute cortical (white matter) injury to the brain. The objective of this study, conducted at Louisiana State University under the leadership of Dr. Ludmila Belayev, was to compare two proliferative agents, hCG plus EPO versus prolactin plus EPO, in a rat animal model of TBI. Top-line analysis shows that both regimens work equally well to reverse the behavioral and anatomical effects of TBI. Formal data from this study will be presented in the future in written and oral format.

Building upon the results of this animal study, and those previously obtained, a Phase IIa TBI clinical study was anticipated to start at one site in Canada in Q3 2008. This study was also placed on clinical hold at the request of Health Canada, and we are now working with Health Canada to lift the hold.

### *Multiple Sclerosis*

SCT has substantial intellectual property relating to the use of regenerative therapies for treating demyelinating diseases such as multiple sclerosis ("MS"). Scientific investigations by Dr. Samuel Weiss from the University of Calgary have characterized two potentially important therapeutic effects of prolactin on the CNS. In these published studies prolactin has been shown to act as both a neurogenic agent to increase the number of progenitor cells that mature into neurons and as an agent that promotes oligodendrocyte production and remyelination of the brain and spinal cord.

SCT was recently granted two key United States patents and one Australian patent for the use of prolactin in neurologic diseases based on the demonstrated insights into the effect of prolactin by Dr. Samuel Weiss. Moreover, the publication of those studies in high impact journals strongly support and validate the concept that prolactin may represent a potential new therapeutic platform

for the treatment of white matter injury, and an impetus for a clinical program aimed at treating patients with MS.

Successful completion of a preliminary non-clinical study undertaken by Dr. V. Wee Yong, a Professor in the Departments of Oncology and Clinical Neurosciences at the University of Calgary, is expected to quickly evolve into a clinical program to demonstrate efficacy in patients diagnosed with multiple sclerosis. The non-clinical results will be announced in September 2009 at an international MS conference by Dr. V. Wee Yong, and the follow-on clinical study that will be lead by Dr. Luanne Metz, a neurologist at the Foothills Medical Center and a Professor in the Department of Clinical Neurosciences at the University of Calgary, is anticipated to begin in the second half of 2009. This study will be funded by an outside grant to the University of Calgary by the Canadian Stem Cell Network.

### **Patents and Proprietary Rights**

The Company's NTx®-265 technology was originally developed primarily by Dr. Samuel Weiss at an Alberta-based university. We acquired 100% ownership of this intellectual property from Dr. Weiss and his co-inventors in exchange for 3,636,364 shares in the Company and \$2,000 in cash consideration. The Company was formed specifically to commercialize this technology.

The Company currently owns 80 pending patent applications, six issued U.S. patents, four issued Australian patents, one issued Japanese patent, and two issued Indian patents. These make up 15 patent families which have been filed in the U.S. and internationally.

Our intellectual property portfolio covers several methods and treatments for neurological disorders through the use of various approved drugs or other agents. In addition to NTx®-265, our intellectual property portfolio anticipates adding other products in our pipeline, as well as forming out-licensing opportunities. We intend to protect additional intellectual property developed by the Company through the filing of patent applications within the appropriate jurisdictions throughout the world.

Additionally, during the term of a research contract with an Alberta-based university and the laboratory of Dr. Weiss, under which we pay consideration to such Alberta-based university, we in turn acquire 100% ownership in any new intellectual property developed by Dr. Weiss and his research group pertaining to the development of novel methods to induce neurogenesis. Through this agreement the Company continues to file intellectual property protection around these assets, the cost of which is expensed.

### **Financial performance**

The Company's loss for the six month period ended June 30, 2009 decreased by \$1,018,030 to \$1,873,995 (\$0.01 per common share) from the loss of \$2,892,025 (\$0.03 per common share) reported for the six month period ended June 30, 2008. The primary reasons for the decrease in loss were decreases in research and development costs, general and administration expenses, management and consulting fees and deemed interest charges offset by a decrease in interest income earned during the period.

Detailed analysis follows:

### **Research and Development**

The Company's research and development costs consist primarily of fees paid to external service providers. SCT's research and development expenses are expected to increase significantly over

the next few years as products advanced through clinical trials. As a result of the risks and uncertainties that are discussed in the “Risk and Uncertainties” section, we are unable to precisely estimate the specific timing and future costs of our research and development programs.

All research and development costs are expensed, and total \$8,807,143 since inception.

Research and development costs decreased to \$852,833 for the six months ended June 30, 2009 from \$1,417,626 for the six months ended June 30, 2008. This decrease of \$564,793 was primarily due to the suspension of the phase IIb clinical trials offset by an increase in preclinical development costs throughout the second quarter of 2009 as the Company investigated alternate stroke regimen options from within its patent portfolio that did not involve EPO.

The following is a breakdown of R&D costs for the periods indicated:

	<b>For the three month period ended June 30, 2009</b>	For the three month period ended June 30, 2008	<b>For the six month period ended June 30, 2009</b>	For the six month period ended June 30, 2008	Cumulative from inception on March 31, 2004 to June 30, 2009
	\$	\$	\$	\$	\$
Clinical development	277,988	421,203	318,906	644,043	2,954,884
Preclinical development	(4,000)	80,373	249,052	160,746	1,666,216
Research	53,200	42,000	67,200	84,000	980,374
Salaries and bonuses	87,834	117,677	152,209	237,361	1,279,411
Consulting fees	8,679	68,408	49,160	175,304	831,036
Licensing Costs	-	-	-	-	584,287
Other costs	6,851	43,074	16,306	116,172	510,935
<b>Research and development expenses</b>	<b>430,552</b>	<b>772,735</b>	<b>852,833</b>	<b>1,417,626</b>	<b>8,807,143</b>

### Professional Fees

Professional fees reflect charges for intellectual property development (i.e. patents), general corporate legal fees with regards to ongoing corporate matters, as well as accounting and audit services.

Since inception, these fees total \$3,058,002. Professional fees for the six months ended June 30, 2009 decreased by \$20,042 to \$337,570 from \$357,612 for the six months ended June 30, 2008.

The following is an analysis of professional fees charges for the periods indicated:

	<b>For the three month period ended June 30, 2009</b>	For the three month period ended June 30, 2008	<b>For the six month period ended June 30, 2009</b>	For the six month period ended June 30, 2008	Cumulative from inception on March 31, 2004 to June 30, 2009
	\$	\$	\$	\$	\$
Auditing and accounting fees	21,168	15,995	21,168	31,128	375,748
Legal fees – Intellectual	112,532	164,322	268,775	292,372	2,310,882

property					
Legal fees – Other	32,330	14,084	47,627	34,112	371,372
Total professional fees	166,030	194,401	337,570	357,612	3,058,002

### Management and Consulting Fees

Management and consulting fees decreased to \$163,616 for the six month period ended June 30, 2009 from \$339,658 for the six month period ended June 30, 2008. This decrease of \$176,042 was due to the cost cutting initiative led by the Company starting in the fourth quarter of 2008. This has included a decrease in Management salaries, the Directors fees paid and a reduction in external consultants employed.

### General and Administration (G&A)

General and administrative expenses decreased by \$386,975 to \$249,383 for the six months ended June 30, 2009 from \$636,358 for the same period in 2008. This was also due to the cost cutting initiative that reduced office costs, staff levels, travel expenses and investor relation costs.

### Stock-based Compensation

Stock-based Compensation since inception total \$1,884,725. Charges for the six months ended June 30, 2009 increased to \$179,757 from \$154,923 for the six months ended June 30, 2008. The increase was due to the recently granted stock options.

The following table shows the granted, exercised, forfeited and outstanding options under the Company's stock option plan as at August 25, 2009. All options have a five year expiry from the date of grant and either vest immediately, six months or three years after the grant date.

Number of Options Granted	Number of Options Exercised	Number of Options Forfeited	Number of Options Outstanding
15,220,000	1,830,000	2,387,500	11,002,500

### Intellectual Property

The value of the intellectual property purchased from Transition Therapeutics Inc. ("Transition") on October 4, 2004 was recorded based on the present value of the purchase price amortized over a 10 year period at 15% as an intellectual property asset.

The change in net intellectual property balance from December 31, 2008 is limited to the effect of amortization calculated during the six month period ended June 30, 2009.

The Company continues to file patents on all new intellectual property that is developed under the research contract with an Alberta-based university and contracts with independent research organizations and internally by the Company.

The Company currently owns 80 pending patent applications, six issued U.S. patents, four issued Australian patents, one issued Japanese patent, and two issued Indian patents. These make up 15 patent families which have been filed in the U.S. and internationally.

## Amortization

Total amortization charges of property and equipment since inception are \$165,651. Amortization charges for property and equipment decreased to \$14,231 for the six months ended June 30, 2009 from \$14,284 for the six months ended June 30, 2008. This decrease of \$53 was due to computer equipment becoming fully amortized in 2009. All amortization was calculated on a straight line basis over the estimated useful lives of the assets.

Amortization charges for intellectual property assets remained constant (\$121,564 for the six month period ended June 30, 2009 and \$121,557 for June 30, 2008). No intellectual property asset additions were made during six month period ended June 30, 2009.

The Company anticipates that intellectual property assets amortization charges will remain within the same level during 2009 as there are no plans for major additions to existing intellectual property assets to be capitalized. All amortization was calculated on a straight-line basis over the estimated useful lives of the assets.

## Revenue

As an early development stage biotechnology company, SCT has not generated any revenues from product sales to date and does not expect to do so for a number of years. This is primarily due to the long time line that is required to develop drugs that are proven in a clinical setting in humans to be safe and useful for treating a particular disease state. Revenues to date include only interest income generated on our cash balances.

Interest income for the six month period ended June 30, 2009 was \$14,707 (\$2,686 for the three month period then ended) as compared to \$185,808 for the six month period ended June 30, 2008. This decrease of \$171,101 in interest income primarily resulted from lower cash balances throughout the six month period ended June 30, 2009 as well as lower interest rates earned on the Company's cash balances during the current period. Since inception the total interest earned by the Company amounted to \$610,548.

## Summary of Quarterly Results

	As at, and for the three months ended							
	2009 June \$	March \$	2008 December \$	September \$	June \$	March \$	2007 December \$	September \$
Revenue <sup>(1)</sup>	<b>2,686</b>	12,021	(16,322)	63,737	68,237	117,571	58,183	35,242
Net loss	<b>989,236</b>	884,759	1,232,781	1,434,711	1,537,839	1,354,186	2,087,895	1,276,496
Basic and diluted loss per common share	<b>0.01</b>	0.01	0.01	0.01	0.01	0.01	0.02	0.02
Total assets	<b>5,839,464</b>	7,235,834	8,248,255	9,468,938	10,616,754	11,994,405	13,085,155	4,499,181
Unrestricted cash and cash equivalents	<b>4,267,042</b>	5,456,232	6,400,486	7,311,748	8,394,583	9,737,180	10,764,097	2,285,870
Total long-term obligations <sup>(2)</sup>	-	1,199	3,192	6,022	7,350	8,678	10,007	11,721

Notes:

(1) Interest income on cash and cash equivalents balances

- (2) Includes capital lease obligations and obligation under share purchase agreement.  
(3) The Company has not declared or paid any dividends since incorporation.

The quarterly results of the Company reflect continuing losses as the Company continues its preclinical and clinical development activities and incurs administrative costs to sustain activities.

## **Liquidity and Capital Resources**

### **Overview**

The Company's primary capital needs are for funds to support its scientific research and development activities including pre-clinical and clinical trials and for working capital.

The Company's unrestricted cash and short-term investments totaled \$4,267,042 at June 30, 2009. The Company may require additional funding in order to complete the clinical trials. There is no assurance that such financing will be available if and when required.

As of June 30, 2009 the working capital (current assets minus current liabilities) of the Company was \$4,241,743 (\$5,803,377 as of December 31, 2008).

Outstanding securities as of June 30, 2009 totaled 132,802,497 common shares, 18,975,000 share purchase warrants, and 11,002,500 common share options.

Outstanding securities as of August 25, 2009 are 134,680,497 common shares, 17,097,000 common share purchase warrants, and 11,002,500 common share options.

The Company has raised significant operating capital since its inception on March 31, 2004. On January 6, 2005 the Company closed its Initial Public Offering issuing 34,000,000 common shares at a price of \$0.25 per share which raised gross proceeds of \$8,500,000. On February 1, 2007 the Company closed a \$2.0 million private placement of 10 million units; each unit consisting of one common share of SCT and one-half of one common share purchase warrant. Each full warrant entitled the holder to purchase one additional common share of SCT for \$0.25 until February 1, 2009. On March 27, 2007 the Company closed a second \$2.0 million private placement of 4 million units, each unit consisting of one common share of SCT and one-half of one common share purchase warrant. Each full warrant entitled the holder to purchase one additional common share of SCT for \$0.75 per share in the first year and \$1.00 per share until the end of the second year. On November 9, 2007, the Company closed a bought deal financing with a syndicate of underwriters. Gross proceeds of \$12.075 million were raised, which included the exercise in full of a 15% overallotment option, resulting in 34,500,000 Units (the "Units") being sold to the public pursuant to a short form prospectus. The Units were sold to the public at a price of \$0.35 per Unit with each Unit consisting of one common share of the Company and one-half of one common share purchase warrant. Each whole warrant is exercisable to acquire one additional common share of the Company at a price of \$0.50 per share for 30 months. In addition, the Company issued 1,725,000 Broker warrants entitling warrant holders to acquire one common share at a price of \$0.35 per share for a period of 30 months after the closing of the financing. The net proceeds to the Company from the sale of the Units were approximately \$10.9 million after deducting the underwriters' fee and the expenses of the offering. Pursuant to an early warrant exercise incentive program that closed on August 7, 2009, warrant holders exercised 1,878,000 warrants for the same number of common shares and provided the Company with \$300,480 in proceeds.

As of August 25, 2009 the gross proceeds raised since inception by the Company totaled \$26,920,893. These capital resources have provided the means to advance our lead product NTx®-265 through the Phase IIa clinical trial final reporting period and into commencement of the Phase IIb clinical trial program, as well as additional programs for other indications including TBI and MS, and to meet working capital and current corporate needs, including but not limited to costs associated with ensuring the protection of the Company's intellectual property.

The Company's ability to continue operation in the long run is contingent upon its ability to obtain additional sources of funding to finance future operations. Efforts will be made to obtain these additional funds, but there is no assurance in the current economic climate that additional financing will be available on acceptable terms, if at all.

### **Investing Activities**

The Company has invested capital into intellectual property development and patent filing activities and basic corporate office infrastructure. Cash balances are currently invested in interest bearing Guaranteed Investment Certificates, interest-bearing and non interest-bearing bank accounts.

### **Commitments and Contingencies**

#### **[a] Operating leases**

The Company leases its office space under a contract which covers a one year period effective from July 1, 2009. Annual costs under this contract are limited to an annual rent charge of \$55,400 and annual operating costs and property taxes estimated to be \$51,716 with a total committed cost of \$107,116 for the term of the lease.

#### **[b] Research contracts**

The Company has an ongoing research contract with an Alberta-based university. In 2008, the monthly charges under this contract amounted to \$14,000. As part of the Company's cost cutting initiative, this contract was reduced to a monthly cost of \$7,000 for the first six months of 2009.

Expected future costs under a cross-licensing agreement that the Company entered into in 2006 include an ongoing annual license maintenance fee of US \$50,000.

#### **[c] Contingency**

Pursuant to the share purchase agreement from Transition, royalty payments may become due and payable in accordance with this agreement upon realization of sales or licensing of patent rights from intellectual property in the Stem Cell Therapeutics Inc. portfolio. When the Company realizes sales of products or processes, a royalty of 2% of net sales will become payable to Transition. In addition, if patent rights are licensed, a royalty of 5% of the consideration for such licenses will become payable.

The Company entered into a cross licensing agreement in 2006 with a third party. In 2008, the Company paid US\$150,000 as per the agreement (nil in 2007). Future payments of (a) US\$500,000 is payable upon the successful completion of a Phase II clinical trial using the drugs referenced under the cross-license agreement, and (b) US\$1,000,000 payment payable upon its commercialization.

## **Changes to Accounting Policies**

These consolidated financial statements have been prepared using the accounting policies described in the December 31, 2008 audited consolidated financial statements.

### **Recent accounting pronouncements**

In 2006, the Accounting Standards Board (“AcSB”) adopted a new strategic plan for financial reporting in Canada, “Accounting Standards in Canada: New Directions”. For publicly accountable enterprises (“PAEs”), the AcSB will converge Canadian GAAP with International Financial Reporting Standards (“IFRS”) over a period from 2006 to 2011. After this time period, Canadian GAAP will be replaced by IFRS and cease to exist as a separate, distinct basis of financial reporting for PAEs. Canada will continue to maintain its own standard-setting capability to carry out the strategic direction outlined above, although roles, structures, processes and resources may evolve.

In 2009, the Company plans to commence the process to transition from current Canadian GAAP to IFRS. The Company’s transition plan, which in certain cases will be in process concurrently as IFRS is applied, includes the following three phases:

1. Scoping and diagnostic phase: This phase involves performing a high-level diagnostic assessment to identify key areas that may be impacted by the transition to IFRS. As a result of the diagnostic assessment, the potentially affected areas are ranked as high, medium or low priority.
2. Impact analysis, evaluation and design phase: In this phase, each area identified from the scoping and diagnostic phase will be addressed in order of descending priority. This phase involves specification of changes required to existing accounting policies, information systems and business processes, together with an analysis of policy alternatives allowed under IFRS.
3. Implementation and review phase: This phase includes execution of changes to information systems and business processes, completing formal authorization processes to approve recommended accounting policy changes and training. At the end of the implementation and review phase the Company will be able to compile financial statements compliant with IFRS.

The regulatory bodies that establish Canadian GAAP and IFRS have significant ongoing projects that could affect the ultimate differences that impact the Company’s consolidated financial statements in future years.

### **Risks and Uncertainties**

Prospects for companies in the biotechnology industry may generally be regarded as uncertain given the nature of the industry. Accordingly, investments in biotechnology companies should be regarded as highly speculative. The realization of the Company’s long-term potential will be dependent upon the successful development and commercialization of products and product candidates currently under development. The Company can make no assurance that these products and product candidates will be developed or that they will receive regulatory approval. New products and product candidates currently in the research and development stages are the highest risk stages for a company in the biotechnology industry.

SCT can make no assurance that its research and development programs will result in commercially viable products and product candidates. To achieve profitable operations, the Company, alone or with others, must successfully develop, launch and market its products and

product candidates. To obtain regulatory approvals for the products and product candidates being developed and to achieve commercial success, clinical trials must demonstrate that the products and product candidates are safe for human and/or animal use and that they demonstrate efficacy. Unsatisfactory results obtained from a particular study relating to a research and development program may cause the Company or its collaborators to abandon its commitments to that program. SCT can make no assurance that any future tests, if undertaken, will yield favorable results.

The continuation of the Company's research and development activity and the commercialization of its stem cell related technologies are dependent on the Company's ability to complete its research and development programs, achieve future profitable operations and finance its cash requirements. It will be necessary for the Company to raise additional funds for the continuing development and commercialization of its programs. The value of the Company's intangible assets could become impaired should its research and development activities change significantly or cease.

The Company has a significant number of patent filings in progress as well as others that were acquired through the Stem Cell Therapeutics Inc. purchase. The Company's success is dependent upon its ability to obtain patent grants in relevant jurisdictions; however, there is no guarantee patents will be granted, and, if granted, the Company may not be able to successfully defend any subsequent infringements to these patents. The Company is currently unaware that it has infringed any existing patents issued to third parties and the Company's success will, in part, depend on operating without such infringement. The presence of such patents could severely limit the Company's ability to conduct its existing research and/or require financial resources to defend litigation, which may be in excess of the Company's ability to raise such funds. Additionally, the Company relies on trade secrets, know-how and other proprietary information as well as requiring its employees, consultants, advisors and collaborators to sign confidentiality agreements.