

**STEM CELL**  

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**THERAPEUTICS**

**Stem Cell Therapeutics Corp.**

Management Discussion and Analysis  
For the period ended September 30, 2009

Dated: November 23, 2009

Dated November 23, 2009

The following information should be read in conjunction with the Company's unaudited financial statements as at and for the nine months ended September 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. and its wholly owned subsidiary Stem Cell Therapeutics Inc. 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 November 23, 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 beginning 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 ‘dose response design study’ (“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. The Phase IIb trial is being conducted at clinical sites in India, Canada and the United States. 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 the same design, as well as safety and efficacy endpoints.

On August 11, 2009, the Company announced the enrollment of its first patient in the modified REGENESIS Phase IIb stroke trial. It is expected that the Company will complete recruiting towards the end of Q1 2010 or early Q2 2010 in the modified REGENESIS phase IIb stroke trial using NTx®-265. A top-line read of the data is anticipated to be available at the end of Q2 2010 to early Q3 2010.

The estimated timing for the last five objectives for 2009 has been modified, as indicated below.

### **2009 Objectives**

- ✓ Present final BETAS Phase IIa study data at the 2009 International Stroke Conference, including all US and Canadian patient data; completed
- ✓ 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; end of Q1 2010-early Q2 2010
- Top-line read of modified REGENESIS Phase IIb stroke trial data; end of Q2 2010-early Q3 2010
- Initiate and enrol patients in a Phase IIa clinical study for traumatic brain injury; H1 2010
- Initiate clinical Proof-of-Concept study for multiple sclerosis; H1 2010
- Partnership/Co-Development deal in advanced stage for at least one indication; 2010

### **Operating results for the period July 1, 2009 to November 23, 2009**

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.

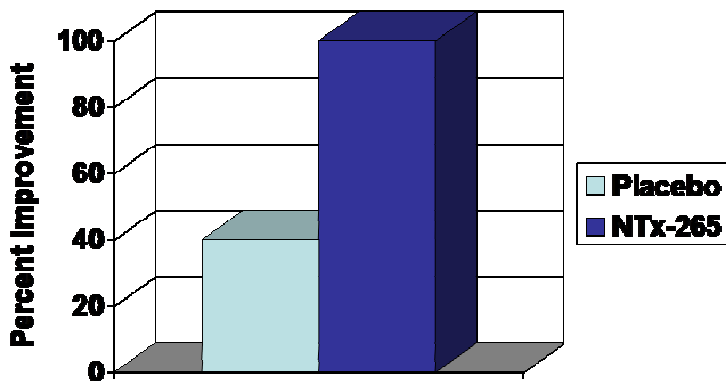
On July 20, 2009, SCT received a No Objection Letter (“NOL”) from Health Canada for the modified REGENESIS protocol using NTx®-265 for a Phase IIb clinical trial treating acute ischemic stroke.

On July 21, 2009, the Company 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.



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, Dr. Alan Moore, President and CEO, presented 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.

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.

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.

On September 11, 2009, Dr. V. Wee Yong, of the Hotchkiss Brain Institute from the University of Calgary, presented on behalf of SCT at the 25<sup>th</sup> Congress of the European Committee for the Treatment and Research in Multiple Sclerosis ("ECTRIMS") held in Düsseldorf, Germany, September 9-12, 2009. Dr. V. Wee Yong's presentation discussed the safety and efficacy of prolactin in the animal model of multiple sclerosis ("MS"), experimental autoimmune encephalomyelitis. The result of the work Dr. Yong and his team have done, has led to the design of a clinical trial in MS with Dr. Yong's colleagues at the University of Calgary, specifically Drs. Luanne Metz and Fiona Costello of the MS Clinic at the Foothills Medical Centre in Calgary, Alberta, and SCT.

On September 23, 2009, Dr. Alan Moore, President and CEO, was featured in the panel discussion "Commercialization of Stem Cells and International Market Trends" at the 2009 World Stem Cell Summit being held in Baltimore, Maryland, September 21-23.

On October 2, 2009, Dr. Alan Moore, presented at the Banff Venture Forum 2009 where he provided an overview of the Company's clinical and pre-clinical stage programs, including the Phase IIb stroke trial with Drs. Steven C. Cramer of the University of California, Irvine and Michael D. Hill of the Foothills Hospital at the University of Calgary, as co-lead investigators; as well as the soon-to-commence multiple sclerosis ("MS") phase II trial with prolactin, lead by Drs. Luanne Metz and Fiona Costello of the MS Clinic at the Foothills Medical Centre in Calgary, Alberta.

On October 8, 2009, SCT announced that it had entered into an Agent agreement under which they agreed to raise approximately \$1.0 million in connection with the sale of 8,340,000 units of the Corporation ("Units") at a price of \$0.12 per Unit (the "Offering"). Each Unit consisted of one common share of the Corporation ("Common Share") and one common share purchase warrant (the "Warrants"). Each Warrant entitles the holder thereof to purchase one Common Share at a price of \$0.15 at any time during the period of 12 months from the closing date. Additionally, SCT has granted the Agent an option to increase the Offering by up to \$500,000 on the same terms. Concurrently, the Corporation undertook to sell \$1.0 million of additional Units on a non-brokered private placement basis on the same terms as the Offering.

Dr. Alan Moore, President and CEO of SCT, commented on the Offering as follows:

"This financing will provide us with additional working capital to lengthen our runway after completion of the NTx™-265 stroke trial to facilitate potential partnering discussions. It will also allow us to support the initiation of a Phase II multiple sclerosis trial. We are pleased with the recruiting rate of the stroke trial to date, which currently stands at 17 enrolled patients. We have 10 sites recruiting patients at this time and expect to have additional sites recruiting by the end of the month. We are gratified with the support shown by our investors and the progress we have made at this early stage of the stroke trial."

On October 29, 2009, SCT announced that it had closed the previously announced financing. In total \$2,186,941 of gross proceeds were raised in this financing as consideration for the issuance of 18,224,507 units (“the Units”). The Units were sold to the public at a price of \$0.12 per Unit, with each Unit consisting of one common share of SCT (“Common Share”) and one common share purchase warrant (“Warrant”). Each Warrant is exercisable to acquire one additional Common Share at a price of \$0.15 per share for 12 months from the closing date. A total commission of \$165,835 was paid to registered dealers in connection with the financing. Additionally, as part of the Agent agreement, SCT issued 474,476 Broker Warrants. Each Broker Warrant is exercisable to acquire one Common Share at a price of \$0.12 per share for 12 months from the closing date.

On November 12, 2009, Dr. Allen Davidoff, Vice President of Product Development, presented at the 2009 Neural Regeneration Workshop which took place in Albuquerque, New Mexico at the Sandia National Laboratories, a U.S. Government facility. Dr. Davidoff discussed “A drug based approach to Neurogenesis and recovery after acute neurologic injury”. Sandia National Laboratories and the Center for Neurotechnology Studies of the Potomac Institute for Policy Studies hosted a workshop series to gather information on the restoration of neural function through treatments involving replacement of injured and diseased brain tissue. One of the key objectives of this workshop series was to discover treatments that restore lost or damaged brain tissue in order to support function recovery, specifically relating to traumatic brain injury developed in combat. Two parallel workshops were held, the first was in Washington DC on November 4, 2009; and the second in Albuquerque, NM on November 12, 2009. The objective of these workshops was to assess the scientific and technical state-of-the-art treatments and chart a path of research and development leading to innovation in the treatment of brain injury and disease through restoration of neural tissue.

On November 20, 2009, SCT announced it has been advised by the Data Safety Monitoring Board (“DSMB”) that a regularly scheduled safety analysis has been completed and the DSMB has recommended the Phase IIb stroke trial to continue as per the protocol. The DSMB is a group of independent clinical experts that review the ongoing conduct of a clinical trial to ensure continuing patient safety.

Dr. Alan Moore, President and CEO, commented as follows:

“We are very pleased to receive a positive safety review of the Phase IIb stroke trial. Review results and enrollment updates will be announced after each DSMB meeting as progress continues for the Phase IIb trial. We are also happy to report that 32 patients are currently enrolled in our Phase IIb stroke study. At this time, we estimate that Phase IIb patient enrollment will be complete by the end of Q1 2010 or early in Q2 2010. This will be followed by a 90-day period for completion of patient assessments so we expect top-line data to be available by the end of Q2 2010 or early in Q3 2010.”

## **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.

Due to an unrelated German clinical study, the REGENESIS Phase I Ib 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 'dose response design study' ("modified") REGENESIS Phase I Ib 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. The Phase I Ib trial is being conducted at clinical sites in India, Canada and the United States. 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 the same design, as well as safety and efficacy endpoints.

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 I Ib 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 I Ib 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 I Ib clinical stroke program.

The Company is currently recruiting patients for the modified REGENESIS Phase I Ib stroke trial and expects to complete all patient recruitment near the end of Q1 2010, early Q2 2010. Given that the protocol has a 90 day end-point, we anticipate a top-line data read by the end of Q2 2010, early Q3 2010. As of November 23, 2009, we have enrolled 34 patients in the modified REGENESIS Phase I Ib stroke trial and 12 sites are recruiting for the trial.

## *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.

The successful completion of a preliminary non-clinical study was undertaken by Dr. V. Wee Yong of the Hotchkiss Brain Institute and a Professor in the Departments of Oncology and Clinical Neurosciences at the University of Calgary. The non-clinical results were presented by Dr. V. Wee Yong on September 11, 2009 at the 25<sup>th</sup> Congress of European Committee for the Treatment and Research in Multiple Sclerosis held in Dusseldorf, Germany. The follow-on clinical study that will be lead by Drs. Luanne Metz and Fiona Costello, of the MS Clinic at the Foothills Medical Centre in Calgary, is anticipated to begin H1 2010. This study will be funded by an outside grant to the University of Calgary by the Canadian Stem Cell Network, excluding drug costs.

## **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, seven 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 nine month period ended September 30, 2009 decreased by \$957,537 to \$3,369,200 (\$0.03 per common share) from the loss of \$4,326,737 (\$0.04 per common share) reported for the nine month period ended September 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 an increase in the stock option expense and 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 \$9,660,741 since inception.

Research and development costs decreased to \$1,706,431 for the nine months ended September 30, 2009 from \$2,162,370 for the nine months ended September 30, 2008. This decrease of \$455,939 was primarily due a reduction of phase IIb clinical trial consulting fees, salaries and bonuses, offset by an increase in preclinical development costs throughout 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 September 30, 2009</b>	For the three month period ended September 30, 2008	<b>For the nine month period ended September 30, 2009</b>	For the nine month period ended September 30, 2008	Cumulative from inception on March 31, 2004 to September 30, 2009
	\$	\$	\$	\$	\$
Clinical development	651,486	451,207	970,392	1,095,250	3,606,370
Preclinical development	(3,243)	31,374	245,809	192,120	1,662,973
Research	26,600	42,000	93,800	126,000	1,006,974
Salaries and bonuses	78,833	76,165	231,043	313,526	1,358,245
Consulting fees	18,727	67,728	67,887	243,032	849,763
Licensing Costs	54,800	51,075	54,800	51,075	639,087
Other costs	26,394	25,195	42,700	141,367	537,329
Research and development expenses	853,597	744,744	1,706,430	2,162,370	9,660,740

### 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 \$3,205,455. Professional fees for the nine months ended September 30, 2009 decreased by \$27,348 to \$485,023 from \$512,371 for the nine months ended September 30, 2008.

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

	<b>For the three month period ended September 30, 2009</b>	For the three month period ended September 30, 2008	<b>For the nine month period ended September 30, 2009</b>	For the nine month period ended September 30, 2008	Cumulative from inception on March 31, 2004 to September 30, 2009
	\$	\$	\$	\$	\$
Auditing and accounting fees	10,000	-	31,168	31,128	385,748
Legal fees – Intellectual property	134,952	137,655	403,727	430,027	2,445,834
Legal fees – Other	2,501	17,104	50,128	51,216	373,873
Total professional fees	147,453	154,759	485,023	512,371	3,205,455

### Management and Consulting Fees

Management and consulting fees decreased to \$236,002 for the nine month period ended September 30, 2009 from \$592,538 for the nine month period ended September 30, 2008. This decrease of \$356,536 was due to the cost cutting initiative led by the Company starting in the fourth quarter of 2008 and a severance payment made in 2008. The cost cutting initiative 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 \$428,741 to \$395,544 for the nine months ended September 30, 2009 from \$824,015 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 \$2,048,970. Charges for the nine months ended September 30, 2009 increased to \$344,404 from \$237,051 for the nine months ended September 30, 2008. The increase was due to the stock options granted in 2009.

The following table shows the granted, exercised, forfeited and outstanding options under the Company's stock option plan as at November 23, 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.

<b>Number of Options Granted</b>	<b>Number of Options Exercised</b>	<b>Number of Options Forfeited</b>	<b>Number of Options Outstanding</b>
<b>16,355,000</b>	<b>1,830,000</b>	<b>2,507,500</b>	<b>12,017,500</b>

## 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 nine month period ended September 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, seven 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 \$172,627. Amortization charges for property and equipment decreased to \$21,207 for the nine months ended September 30, 2009 from \$21,629 for the nine months ended September 30, 2008. This decrease of \$422 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 increased slightly to \$182,346 for the nine month period ended September 30, 2009 from \$182,337 for the nine month period ended September 30, 2008.

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 nine month period ended September 30, 2009 was \$15,026 (\$319 for the three month period then ended) as compared to \$249,545 for the nine month period ended September 30, 2008. This decrease of \$234,519 in interest income primarily resulted from lower cash balances throughout the nine month period ended September 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 \$610,867.

## Summary of Quarterly Results

	As at, and for the three months ended							
	2009			2008				2007
	September	June	March	December	September	June	March	December
	\$	\$	\$	\$	\$	\$	\$	\$
Revenue <sup>(1)</sup>	319	2,686	12,021	(16,322)	63,737	68,237	117,571	58,183
Net loss	1,495,524	989,236	884,759	1,232,781	1,434,711	1,537,839	1,354,186	2,087,895
Basic and diluted loss per common share	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02
Total assets	5,006,769	5,839,464	7,235,834	8,248,255	9,468,938	10,616,754	11,994,405	13,085,155
Unrestricted cash and cash equivalents	3,517,483	4,267,042	5,456,232	6,400,486	7,311,748	8,394,583	9,737,180	10,764,097
Total long-term obligations <sup>(2)</sup>	-	-	1,199	3,192	6,022	7,350	8,678	10,007

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 \$3,517,483 at September 30, 2009.

As of September 30, 2009 the working capital (current assets minus current liabilities) of the Company was \$3,279,422 (\$5,803,377 as of December 31, 2008). Subsequent to the recent financing which closed on October 29, 2009, the working capital as of November 23, 2009 is estimated to be \$4.3 million.

Outstanding securities as of September 30, 2009 totaled 134,680,497 common shares, 17,097,000 share purchase warrants, and 12,017,500 common share options.

Outstanding securities as of November 23, 2009 are 152,905,004 common shares, 34,070,983 common share purchase warrants, and 12,017,500 common share options.

The Company has raised significant operating capital since its inception on March 31, 2004. As of November 23, 2009 the gross proceeds raised by the Company totalled \$29,107,834.

In 2009, the Company has raised at total of \$2,487,421 in gross proceeds. 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. Proceeding after a financing which closed on October 29, 2009, a total of \$2,186,941 gross proceeds were raised as consideration for the issuance of 18,224,507 units at a price of \$0.12. Each unit consisted of one common share of the Corporation and one common share purchase warrant. Each Warrant is exercisable to acquire one additional Common Share at a price of \$0.15 per share for 12 months from the closing date. A total commission of \$165,835 was paid to registered dealers in connection with the financing. Additionally, the Agent acting on behalf of the Company received 474,476 Broker Warrants. Each Broker Warrant is exercisable to acquire one Common Share at a price of \$0.12 per share for 12 months from the closing date.

The capital resources raised by the Company, have provided the means to advance its 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.

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.