

ProtoX

THERAPEUTICS

2009 annual report

## **MANAGEMENT'S DISCUSSION AND ANALYSIS**

The following management's discussion and analysis ("MD&A") has been prepared as of March 29, 2010 and should be read in conjunction with our audited financial statements for the year ended December 31, 2009 and the Company's Annual Information Form, dated March 29, 2010 (collectively known as the "Financial Statements"). All the financial information has been prepared in accordance with Canadian generally accepted accounting principles ("Canadian GAAP") and all dollar amounts are expressed in Canadian dollars unless otherwise noted. Additional information relating to Protox Therapeutics Inc., including the Company's Financial Statements, can be found on SEDAR at [www.sedar.com](http://www.sedar.com) and on our website at [www.protoxtherapeutics.com](http://www.protoxtherapeutics.com).

## **ABOUT FORWARD-LOOKING STATEMENTS**

This document contains forward-looking statements, which reflect our current expectations regarding future events. Forward-looking statements may include such words as "plans", "expects", "estimates", "forecasts", "intends", "anticipates", "believes" or "continues" or variations of such words and phrases or statements that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved. With respect to forward-looking statements and information included herein, we have made numerous assumptions including among other things, assumptions about our future financing requirements and our ability to meet our obligations, our ability to meet regulatory requirements, the anticipated market for our products and our ability to achieve our goals. Even though our management believes that the assumptions made and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking statements will prove to be accurate. By their nature, forward-looking statements and information are based on assumptions and involve known and unknown risks, uncertainties and other factors, many of which are beyond the Company's control that may cause our actual results, events or developments to differ materially from those that are expressed or implied by such forward-looking information. Such risks, uncertainties and other factors include, among other things, the following: negative results from our clinical studies; drug product supply for our clinical trials; inability to fund our development programs; unexpected delays in drug discovery, clinical development and manufacturing; program delays due to reliance on third-party service providers; raw material and operating costs; changes in government regulation; fluctuations in demand and supply for our products; industry production levels; general economic and business conditions; our ability to execute our business plan; and those additional risks set forth under the heading "Risk Factors" in our Annual Information Form for our financial year ending December 31, 2009. Should one or more of these risks or uncertainties materialize, or should assumptions underlying the forward-looking statements or information prove incorrect, actual results may vary materially from those described herein as intended, planned, anticipated, believed, estimated, expected or continued. Accordingly, readers should not place undue reliance on forward-looking statements or information. We undertake no obligation to reissue or update forward-looking statements or information as a result of new information or events after the date hereof except as may be required by law. All forward-looking statements and information made in this document are qualified by this cautionary statement pursuant to the "safe harbour" provisions of applicable securities legislation.

## **COMPANY OVERVIEW**

Protox Therapeutics Inc. (the "Company" or "Protox") is a biopharmaceutical company focused on the research, development and commercialization of novel receptor targeted therapeutic fusion proteins. These fusion proteins are designed to specifically deliver potent payloads to targeted tissues or cells to either cause cell death or promote survival without the side-effects normally associated with conventional therapeutics.

Protox is advancing a pipeline of receptor targeted therapeutic fusion proteins based on three complementary technology platforms: PORxin™, INxin™ and HUMxin™. The payloads used to generate our lead compounds are derived from genetically engineered bacterial toxins or fully human Bcl-2 family of proteins. Our current focus is on the PORxin platform and our lead candidate, PRX302, has now completed three clinical trials for the treatment of benign prostatic hyperplasia ("BPH", commonly known as enlarged prostate) as well as localized prostate cancer. The INxin candidate, PRX321 has received approval from the U.S. Food and Drug Administration ("FDA") for a Phase 2b (pre-pivotal) clinical trial for the treatment of recurrent glioblastoma multiforme ("GBM") - the most lethal form of brain cancer. Advancement of the INxin program will occur once partners or collaborators have been secured to fund further development activities. The HUMxin platform is in pre-clinical development and will be advanced once the Company is successful in securing non-dilutive research grants.

The Company continues to work in partnership with co-inventors of the PORxin, INxin and HUMxin platforms as well as experts and key opinion leaders, or KOLs, in the field in order to guide the Company in the successful development of our lead candidates as well as strengthen our product pipeline.

## **ACHIEVEMENTS & HIGHLIGHTS**

The following are the achievements and highlights since 1<sup>st</sup> January, 2009:

- In December, 2009, the Company completed its multi-centre, double-blinded placebo controlled Phase 2b study of PRX302 (study name: TRIUMPH) in patients with moderate to severe benign prostatic hyperplasia. Positive top-line results from the study were released on January 11, 2010 indicated that the TRIUMPH study achieved its primary clinical endpoint of a statistically significant improvement in International Prostate Symptom Score for patients treated with PRX302 versus subjects receiving placebo.
- The Company announced positive 12 month data from our open-label Phase 2 study of PRX302 in males with moderate to severe benign prostatic hyperplasia. The study results indicated that those patients who received an optimal dose of PRX302 continued to demonstrate significant symptomatic relief at 12 months following a single treatment. The results from this study demonstrate the durable impact that this novel therapeutic has on potentially improving the quality of life of patients suffering with BPH.
- Data from the Phase 2 clinical study of PRX302 in patients with moderate to severe benign prostatic hyperplasia was presented at the 2009 Annual Meeting of the American Urological Association, the world's largest gathering of urology professionals.
- In May 2009, the Company closed a brokered private placement raising net proceeds of \$2.0 million from the issuance of 8,554,004 common shares. Proceeds included approximately \$800,000 from the exercise of an over-allotment option by the agent.

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- On March 16<sup>th</sup> 2010, the Company closed a brokered private placement raising net proceeds of \$4.8 million from the issuance of 11,285,388 units at a price of \$0.45 per unit. Each Unit is comprised of one common share of Protox and one-half of a common share purchase warrant. Each whole warrant entitles the holder to purchase one common share of Protox at a price of \$0.65 for a five year period from closing date subject to an acceleration of the expiry date in certain circumstances.
- An allowance was obtained in Japan by the Japan Patent Office for the Company's composition patent of PRX302 and its use in prostate cancer. In addition, an allowance in China was obtained for the Company's patent covering composition of PRX302 and its use in prostate cancer.
- The Company and/ or its collaborators published or presented 10 papers in various peer reviewed journals and international conferences based on the Company's PORxin, INxin and HUMxin platforms.
- Dr. Alex Giaquinto was appointed to the Board of Directors in June 2009. Dr. Giaquinto is a 35 year veteran of the pharmaceutical industry during which time he held a number of senior regulatory affairs positions with Schering-Plough.
- The Company appointed Mr. John Parkinson as Chief Financial Officer in March 2009. Previously he was Vice President, Finance at Aspreva Pharmaceuticals and prior to that he worked with KPMG for 10 years.

## **RESEARCH & DEVELOPMENT UPDATE**

### **PORxin Platform**

#### *Placebo controlled BPH Study:*

During 2009, the Company continued to advance its program for the treatment of benign prostatic hyperplasia. The Company's third clinical trial of PRX302 in BPH - a multi-centre, double blinded, placebo controlled Phase 2b study (study name: TRIUMPH) in males with moderate to severe BPH - was initiated and completed during the year, with top level results released on January 11, 2010.

The study achieved its primary clinical endpoint of a statistically significant improvement in International Prostate Symptom Score (IPSS) for patients treated with PRX302 versus subjects receiving placebo. IPSS is a validated accepted clinical end-point used to assess the treatment benefit in BPH clinical studies. The IPSS index is measured on a 0-35 scale with 0 defined as having no problems and 35 defined as the high end of severe symptoms.

Enrolment criteria included baseline IPSS scores greater than or equal to 15, a maximum urinary flow rate (Q<sub>max</sub>) of less than 12 milliliters per second and prostate volume between 30 and 100 milliliters. Each subject was treated with either PRX302 (3 µg/mL) or placebo at a volume equivalent to 20 percent of the total prostate volume via a single ultrasound guided injection into each lobe of the prostate.

The trial's primary clinical endpoint of the study was to determine the efficacy of PRX302, as demonstrated at 90 days post-treatment, by a statistically significant improvement in IPSS from baseline when compared to placebo.

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Of the 73 per protocol efficacy evaluable subjects, 52 received PRX302 and 21 received placebo. The PRX302 arm showed an average IPSS improvement at 90 days of 9.1 ( $\pm$  5.9) points versus an average IPSS improvement of 5.8 ( $\pm$  5.4) points for the placebo arm, a statistically significant improvement of 3.3 points ( $p=0.0238$ , ANCOVA). Baseline average IPSS for the PRX302 and placebo groups were 23.5 and 22.9 points, respectively.

A sub-group analysis was performed for subjects with severe BPH (baseline IPSS $>22$ ,  $n=40$ ). Results of this sub-group analysis showed that those treated with PRX302 had an average IPSS improvement at 90 days from baseline of 10.8 ( $\pm$  6.0) versus an improvement of 5.8 ( $\pm$  6.2) for those receiving placebo for an overall 5.0 point improvement over placebo. No significant safety issues were identified in this study. There were no drug related serious adverse events or Grade 3 or greater adverse events reported in the study. PRX302 related adverse events were mild to moderate, transient in nature (resolved within days) and localized to the urinary tract. In addition, no sexual dysfunction was reported in any of the subjects.

A total of 92 subjects were enrolled on a 2-to-1 basis (treatment to placebo) and randomized based on their baseline IPSS and prostate size. At 90 days, the number of per protocol efficacy evaluable subjects was 21 (mean age of 64.5 years) of the 31 that were dosed at baseline in the placebo arm and 52 (mean age of 63.7 years) of the 61 dosed at baseline in the PRX302 arm. The decrease in efficacy evaluable subjects was due to protocol violations, medical interventions, or patient withdrawal and included three subjects that needed surgery to treat BPH (all from the placebo arm).

Detailed results from this clinical trial will be presented by Professor Mostafa Elhilali, the Chief Co-Principal Investigator of the study, during a podium session at the Annual Meeting of the American Urological Association to be held in San Francisco, May 29 – June 3, 2010.

The Chief Co-Principal investigators for the TRIUMPH study were Dr Mostafa M. Elhilali, OC, M.D., Ph.D., Stephen Jarislowsky Chair in Urology at McGill University and Dr. Peter Pommerville, M.D., Director of Research at Can-Med Clinical Research Centre in Victoria, B.C. The study was conducted at 9 sites across Canada.

*Open label BPH study:*

During the third quarter of 2009, the Company announced positive 12 month data from its open-label Phase 2 study of PRX302 in males with moderate to severe benign prostatic hyperplasia. The study results indicate that those patients who received an optimal dose of PRX302 continued to demonstrate significant symptomatic relief at 12 months following a single treatment. A twelve point improvement in the International Prostate Symptom Score was observed in this patient group after one year following a single treatment, almost double that seen with oral therapies and comparable to many surgical procedures. The results demonstrate the durable impact that this novel therapeutic has on potentially improving the quality of life of patients suffering with BPH and demonstrates the ability of PRX302 to improve lower urinary tract symptoms (LUTS) while maintaining a good safety profile.

In this Phase 2 open-label volume optimization study, 13 of the 18 patients received the optimum PRX302 dosing of  $> 1\text{mL}$  per deposit. A total of 11 of the 13 patients were evaluable at 12-months and continued to show a statistically significant and sustained improvement in IPSS of 12.1 points ( $p= 0.0003$ ) representing a 55% improvement when compared to baseline. In addition

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to IPSS, Quality of Life (QoL) scores improved significantly by an average of 3.18 points or 67% ( $p < 0.0001$ ) at 12 months post-treatment. Furthermore, prostate volume at 12 months post-treatment decreased significantly by 29% ( $p=0.02$ ). Finally, the average maximum urine flow rate (Qmax) increased from 10.7mL/sec at screening to 15.2 mL/sec at 12 months for a 42% improvement in patients receiving the optimum dose.

No safety issues were identified in this study, as increasing volumes of PRX302 were seen to be well tolerated. No PRX302 related serious adverse events or Grade 3 or greater adverse events have been reported to date. The PRX302 related adverse events were mild to moderate, transient in nature (resolved within days) and localized to the urinary tract. In addition, no sexual dysfunction has been reported in any of the subjects dosed to date.

This was a single-arm, open-label, multi-centre, Phase 2 study in which increasing volumes of PRX302, at a fixed concentration of 3  $\mu\text{g/mL}$ , was administered into the prostates of men with moderate to severe BPH. Three cohorts of six subjects each received PRX302 at volumes equivalent to 10%, 20% or 30% of prostate volume. The intended volume for each subject was administered via a single injection consisting of three deposits into each lobe of the prostate under ultrasound guidance. Therapeutic activity was measured by the change in IPSS when compared to screening. In addition, changes in QoL scores and prostate volume, Qmax were also monitored. A total of 18 patients who were refractory, intolerant or unwilling to use alpha-blockers were enrolled in this study. Patient parameters at screening were as follows: age - 66.1 years (range: 49-80); prostate size - 49.2 cc (range: 30.0-74.0 cc); IPSS - 20.2 (range: 13-30); QoL - 4.5 (range: 3-6).

Detailed 12-month results from this Phase 2 open-label clinical trial were presented by Dr. Pommerville at the 30th World Congress of the Societe Internationale d'Urologie held in Shanghai in November 2009.

### **INxin Platform**

Based on encouraging Phase 1 and 2a study results of PRX321, the Company had anticipated initiating in 2009 a multi-centre Phase 2b (pre-pivotal) clinical trial in patients with recurrent malignant glioblastoma multiforme ("GBM"). Although the preparations for the study were completed, including FDA approval to proceed, patient enrolment was deferred until a suitable partner is identified to fund further clinical development of this program. The deferral of enrolment of this GBM study has enabled the Company to conserve cash and allocate resources to our lead PRX302 BPH clinical program.

The Company continues to support a collaborative research program with the FDA under the terms of a collaborative research and development agreement (CRADA) to further investigate IL-4R-directed agents such as PRX321 on various human tumours, including bladder and thyroid cancers.

In addition, the Company is currently collaborating with Dr. Bhaumik Patel, MD, PhD, on a research program evaluating PRX321 for colon, pancreatic and gastric cancer stem cells. This collaboration is being performed under a CRADA with the U.S. Department of Veterans Affairs and Metropolitan Detroit Research and Education Foundation.

An investigator-initiated collaboration is also underway with Dr. Robert Cameron, MD, at UCLA on evaluating PRX321 for treatment of malignant mesothelioma.

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**HUMxin Platform**

HUMxin, a next-generation platform technology in-licensed in 2007, is being developed in collaboration with the U.S. National Institutes of Health with an objective to develop novel receptor targeted fusion proteins, using the fully human Bcl-2 family of proteins as payloads, in order to accelerate or prevent apoptosis (programmed cell death). Further advancement of this program will take place once the Company has secured research grants to fund the ongoing costs.

In 2009, the Company continued collaborative research with the University of Alabama at Birmingham under the direction of Dr. Candace Floyd. This collaboration focused on three HUMxin compounds (PRX341, PRX342 and PRX343) and generated impressive preliminary results. All three compounds were shown to have a protective effect in animal models of spinal cord injury. The data from a large placebo-controlled double blinded study demonstrated significant functional improvement post-spinal cord injury in the rat as determined using two different types of injury assessments. In addition, the HUMxin compounds were shown to induce significant increases in neuronal survival, double the percentage of spared white matter, substantially reduce apoptotic cell death and promote significant recovery of lower urinary tract function. Subsequent studies in a guinea pig model of spinal cord injury also showed significant neural survival. Thus, based on these preliminary studies, HUMxin compounds are able to inhibit neuron apoptosis, thereby promoting the recovery of injured neurons and potentially delaying the progression of neurodegenerative diseases.

**Publications - Clinical, Pre-Clinical and Collaborative Research Programs**

During 2009, the following papers were published in peer reviewed journals or presented at various international conferences:

Title	Senior Author	Publication or Conference
Convection-enhanced drug delivery of interleukin-4 Pseudomonas exotoxin (PRX321): increased distribution and magnetic resonance monitoring	Dr. Zvi Ram	The Journal of Pharmacology and Experimental Therapeutics, Online issue dated, May 28, 2009
Long-term safety of combined intracerebral delivery of free gadolinium and targeted chemotherapeutic agent PRX321	Dr. John Sampson	Neurological Research, Online issue dated December 21, 2009

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Title	Senior Author	Publication or Conference
A review of studies on targeting interleukin-4 receptor for central nervous system malignancy	Dr BH Joshi	Current Molecular Medicine, August 2009, Volume 9(6), p.732-739
Identification and characterization of interleukin-4 receptor alpha chain human anaplastic thyroid carcinoma and targeting of IL-4 receptor for therapy	Dr. Raj Puri	24 <sup>th</sup> Annual Meeting of the International Society for Biological Therapy for Cancer, October 29-31, 2009, Washington, DC
<i>In vivo</i> overexpression of Interleukin 4 Receptor $\alpha$ (IL-4R $\alpha$ ) in a mouse model of human bladder carcinoma sensitizes tumors to recombinant chimeric immunotoxin consisting of Interleukin 4 and <i>Pseudomonas</i> exotoxin	Dr. Raj Puri	24 <sup>th</sup> Annual Meeting of the International Society for Biological Therapy for Cancer, October 29-31, 2009, Washington, DC
A PSA-activated protoxin (PRX302) administered transperineally to men with BPH is well tolerated and induces reduction in prostate volume and symptomatic relief	Dr. Peter Pommerville	Annual Meeting of the American Urological Association, 25 <sup>th</sup> – 30 <sup>th</sup> April, 2009 Chicago, USA
PRX302, a PSA-Activated Protoxin, is Well Tolerated and Induces Symptomatic Relief and Prostate Volume Reduction when Administered Transperineally to Men with BPH	Dr. Peter Pommerville	64 <sup>th</sup> Annual Meeting of the Canadian Urological Association, June 28 – July 1, 2009, Toronto, Canada
A PSA-activated protoxin (PRX302) administered transperineally to men with symptomatic benign hyperplasia is well tolerated and exhibits signs of activity	Dr. Peter Pommerville	Annual Congress of the European Association of Urology, 17 <sup>th</sup> – 21 <sup>st</sup> March, 2009, Stockholm, Sweden

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Title	Senior Author	Publication or Conference
PRX302 is a transperineally administered, PSA-activated protoxin that produces symptomatic relief in men with moderate to severe BPH	Dr Peter Pommerville	30 <sup>th</sup> Congress of Société Internationale d'Urologie, November 1-5, 2009, Shanghai, China
PRX303 is an IL-2 Proaerolysin Fusion Protein Toxin that Selectively Targets and Kills FOXP3 Regulatory T Cells: Potential Role as a Vaccine Adjuvant	Dr. Sam Denmeade	2009 Whistler Keystone Symposium: targeted Cancer Therapies, March 27 – April 1, 2009, Whistler, BC
Bcl fusion proteins: Therapeutic implications after spinal cord injury	Dr. Candace Floyd	2009 Joint Symposium of the International and National Neurotrauma Societies, September 7-11, 2009, Santa Barbara, California

**INTELLECTUAL PROPERTY**

We regard our patent and other proprietary technology rights as one of the foundation blocks upon which we continue to build a successful biopharmaceutical development company and, therefore, we file and prosecute patent applications to protect our proprietary discoveries.

During 2009, we supplemented our patent portfolio with allowances in Japan and China for the Company's patent covering composition of PRX302 and its use in prostate cancer.

Patents and patent applications covering the PORxin technology licensed or owned by the Company are currently being prosecuted under the following five patent families:

- i) Proaerolysin Containing Protease Activation Sequences and Methods of Use for Treatment of Prostate Cancer;
- ii) Method of Treating or Preventing Benign Prostatic Hyperplasia Using Modified Pore-Forming Proteins;
- iii) Modified Pore-Forming Protein Toxins and Use Thereof;
- iv) Modified Protein Toxins and Use Thereof for Treating Disease; and
- v) Method and Composition for Treating Prostatitis.

Eight issued patents in various territories, including the U.S., as well as Japan, Australia, India, China and South Africa, cover composition of matter and method of use for the PRX302 drug candidate and the PORxin technology. Several other patent applications are pending internationally.

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The INxin technology licensed by the Company is covered by issued patents and patent applications under the following six patent families:

- i) Fusion Proteins Comprising Circularly Permuted Ligands;
- ii) Circularly Permuted Ligands and Circularly Permuted Chimeric Molecules;
- iii) Convection-Enhanced Drug Delivery;
- iv) Method for Convection-Enhanced Delivery of Therapeutic Agents;
- v) Targeted Cargo Protein Combination Therapy; and
- vi) Treating Cancer Stem Cells Using Targeted Cargo Proteins.

Seven issued patents in the U.S., Europe, Canada and Australia cover the composition of matter and method of use of the PRX321 drug candidate and the INxin technology. Several other patent applications have been filed by the Company and are pending. As PRX321 has been granted Orphan Drug Status by the FDA and EMEA, the market exclusivity of PRX321 will be extended by seven and ten years, respectively, if the drug candidate is successfully approved. Under the terms of the FDA CRADA, Prottox has an exclusive option to license any future inventions developed under this INxin research program.

The HUMxin technology licensed by the Company is covered by worldwide patent applications under the following patent family: methods and compositions for Inhibiting Cell Death or Enhancing Cell Proliferation.

In relation to the HUMxin technology and intellectual property being developed under the NINDS CRADA, Prottox has an exclusive option to license any future inventions developed under this HUMxin research program.

**SELECTED FINANCIAL INFORMATION**

**Summary annual results for the three most recently completed years (audited):**

<b>Years ended December 31:</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>
Net loss (in thousands)	\$ (7,944.5)	\$ (8,919.1)	\$ (7,446.1)
Loss per share	(0.10)	(0.12)	(0.13)
Total assets (in thousands)	2,778.1	8,458.1	12,913.7

The Company has not earned any revenue in any of its previous fiscal years, other than income from interest earned on the Company's investment balances. We anticipate that this will continue into the foreseeable future.

Expenses, in particular research and development costs, are influenced by a number of factors including the scope of clinical development and research programs pursued; the type and size of clinical trials undertaken; the number of clinical trials that are active during a particular period of time; the rate of patient enrollment; and are ultimately a function of decisions made to continue the development and testing of a product candidate based on supporting safety and efficacy from clinical trial results. Consequently, expenses vary from period to period. General and administrative expenses will be dependent on the personnel and infrastructure required to support the corporate, clinical and business development objectives and initiatives of the Company.

## **RESULTS OF OPERATIONS**

### **Year ended December 31, 2009 compared to the year ended December 31, 2008:**

The net and comprehensive loss reported for the year ended December 31, 2009 ("2009-FY") totaled \$7.9 million or \$0.10 per share compared to \$8.9 million or \$0.12 per share for the year ended December 31, 2008 ("2008-FY").

Total expenses for the year ended December 31, 2009 decreased by \$1.0 million over the preceding year primarily due to the Company's efforts to focus its resources on the lead program, PRX302 for the treatment of BPH. Activities in the Company's other programs, including its INxin and HUMxin platforms, were limited and clinical activities related to them have been deferred until grant or other sources of financing has been secured. Efforts to reduce costs across all areas of the Company, including general and administration, also were successful in reducing the net loss compared to the prior year.

#### *Research and Development Costs*

Research and development ("R&D") costs for the 2009-FY period totaled \$5.5 million representing a \$681,000 (11%) decrease from \$6.2 million incurred during the 2008-FY comparative period, reflecting the effects of the consolidation of our research and development programs to focus on the lead BPH program.

Clinical and regulatory costs incurred in 2009 for our PRX302 clinical programs for the treatment of BPH and prostate cancer as well as basic maintenance activities associated with our reduced PRX321 program totaled \$4.8 million compared to \$4.9 million for 2008. The decrease is driven by the significant drop in our non-BPH programs from the previous year with the narrowing of the Company's focus to the core BPH program, offset by the high costs of the TRIUMPH study which was initiated and completed during 2009.

Research and development costs are expected to decrease in 2010 as our overall clinical activity will decline as we concentrate on our efforts on regulatory activities associated with preparing our BPH program for a phase 3 study and to be partner-ready.

#### *General and Administrative Costs*

2009-FY general and administrative ("G&A") costs of \$2.1 million decreased \$186,000 (8%) from the \$2.3 million incurred during 2008-FY. General and administrative costs will generally vary from period to period depending on the specific business development, market research and shareholder relations initiatives undertaken and related travel required at such time to support the Company's corporate objectives. The general and administrative costs incurred in 2009 reflect the shift in efforts implemented in the first quarter of 2009 to consolidate and focus operations on our lead clinical BPH program and the Company's efforts to stabilize and reduce overhead costs in the future. This reduction in G&A costs will provide the Company with more resources to focus on the completion of its clinical programs. General and administrative costs are expected to continue to decline in 2010.

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*Stock Based Compensation*

Stock based compensation costs of \$339,000 for 2009-FY decreased \$77,000 (19%) from the \$416,000 incurred during 2008-FY. This decrease was driven by the reduction in the weighted average exercise price of the options outstanding during the period.

*Interest Income*

During 2009-FY the Company earned interest income of \$48,000 compared to \$293,000 for 2008-FY. Interest income earned during a particular period is a function of investment products, interest rate and / or investment yields available when funds become available for reinvestment as well as average cash balances invested. Consequently, interest income and investment returns have declined as a result of lower balances available to earn investment income, and a sharp decline in returns available in the market.

*Foreign Exchange Gain*

For 2009-FY, the Company recorded a foreign exchange gain of \$50,000 compared to a loss of \$171,000 during the 2008-FY period. This reflects the more stable currency markets in 2009, particularly the Canadian versus US dollar, and the Company's efforts to match foreign currency expenditures and deposits.

**RESULTS OF OPERATIONS**

**Three months ended December 31, 2009 compared to the three months ended December 31, 2008:**

**Summary of quarterly results for the eight quarters to December 31, 2009 (unaudited, in thousands, except per share data):**

Three months ended:	<b>December 31 2009</b>	<b>September 30 2009</b>	<b>June 30 2009</b>	<b>March 31 2009</b>
Interest income	\$ 1	\$ 3	\$ 10	\$ 32
Total expenses	1,719	2,211	1,814	2,296
Net loss	(1,717)	(2,150)	(1,812)	(2,263)
Loss per share	(0.02)	(0.03)	(0.02)	(0.03)
Three months ended:	<b>December 31 2008</b>	<b>September 30 2008</b>	<b>June 30 2008</b>	<b>March 31 2008</b>
Interest income	\$ 63	\$ 90	\$ 50	\$ 87
Total expenses	2,555	2,587	1,936	2,132
Net loss	(2,491)	(2,496)	(1,886)	(2,044)
Loss per share	(0.03)	(0.03)	(0.03)	(0.03)

The Company reported a net and comprehensive loss of \$1.7 million or \$0.02 per share in three months ended December 31, 2009 ("2009-Q4") compared to \$2.5 million or \$0.03 per share for the three months ended December 31, 2008 ("2008-Q4") - a drop of \$774,000 and a drop of \$433,000 over the previous quarter. The reduction from the comparative period in 2008 is a result of the

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Company's focus on the core BPH program as well as non-recurring clinical drug supply costs incurred in 2008-Q4 with respect to the then planned PRX321 study of GBM.

*Research and Development Costs*

Research and development costs for the quarter ended December 31, 2009 dropped from the comparative quarter in 2008 by \$447,000 to \$1.2 million reflecting the maturing effects of the consolidation of our research and development programs to focus on the lead BPH program. We exited the quarter with one active clinical program – our BPH TRIUMPH study – compared to three active programs in the last quarter of 2008.

*General and Administrative Costs*

General and administrative costs were \$206,000 lower in 2009-Q4 as compared to 2008-Q4 as the cost reduction programs introduced early in 2009 matured.

*Stock Based Compensation*

Stock based compensation costs of \$81,000 for the quarter ended December 31, 2009 increased by \$27,000 from the comparative quarter in 2008. This increase is due to the issuance of 2.4 million options in the latter half of 2009.

*Interest Income*

The Company did not earn any material interest income in the last quarter of 2009, compared to \$64,000 in the comparative quarter in 2008 due to lower available market returns and lower balances available to earn investment income.

*Foreign Exchange Gain*

The Company recorded a foreign exchange gain of \$51,000 in the quarter ended December 31, 2009 compared to a loss of \$153,000 during the last quarter of 2008. The loss in 2008-Q4 was due to the sharp decline in the Canadian dollar in the last quarter of 2008, where as the Canadian dollar increased modestly in value in the last quarter of 2009.

**LIQUIDITY AND CAPITAL RESOURCES**

Since inception, the Company has devoted its resources to funding R&D programs, including discovery research, preclinical studies and clinical trial activities which has resulted in an accumulated deficit of \$38.3 million as of December 31, 2009. With current revenues consisting only of interest earned on excess cash, losses are expected to continue while the Company's clinical programs are progressed.

At December 31, 2009, the Company had cash and cash equivalents of \$1.8 million, representing a net decrease of \$4.9 million from December 31, 2008. The Company had working capital of \$818,000 at December 31, 2009, a decrease of \$5.4 million from December 31, 2008.

The Company utilized cash resources of \$7.5 million during 2009 to fund continuing operations, a decrease of \$1.1 million from the previous year. The Company's average monthly consumption

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of cash for operating and investing activities during 2009-FY was \$575,000 compared to \$767,000 during 2008-FY.

On March 16, 2010, the Company closed a brokered private placement raising net proceeds of \$4.8 million from the issuance of 11.3 million units, with each unit comprised of one common share of Protox and one-half of a common share purchase warrant. Each whole warrant entitles the holder to purchase one common share of Protox at a price of \$0.65 for a five year period from closing date subject to an acceleration of the expiry date in certain circumstances. The additional cash resources from the successful private placement will enable the company to continue its research and development program.

Since early 2009, the Company has undertaken a comprehensive review of current development and discovery programs, operations and anticipated expenditures with the view to reduce or defer costs where possible in order to maximize available funds for priority initiatives. Management believes that current cash resources should enable the Company to execute its core business plan and meet its projected cash requirements into Q2-2011. The Company's working capital may not be sufficient to meet its stated business objectives in the event unforeseen circumstances or a change in the strategic direction of the Company. When, or if, the Company requires additional capital, there can be no assurance that the Company will be able to obtain further financing on favorable terms, if at all.

As required, the Company will continue to finance its operations through the sale of equity or pursue non-dilutive funding sources available to the Company in the future. Additional funding could also be provided from collaborative arrangements established in the future with pharmaceutical or biotechnology companies in relation to products and technologies under development by the Company.

## **CONTRACTUAL OBLIGATIONS**

### *Lease arrangements*

The Company has entered into long-term operating lease arrangements for the rental of office and laboratory facilities until April 2011 amounting to total commitments of \$108,000.

### *Clinical development programs*

In connection with its clinical development programs, the Company has entered into a number of contracts in the normal course of business that will remain in effect during 2010. These commitments are performance based with payment subject to the achievement of clinical trial milestones and generally may be cancelled with written notice. Total commitments amount to \$532,000.

### *PRX302 License Agreement for Prostate Cancer*

Pursuant to an exclusive license agreement with John Hopkins University and the University of Victoria, the Company has agreed to make cumulative milestone payments over the lifecycle of PRX302 of up to \$2.9 million contingent upon the achievement of certain clinical and regulatory milestones and to pay royalties on commercial sales of resulting products. To December 31, 2009, the Company has paid milestone payments of \$103,000.

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*PRX302 License Agreement for benign prostate hyperplasia*

During 2009, the Company entered an exclusive license agreement with John Hopkins University and the University of Victoria with respect to the use of PRX302 for the treatment of benign prostate hyperplasia and other non-cancer diseases and conditions of the prostate. Pursuant to the terms of this agreement, the company paid an upfront licensing fee of \$45,000. The License agreement requires the company to make payments of \$1.2 million on the achievement of certain clinical and regulatory milestones and to pay royalties on commercial sales of resulting products. To December 31, 2009, the Company has paid milestone payments of \$125,000.

*INxin Technology License Agreement*

Pursuant to an exclusive license agreement with the U.S. Public Health Service ("PHS"), the Company has agreed to make cumulative milestone payments of up to US\$4.0 million contingent upon the achievement of certain clinical and regulatory milestones (for at least three indications) and to pay royalties on commercial sales of resulting products.

*HUMxin Technology License Agreement*

Pursuant to an exclusive license agreement with PHS, the Company has agreed to make cumulative milestone payments of up to US\$4.8 million contingent upon the achievement of certain clinical and regulatory milestones (for at least three indications) and to pay royalties on commercial sales of resulting products.

*Cooperative research and development agreements*

The Company is party to two multi-year Collaborative Research and Development Agreements ("CRADAs") relating to its INxin and HUMxin technology with aggregate commitments of US\$800,000 over the term of the two CRADAs. As of December 31, 2009, the company has future annual commitments remaining of US\$125,000 per year until 2012.

**TRANSACTIONS WITH RELATED PARTIES**

During the year ended December 31, 2009, certain directors provided business advisory and scientific consulting services to the Company pursuant to consulting agreements. The Company incurred expenses of \$94,000 (2008 - \$132,000) under such agreements. These transactions were incurred in the normal course of business and recorded at their exchange amounts.

**CHANGES IN ACCOUNTING POLICIES**

*Goodwill and Intangible Assets*

On January 1, 2009, the Company prospectively adopted CICA Handbook Section 3064 *Goodwill and Intangible Assets* ("Section 3064"). This new accounting standard replaces Section 3062 *Goodwill and Other Intangible Assets* and Section 3450 *Research and Development Costs*. This new accounting standard provides guidance on the recognition of intangible assets in accordance with the definition of an asset and the criteria for asset recognition as well as clarifying the application of the concept of matching revenues and expenses, whether these assets are separately acquired or internally developed. The adoption of this new section did not have a significant impact on the Company's financial statements.

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*Credit Risk*

In January 2009, the CICA issued Emerging Issues Committee ("EIC") Abstract 173 - Credit Risk and the Fair Value of Financial Assets and Financial Liabilities ("EIC-173"). EIC-173 provides guidance on how to take into account credit risk of an entity and counterparty when determining the fair value of financial assets and financial liabilities, including derivative instruments. EIC-173 is applicable for the Company's interim and annual financial statements for its fiscal year ending December 31, 2009, with retroactive application. The adoption of EIC-173 did not result in a material impact on the Company's consolidated financial statements.

*Financial Instruments Disclosure*

The Company has adopted amendments to CICA Handbook Section 3862 *Financial Instruments – Disclosures*, effective December 31, 2009. The disclosure requirements as a result of these amendments are greater than previously required. The new disclosures require an entity to classify fair value measurements using a fair value hierarchy that reflects the significance of the inputs used in making the measurements. The fair value hierarchy shall have the following levels: (a) quoted prices (unadjusted) in active markets for identical assets or liabilities (Level 1); (b) inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e., as prices) or indirectly (i.e., derived from prices) (Level 2); and (c) inputs for the asset or liability that are not based on observable market data (unobservable inputs) (Level 3).

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

*Use of estimates*

The preparation of financial statements in conformity with Canadian GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could significantly differ from those estimates.

*Intangible assets*

Intangible assets include proprietary rights, intellectual property, patent rights and technology rights which have been acquired from third parties. Intangible assets are recorded at cost less accumulated amortization. Following acquisition, the Company evaluates the prospective commercialization of the acquired intangible asset. Depending upon the results of the evaluation, the Company commences amortization of the assets over their expected useful lives, which is generally less than ten years.

*Long-lived assets*

Long-lived assets are amortized over the estimated useful life of the asset and evaluated periodically for impairment in accordance with Section 3063 Impairment of Long-lived Assets ("Section 3063"). Section 3063 requires that long-lived assets, excluding goodwill and assets with infinite useful lives, be evaluated for impairment when events or changes in facts and circumstances indicate that their carrying value may not be recoverable. Events or changes in facts or circumstances include but are not restricted to: a strategic change in business direction; significant decrease in stock price; discontinuance of a product line or development program; or a restructuring. If one of these events or circumstances indicates that the carrying value of an asset may not be recoverable, or that our estimated amortization period was not appropriate, we would

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record an impairment charge against of our long-lived assets. The amount of impairment would be measured as the difference between the carrying value and the fair value of the impaired asset as calculated using a net realizable value methodology. An impairment charge would be recorded as an operating expense in the period of the impairment and as a reduction in carrying value.

Given the continued uncertainty capital markets, an impairment test was carried on definite lived intangible assets at the end of 2009. Based on the assessment, no long-lived assets impairment provision has been recorded to date. However, given the continued economic and capital markets challenges, asset recoverability tests will continue to be performed in future periods.

*Research and development costs*

R&D costs are charged as an expense in the period in which they are incurred. Development costs are charged as an expense in the period in which they are incurred unless they meet generally accepted criteria under Canadian GAAP for deferral and amortization. No development costs have been capitalized to date.

*Patent costs*

The costs incurred in establishing and maintaining patents for intellectual property developed are expensed in the period incurred.

*Stock-based compensation*

The Company grants discretionary stock options for the purchase of common shares.

The Company accounts for all stock-based payments to employees and non-employees using the fair value based method. Under the fair value based method, stock-based payments to employees and non-employees are measured at the fair value of the equity instruments issued. The fair value of stock-based payments to non-employees is periodically re-measured until the services are provided or the options vest, and any change therein is recognized over the period.

**ACCOUNTING PRONUCEMENTS FOR FUTURE ADOPTION**

*International Financial Reporting Standards*

In February 2008, the Accounting Standards Board of Canada confirmed that Canadian GAAP for publicly accountable enterprises will be converged with International Financial Reporting Standards ("IFRS") effective for fiscal years beginning on or after January 1, 2011. The Company will therefore be required to report using IFRS commencing with its unaudited interim consolidated financial statements for the three months ended March 31, 2011, which must include the interim results for the three months ended March 31, 2010 prepared on the same basis. IFRS uses a conceptual framework similar to Canadian GAAP, but there are some significant differences on recognition, measurement and disclosures.

Implementing IFRS will have a limited impact on accounting, financial reporting and supporting IT systems and processes. It may also have an impact on actual commitments involving GAAP based clauses, long-term employee compensation plans and performance metrics. Accordingly, the Company is in the process of developing its IFRS changeover plan which will include considerations such as measures to provide extensive training to key finance personnel, to review contracts and agreements and to increase the level of awareness and knowledge amongst

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management, the Board of Directors and the Audit Committee. Additional resources may be engaged to ensure the timely conversion to IFRS.

The Company has completed a diagnostic between Canadian GAAP and IFRS. While the effects of IFRS have not yet been fully determined, the Company has identified a number of areas where it is likely to be impacted by changes in accounting policy. These include:

- Property and equipment
- Intangible assets
- Impairment of assets
- Provisions and contingent liabilities
- Share-based payments
- Related party disclosure
- Presentation of statement of cash flows

As a first time adopter of IFRS, the Company is required to apply IFRS 1 "*First time adoption of International Financial Reporting Standards*". A number of exemptions are available under this Standard which the Company is currently evaluating including electing to use fair value at the transition date as deemed cost for capital assets in certain circumstances.

The implementation of IFRS is not expected to result in a material change to the financial statements.

## **RISKS AND UNCERTAINTIES**

The Company is subject to risks, events and uncertainties, or "risk factors", associated with being in the biopharmaceutical industry, and being an enterprise with projects in the research and development stage. Such risk factors could cause reported financial information to not necessarily be indicative of future operating results or of future financial position. The Company cannot predict all of the risk factors, nor can it assess the impact, if any, of such risk factors on the Company's business or the extent to which any factor, or combination of factors, may cause future results or financial position to differ materially from either those reported or those projected in any forward-looking statements. Accordingly, historical financial information and forward-looking statements should not be relied upon as a prediction of future results.

The Company is at an early stage of development and has incurred losses and will continue to incur losses in the foreseeable future. Developing new technologies will require further significant time and expense. It may be a number of years before the Company's technology begins to generate revenues, if at all. There can be no assurance that any of the Company's developments will be successful or successful enough to be commercially viable. The Company will need to raise additional funds to continue research and development and clinical trials necessary for market approval. The Company cannot guarantee that financing will be available or that terms for additional financing will be favourable.

As previously described, the Company expects cash and cash equivalents on hand will be sufficient to fund operations into the second quarter of 2011. Funding requirements may vary depending on a number of factors including progress in research and development, the cost associated with conducting clinical trials and the regulatory approval process and the costs of enforcing and prosecuting patent claims and other intellectual property rights.

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The Company's primary market risk is the exposure to foreign currency exchange rate fluctuations. This risk arises from the Company's holdings of foreign currency denominated cash, accounts payable, cash equivalents, and short-term investments. Changes in foreign currency exchange rates can create significant foreign exchange gains or losses to the Company. The Company's current foreign currency risk is primarily with the U.S. dollar. The Company has minimal exposure to interest rate risks as it does not have long-term financial liabilities.

Additional information with respect to these and other risks affecting the Company is described in the section "Risk factors" in the Company's Annual Information Form dated March 29, 2010. Reference should be made to the notes to the financial statements for the year ended December 31, 2009 and to the Company's other continuous disclosure materials filed from time to time with Canadian securities regulatory authorities, which are available online at [www.sedar.com](http://www.sedar.com).

## **DISCLOSURE CONTROLS AND PROCEDURES**

The Company maintains a set of disclosure controls and procedures designed to ensure that information required to be disclosed in filings is recorded, processed, summarized and reported within the time periods specified in the Canadian Securities Administrators' rules and forms. Our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") have designed our disclosure controls and procedures, or caused them to be designed under their supervision, as of December 31, 2009, to provide reasonable assurance that material information relating to the Company was made known to them and reported as required. The CEO and CFO have evaluated the effectiveness of the Company's disclosure controls and procedures as of December 31, 2009 and concluded that they provide reasonable assurance that material information relating to the Company was made known to them and reported as required.

## **INTERNAL CONTROL OVER FINANCIAL REPORTING**

Our CEO and CFO are responsible for the design of internal controls over financial reporting, or for causing them to be designed under their supervision and, as of December 31, 2009, for evaluating the effectiveness of such internal controls, to provide reasonable assurance regarding the reliability of financial reporting and the preparation and fair presentation of external financial statements in accordance with Canadian GAAP. Regardless of how well an internal control system is designed and operated, it can provide only reasonable, not absolute, assurance that it will prevent or detect all misstatements resulting from error or fraud due to the inherent limitations of any internal control system. The CEO and CFO evaluated the design and effectiveness of the Company's internal controls over financial reporting based on the framework established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and concluded that the Company's internal control over financial reporting was effective as of December 31, 2009. There were no changes that occurred during the year ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, the Company's internal controls over financial reporting.

## **OTHER MD&A REQUIREMENTS**

### **Outstanding Share Data**

On March 16, 2010, the Company issued 11.3 million units under the terms of a brokered private placement, with each unit comprised of one common share of Protox and one-half of a common

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share purchase warrant. Each whole warrant entitles the holder to purchase one common share of Protox at a price of \$0.65 for a five year period from closing date subject to an acceleration of the expiry date in certain circumstances.

As at the date of this report, the Company has 96,037,698 common shares issued and outstanding.

In addition, the Company has 6,647,500 options outstanding to purchase common shares of the Company. Of the options currently outstanding, approximately 3.9 million are exercisable into an equivalent number of common shares of the Company at exercise prices ranging from \$0.50 to \$1.00 and with an average exercise price of \$0.69.

The Company also has 7,151,073 common share purchase warrants outstanding which expire between May 2010 and March 2015 and entitle warrant holders to purchase common shares at a prices ranging between \$0.27 and \$0.71. The weighted average warrant price is \$0.60 and the weighted average remaining term is 4.1 years. Furthermore, 6,367,269 of these common share purchase warrants are subject to an acceleration of the expiry date if the closing price of the underlying Common Shares is higher than \$1.75 per common share for a period of 10 consecutive trading days.

For a detailed summary of the outstanding securities convertible into, exercisable or exchangeable for voting or equity securities as at December 31, 2009, refer to Note 8(b) and (d) in the audited 2009 annual financial statements of the Company.

March 29, 2010

## **Auditors' Report**

### **To the Shareholders of Protox Therapeutics Inc.**

We have audited the balance sheets of **Protox Therapeutics Inc.** as at December 31, 2009 and 2008 and the statements of operations, comprehensive loss and deficit and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with Canadian generally accepted auditing standards. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation.

In our opinion, these financial statements present fairly, in all material respects, the financial position of the Company as at December 31, 2009 and 2008 and the results of its operations and its cash flows for the years then ended in accordance with Canadian generally accepted accounting principles.

(signed) PricewaterhouseCoopers LLP

### **Chartered Accountants**

# Protox Therapeutics Inc.

Balance Sheets

As at December 31, 2009 and 2008

	December 31, 2009 \$	December 31, 2008 \$
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	1,768,305	6,652,810
Short-term investments	-	612,412
Other receivables	176,871	152,855
Prepaid expenses	88,638	41,225
	2,033,814	7,459,302
<b>Property and equipment</b> (note 6)	34,146	79,224
<b>Intangible assets</b> (note 7)	720,150	919,488
	2,788,110	8,458,014
<b>Liabilities</b>		
<b>Current liabilities</b>		
Accounts payable	995,839	514,906
Accrued liabilities	216,204	766,778
Current portion of lease obligations	3,662	4,995
	1,215,705	1,286,679
<b>Long-term portion of lease obligations</b>	-	3,325
	1,215,705	1,290,004
<b>Shareholders' Equity</b>		
<b>Common shares</b> (note 8(a))	34,571,941	32,628,223
<b>Common share purchase warrants</b> (note 8(b))	224,452	158,169
<b>Contributed Surplus</b> (note 8(c))	5,119,681	4,780,754
<b>Deficit accumulated during the development stage</b>	(38,343,669)	(30,399,136)
	1,572,405	7,168,010
	2,788,110	8,458,014
<b>Nature of operations and liquidity risk</b> (note 1)		
<b>Commitments</b> (note 12)		
<b>Subsequent events</b> (note 14)		
<b>Approved by the Board of Directors</b>		

/s/ Frank Holler Director

/s/ James Miller Director

The accompanying notes are an integral part of these financial statements.

# Protox Therapeutics Inc.

## Statements of Operations, Comprehensive Loss and Deficit For the years ended December 31, 2009 and 2008

	2009 \$	2008 \$	Cumulative from inception to December 31, 2009 \$
<b>Expenses</b>			
Research and development	5,541,729	6,222,494	24,828,737
General and administrative	2,112,518	2,298,190	10,851,270
Stock-based compensation (note 8(d))	338,927	416,321	2,623,503
Amortization of property and equipment	48,162	90,241	424,753
Write-off of property and equipment (note 6)	-	13,418	13,418
	8,041,336	9,040,664	38,741,681
<b>Other income (expense)</b>			
Interest income	47,643	292,970	937,911
Interest expense	(353)	(607)	(17,814)
Forgiveness of debt	-	-	7,485
Foreign exchange gain (loss)	49,513	(170,759)	(529,570)
	96,803	121,604	398,012
<b>Net and comprehensive loss for the year</b>	(7,944,533)	(8,919,060)	(38,343,669)
<b>Deficit accumulated during the development stage - Beginning of period</b>	(30,399,136)	(21,480,076)	-
<b>Deficit accumulated during the development stage - End of period</b>	(38,343,669)	(30,399,136)	(38,343,669)
<b>Basic and diluted loss per share</b>	(0.10)	(0.12)	
<b>Weighted average number of outstanding shares - basic and diluted</b>	81,171,259	72,940,568	

The accompanying notes are an integral part of these financial statements.

# Protox Therapeutics Inc.

## Statements of Cash Flows

For the years ended December 31, 2009 and 2008

	2009 \$	2008 \$	Cumulative from inception to December 31, 2009 \$
<b>Cash flows from operating activities</b>			
Loss for the period	(7,944,533)	(8,919,060)	(38,343,669)
Items not affecting cash			
Stock-based compensation (note 8(d))	338,927	416,321	2,623,503
Amortization of property and equipment	48,162	90,241	575,929
Amortization of intangible assets	199,337	221,804	524,042
Write-off of property and equipment (note 6)	-	13,418	13,418
Other	-	-	227,350
Change in non-cash working capital			
Other receivables	(24,016)	13,938	(164,122)
Prepaid expenses	(47,413)	(11,272)	(80,451)
Accounts payable	480,932	(227,703)	926,019
Accrued liabilities	(550,572)	(185,019)	216,204
	(7,499,176)	(8,587,332)	(33,481,777)
<b>Cash flows from investing activities</b>			
Decrease (increase) in short-term investments	612,412	(612,412)	-
Purchase of property and equipment	(3,084)	(17,275)	(472,318)
Acquisition of intangible assets	-	-	(1,290,528)
	609,328	(629,687)	(1,762,846)
<b>Cash flows from financing activities</b>			
Issuance of common shares from private placements - net of issuance cash costs (note 8(a))	1,997,628	4,379,800	23,224,939
Issuance of common shares from public offering	-	-	3,819,922
Cash acquired on reverse takeover	-	-	1,064,754
Issuance of preferred shares	-	-	651,110
Issuance of common shares on exercise of warrants	12,373	18,851	8,019,951
Issuance of common shares on exercise of options	-	69,151	240,591
Capital lease financing	-	-	135,204
Capital lease payments	(4,658)	(7,991)	(131,543)
Due to shareholder	-	-	(12,000)
	2,005,343	4,459,811	37,012,928
<b>(Decrease) increase in cash and cash equivalents</b>	(4,884,505)	(4,757,208)	1,768,305
<b>Cash and cash equivalents - Beginning of period</b>	6,652,810	11,410,018	-
<b>Cash and cash equivalents - End of period</b>	1,768,305	6,652,810	1,768,305

Supplemental cash flow information (note 13)

The accompanying notes are an integral part of these financial statements.

# Protox Therapeutics Inc.

Notes to Financial Statements

December 31, 2009 and 2008

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## 1 Nature of operations and liquidity risk

Protox Therapeutics Inc. (“Protox” or the “Company”) is a development stage biopharmaceutical company that focuses on the research, development and commercialization of receptor targeted therapeutic fusion proteins for the treatment of disease. These fusion proteins specifically deliver potent payloads derived from engineered bacterial toxins or fully human Bcl-2 derived proteins to target cancer and other diseased cells. The Company is considered to be in the development stage as most of its efforts have been devoted to basic research and development activities to date. The eventual profitability of the Company and its ability to continue operating as a going concern are dependent upon obtaining additional financing as required, successful development and commercialization of its products, receiving regulatory approvals and generating cash from operations.

Protox Therapeutics Inc. was incorporated under the Company Act of British Columbia and commenced operations on January 11, 2002.

Management believes that with the addition of the net proceeds of \$4.8 million from the financing completed on March 16, 2010 (refer to note 14), current cash resources should enable the Company to execute its core business plan and meet its projected cash requirements into the second quarter of 2011. However, the Company's working capital may not be sufficient to meet its stated business objectives in the event of unforeseen circumstances or a change in the strategic direction of the Company. When, or if, the Company requires additional capital, there can be no assurance that the Company will be able to obtain further financing on favourable terms, if at all.

As required, the Company will continue to finance its operations through the sale of equity or pursue non-dilutive funding sources such as collaborative arrangements with pharmaceutical or biotechnology companies in relation to products and technologies under development by the Company.

## 2 Significant accounting policies

### a) Generally accepted accounting principles

These financial statements have been prepared in accordance with accounting principles generally accepted in Canada (“Canadian GAAP”) and are presented in Canadian dollars.

### b) Change in accounting policies

On January 1, 2009, the Company prospectively adopted Canadian Institute of Chartered Accountants (“CICA”) Handbook Section 3064, *Goodwill and Intangible Assets*. This new accounting standard provides guidance on the recognition of intangible assets in accordance with the definition of an asset and the criteria for asset recognition as well as clarifying the application of the concept of matching revenues and expenses, whether these assets are separately acquired or internally developed. The adoption of this new section did not significantly impact the Company's financial statements.

# Protox Therapeutics Inc.

## Notes to Financial Statements

December 31, 2009 and 2008

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In January 2009, the CICA issued Emerging Issues Committee Abstract 173, *Credit Risk and the Fair Value of Financial Assets and Financial Liabilities* (“EIC-173”). EIC-173 provides guidance on how to take into account credit risk of an entity and counterparty when determining the fair value of financial assets and financial liabilities, including derivative instruments. The Company adopted EIC-173 on January 1, 2009, and the adoption did not impact the Company’s financial statements.

Effective December 31, 2009, the Company adopted amendments to CICA Section 3862, *Financial Instruments - Disclosures*. The disclosure requirements as a result of these amendments are greater. The new disclosures require an entity to classify fair value measurements using a fair value hierarchy that reflects the significance of the inputs used in making the measurements. The fair value hierarchy shall have the following levels: (a) quoted prices (unadjusted) in active markets for identical assets or liabilities (Level 1); (b) inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e., as prices) or indirectly (i.e., derived from prices) (Level 2); and (c) inputs for the asset or liability that are not based on observable market data (unobservable inputs) (Level 3). The Company adopted the new standard, and additional disclosures are included in note 4.

### c) Future accounting changes

#### *International Financial Reporting Standards*

In February 2008, the Accounting Standards Board of Canada confirmed that Canadian GAAP for publicly accountable enterprises will be converged with International Financial Reporting Standards (“IFRS”) effective for fiscal years beginning on or after January 1, 2011. The Company will therefore be required to report using IFRS commencing with its unaudited interim financial statements for the three months ended March 31, 2011, which must include the interim results for the three months ended March 31, 2010 prepared on the same basis.

IFRS uses a conceptual framework similar to Canadian GAAP, but there are some significant differences on recognition, measurement and disclosures.

### d) Development stage company

The accompanying financial statements have been prepared in accordance with the provisions of Accounting Guideline No. 11, *Enterprises in the Development Stage*.

### e) Use of estimates

The preparation of financial statements in conformity with Canadian GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could significantly differ from those estimates, including estimates relating to long-lived and intangible assets, warrant value, other equity and stock-based compensation.

# Protox Therapeutics Inc.

## Notes to Financial Statements

December 31, 2009 and 2008

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### f) Cash and cash equivalents

Cash and cash equivalents consist of cash on deposit and highly liquid short-term interest bearing securities with a maturity at the date of purchase of 90 days or less. Cash and cash equivalents are classified as held-for-trading and measured at fair value. Gains and losses resulting from the change in fair values of cash and cash equivalents are included in interest income in the statements of operations, comprehensive loss and deficit.

### g) Short-term investments

Short-term investments consist of guaranteed investment certificates, bankers' acceptances and commercial paper with original terms to maturity of more than 90 days but less than one year, and are recorded at cost plus accrued interest. The carrying value of short-term investments approximates their market value.

### h) Property and equipment

Property and equipment are stated at cost less accumulated amortization. Amortization is recorded on a straight-line basis over the estimated lives of the property and equipment as follows:

Computer hardware and software	3 years
Laboratory equipment	4 years
Furniture and fixtures	5 years
Leasehold improvements	term of the lease

### i) Intangible assets

Intangible assets include proprietary rights, intellectual property, patent rights and technology rights which have been acquired from third parties. Intangible assets are carried at cost less accumulated amortization. The Company evaluates the useful economic life of the specific intangible asset and amortizes the asset accordingly. The intangible assets are amortized on a straight-line basis over 7 years.

### j) Impairment of long-lived assets

The Company periodically reviews the useful lives and the carrying value of its long-lived assets. Long-lived assets are reviewed for impairment upon the occurrence of events or changes in circumstances indicating that the carrying value of the asset may not be recoverable, as measured by comparing their net book value to the estimated undiscounted future cash flows generated by their use. Impaired assets are recorded at fair value, determined principally using discounted future cash flows expected from their use and eventual disposition. As at December 31, 2009 and 2008, no such impairment losses were recorded.

# Protox Therapeutics Inc.

Notes to Financial Statements

December 31, 2009 and 2008

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## **k) Leases**

Lease arrangements are classified as either capital or operating. Leases that transfer substantially all benefits and risks of ownership are accounted for as capital leases. At the time a capital lease is entered into, an asset is recorded together with its related long-term obligation to reflect the purchase and financing. All other leases are accounted for as operating wherein rental payments are expensed as incurred.

## **l) Research and development costs**

Research and development costs are charged as an expense in the period in which they are incurred. Development costs are charged as an expense in the period in which they are incurred unless they meet generally accepted criteria under Canadian GAAP for deferral and amortization. No development costs have been capitalized to date.

## **m) Patent costs**

The costs incurred in establishing and maintaining patents for intellectual property developed are expensed in the period incurred.

## **n) Future income taxes**

Future income taxes are recognized for the future income tax consequences attributable to differences between the carrying values of assets and liabilities and their respective income tax bases. Future income tax assets and liabilities are measured using substantively enacted income tax rates expected to apply to taxable income in the years in which temporary differences are expected to be recovered or settled. The effect on future income tax assets and liabilities of a change in rates is included in operations in the period that includes the substantive enactment date. A valuation allowance is recorded against the future tax asset to the extent that it is more likely than not that some or all of the future tax assets will not be realized.

## **o) Loss per share**

Basic and diluted loss per share are calculated using the weighted average number of common shares outstanding. The outstanding warrants and options have been excluded from the calculation of diluted loss per share because their inclusion would be anti-dilutive.

## **p) Stock-based compensation**

The Company grants discretionary stock options for the purchase of common shares.

The Company accounts for all stock-based payments to employees and non-employees using the fair value based method. Fair value is determined using the Black-Scholes option pricing model and, as such, stock-based payments to employees and non-employees are measured at the fair value of the equity instruments issued. The fair value of stock-based payments to non-employees is periodically re-measured until the services are provided or the options vest, and any change therein is recognized over the period.

# Protox Therapeutics Inc.

Notes to Financial Statements

December 31, 2009 and 2008

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## q) Translation of foreign currency

The functional currency of the Company is the Canadian dollar. Accordingly, monetary items denominated in a foreign currency are translated into Canadian dollars at exchange rates in effect at the balance sheet date and non-monetary items are translated at rates of exchange in effect when the assets were acquired or obligations incurred. Revenue and expenses are translated at rates in effect at the time of the transactions. Foreign exchange gains and losses are included in the determination of loss for the year.

## 3 Capital disclosure

The Company's objectives when managing capital are to safeguard its accumulated capital and ensure a sufficient liquidity position in order to maintain its ability to continue as a going concern and to advance its research, development and commercialization activities. The capital structure of the Company consists of the components of shareholders' equity.

Since inception, the Company has primarily financed its liquidity needs through a public offering and several private placements of common shares. When possible, the Company tries to optimize its liquidity position through non-dilutive sources, including grants, interest income and strategic partnership arrangements.

The Company manages its capital structure and will make adjustments to it based on economic conditions and the risk characteristics of the underlying assets. The Company, upon approval from its board of directors, will balance its overall capital structure through new share or debt issuances or by undertaking other activities as deemed appropriate under specific circumstances.

The Company is not subject to externally imposed capital requirements.

# Protox Therapeutics Inc.

## Notes to Financial Statements

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### 4 Financial instruments and financial risk management

#### a) Financial instruments

The Company has classified its financial instruments as follows:

Financial instrument	Classification	Measurement	Carrying value at December 31,	
			2009 \$	2008 \$
Cash and cash equivalents	Held-for-trading	Fair value Level 1	1,768,305	6,652,810
Short-term investments	Held-for-trading	Fair value Level 1	-	612,412
Other receivables	Loans and receivables	Amortized cost using the effective interest method	176,871	152,855
Accounts payable and accrued liabilities	Other financial liabilities	Amortized cost using the effective interest method	1,212,043	1,281,684

*(Level 1) - Based on quoted market prices in active markets.*

*(Level 2) - Inputs, other than quoted prices in active markets, that are observable, either directly or indirectly.*

*(Level 3) - Unobservable inputs that are not corroborated by market data.*

For all financial instruments of the Company, the carrying amount is a reasonable approximation of their fair values due to the short-term nature of these instruments. The Company did not have any held-to-maturity or available-for-sale financial instruments, nor did it acquire or hold any derivative products during the years ended December 31, 2009 and 2008.

#### b) Financial risk management

The Company is exposed to certain financial risks, including credit risk, liquidity risk and market risk.

##### *Credit risk*

Credit risk is the risk of an unexpected loss if a customer or third party to a financial instrument fails to meet its contractual obligations and arises principally from the Company's cash and cash equivalents, short-term investments and other receivables. Being in the development stage, the Company does not have any customers. The Company has established investment guidelines relative to diversification, credit ratings and maturities that maintain security and liquidity. These guidelines are periodically reviewed by the Company's audit committee and modified to reflect changes in market conditions. The Company has \$1,103,850 invested in highly rated money market funds and bank guaranteed investment certificates, which are subject to credit risk.

# Protox Therapeutics Inc.

Notes to Financial Statements

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## *Liquidity risk*

These financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they come due. To the extent that the Company does not believe it has sufficient liquidity to meet its current obligations, the board of directors considers securing additional funds through equity, debt or partnering transactions. The board of directors approves the Company's annual operating and capital budgets as well as any material transactions outside the ordinary course of business. Of the accounts payable outstanding totalling \$995,839 as at December 31, 2009, \$463,505 is payable within ninety days and the balance of \$532,334 is payable within one year. All milestone based commitment amounts that became due during fiscal 2009 were paid and no other future commitment payments are included in accrued liabilities as at December 31, 2009 as achievement of the related milestones has yet to occur - refer to Note 12.

## *Market risk*

Market risk is the risk that changes in market prices, such as foreign exchange rates and interest rates, will affect the Company's income or valuation of its financial instruments.

Foreign currency risk is limited to the portion of the Company's business transactions denominated in currencies other than the Canadian dollar, primarily expenses for research and development incurred in US dollars. As at December 31, 2009, US dollar denominated cash and cash equivalents totalled US\$139,342 (2008 - US\$375,798) and foreign denominated accounts payable and accrued liabilities included US\$182,223 (2008 - US\$272,667) and €297,050 (2008 - €18,281). Based on the US dollar and Euro balance sheet exposure at December 31, 2009, with other variables unchanged, a 10% change in the US dollar and Euro compared to the Canadian dollar would not have had a significant impact on net and comprehensive loss.

Interest rate risk relates primarily to cash and cash equivalents and short term investments. At December 31, 2009, with other variables unchanged, a 1% absolute change in interest rates would not have had a significant impact on net and comprehensive loss.

## **5 Projects under development**

The Company's projects under development relate to its three complementary technology platforms: PORxin<sup>TM</sup>, INxin<sup>TM</sup> and HUMxin<sup>TM</sup>.

PORxin is based on an engineered version of proaerolysin, a protein secreted by the bacteria *Aeromonas hydrophilia*. The lead drug from the PORxin platform, PRX302, has been engineered to be activated by the prostate specific antigen ("PSA"), an enzyme that is produced at high levels in the prostates of patients with prostate cancer and benign prostatic hyperplasia ("BPH"). Once PRX302 is activated by PSA, it combines with other activated PRX302 molecules to form a mushroom shaped structure that is able to perforate the cell membrane. The cell contents leak out through the resulting pore and the cell dies.

# Protox Therapeutics Inc.

## Notes to Financial Statements

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INxin is based on a novel protein comprising interleukin-4 (“IL-4”) and *Pseudomonas* exotoxin. The IL-4 portion of the protein binds to IL-4 receptors, which are highly expressed in a large number of primary and metastatic cancer cells. The *Pseudomonas* exotoxin portion causes cell death by arresting protein synthesis.

HUMxin, a next-generation platform, is a program to develop fully humanized receptor targeted therapeutic fusion proteins using the non-immunogenic Bcl-2 family of proteins and is currently in the discovery research stage.

The primary activities associated with these projects include discovery research, pre-clinical testing, clinical trials and other product development and support activities.

Cumulative research and development expenses from inception to December 31, 2009 relating to the projects total \$24,828,737 (2008 - \$19,287,008). Cumulative property and equipment expenditures incurred on these projects from inception to December 31, 2009 total \$309,207 (2008 - \$306,123) for laboratory equipment and leasehold improvements. As at December 31, 2009, the Company has not deferred any development costs due to the inherent uncertainty of these products reaching successful commercialization.

## 6 Property and equipment

Property and equipment consist of the following:

<b>December 31, 2009</b>	<b>Cost</b>	<b>Accumulated</b>	<b>Net book</b>
	<b>\$</b>	<b>amortization</b>	<b>value</b>
		<b>\$</b>	<b>\$</b>
Computer hardware and software	147,807	138,735	9,072
Laboratory equipment	242,871	233,400	9,471
Furniture and fixtures	18,387	17,273	1,114
Leasehold improvements	26,659	12,170	14,489
	<b>435,724</b>	<b>401,578</b>	<b>34,146</b>
<b>December 31, 2008</b>	<b>Cost</b>	<b>Accumulated</b>	<b>Net book</b>
	<b>\$</b>	<b>amortization</b>	<b>value</b>
		<b>\$</b>	<b>\$</b>
Computer hardware and software	144,723	114,781	29,942
Laboratory equipment	242,871	216,783	26,088
Furniture and fixtures	18,387	15,014	3,373
Leasehold improvements	26,659	6,838	19,821
	<b>432,640</b>	<b>353,416</b>	<b>79,224</b>

# Protox Therapeutics Inc.

## Notes to Financial Statements

December 31, 2009 and 2008

During the year ended December 31, 2008, the Company wrote-off certain leasehold improvements no longer in use with a cost of \$36,593 and related accumulated amortization of \$23,175, resulting in a net charge of \$13,418 to the statements of operations, comprehensive loss and deficit. There were no assets written off in 2009.

### 7 Intangible assets

Intangible assets consist of the following:

Patents and technology rights	Cost \$	Accumulated amortization \$	Net book value \$
December 31, 2009	1,395,368	675,218	720,150
December 31, 2008	1,395,368	475,880	919,488

### 8 Shareholders' equity

#### a) Common shares

Authorized: Unlimited (2008 - unlimited) common shares without par value

Issued: 84,493,875 (2008 - 75,894,044)

	Number of shares	Amount \$
Balance - December 31, 2007	68,473,933	28,246,445
Issuance of common shares from private placement at \$0.70 per unit - net of share issuance cash costs of \$448,757	6,897,939	4,379,800
Issuance of common shares as finance fee on private placement - net of share issuance costs of \$67,600	96,571	-
Fair value of warrants issued	-	(158,169)
Issuance of common shares on exercise of warrants	29,000	22,991
Issuance of common shares on exercise of options	396,601	137,156
Balance - December 31, 2008	75,894,044	32,628,223
Issuance of common shares from private placement at \$0.27 per unit - net of share issuance cash costs of \$311,953	8,554,004	1,997,628
Fair value of warrants issued as finance fee on private placement	-	(72,918)
Issuance of common shares on exercise of warrants	45,827	19,008
Balance - December 31, 2009	84,493,875	34,571,941

# Protox Therapeutics Inc.

## Notes to Financial Statements

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In May 2009, the Company closed a brokered private placement raising net proceeds of \$1,997,628 from the issuance of 8,554,004 common shares at \$0.27 per common share. As part of the broker's commissions, the Company issued 503,653 broker warrants to purchase common shares at \$0.27 per common share with an expiry date of May 20, 2011, which have been recorded as a cost of raising capital (Note 8(b)).

In May 2008, the Company completed a brokered private placement financing. The financing consisted of the issuance of 6,897,939 common shares at a price of \$0.70 resulting in gross proceeds of \$4,828,557. In conjunction with the financing, the Company issued 482,855 non-transferable warrants to the agent and 101,558 warrants as a finder's fee with a combined fair value of \$158,169 (Note 8(b)). In addition, 96,571 common shares were issued to the agent as payment of a corporate finance fee in the amount of \$67,600. The cash costs of the financing amounted to \$448,757 resulting in net proceeds of \$4,379,800.

### b) Warrants

At December 31, 2009, the Company had warrants outstanding to purchase 1,042,239 common shares (2008 - 584,413) at a weighted average exercise price of \$0.52 per share (2008 - \$0.71). The warrants will expire as follows: May 23, 2010 - 584,413; May 20, 2011 - 457,826.

The following table summarizes the continuity of the Company's warrants:

	<b>Number outstanding</b>	<b>Weighted average exercise price \$</b>	<b>Fair value at date of grant \$</b>
Balance outstanding - December 31, 2007	10,967,882	0.65	1,578,781
Issued as part of private placement commission	584,413	0.71	158,169
Exercised warrants	(29,000)	0.65	(4,140)
Expired warrants	(10,938,882)	0.65	(1,574,641)
Balance outstanding - December 31, 2008	584,413	0.71	158,169
Issued as part of private placement commission	503,653	0.27	72,918
Exercised warrants	(45,827)	0.27	(6,635)
Balance outstanding - December 31, 2009	1,042,239	0.52	224,452

# Protox Therapeutics Inc.

## Notes to Financial Statements

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The following table summarizes the weighted average assumptions used in the Black-Scholes model with respect to the valuation of warrants issued in 2009 and 2008:

<b>December 31,</b>	<b>2009</b>	<b>2008</b>
Expected hold period to exercise	2 years	2 years
Volatility	89%	59%
Dividend yield	0%	0%
Risk-free interest rate	1.10%	2.99%

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### c) Other equity

At December 31, 2009, the Company had other equity recorded as follows:

	<b>Amount</b>
	<b>\$</b>
Balance outstanding - December 31, 2007	2,857,797
Stock-based compensation	416,321
Expiration of warrants	1,574,641
Issuance of common shares on exercise of options	(68,005)
Balance outstanding - December 31, 2008	4,780,754
Stock-based compensation	338,927
Balance outstanding - December 31, 2009	5,119,681

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### d) Stock options

The Company's stock option plan (the "Plan") provides for the granting of options for the purchase of common shares of the Company at the fair market value of the Company's common shares on the date of the option grant. Options are granted to employees and non-employees. The board of directors or a committee appointed by the board of directors administers the Plan and has discretion as to the number, vesting period and expiry date of each option award. The Plan is based on a cumulative percentage of options issuable up to 10% of the Company's outstanding common shares. As of December 31, 2009, the Company had 84,493,875 common shares issued and outstanding resulting in a maximum of 8,449,388 options issuable.

# Protox Therapeutics Inc.

Notes to Financial Statements

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The following table summarizes the continuity of the Company's stock options:

	Number of options	Weighted average exercise price \$
Balance outstanding - December 31, 2007	4,980,035	0.73
Options granted	985,000	0.81
Options forfeited	(255,000)	0.83
Options expired	(430,934)	0.51
Options exercised	(396,601)	0.17
Balance outstanding - December 31, 2008	4,882,500	0.81
Options granted	2,405,000	0.51
Options expired	(550,000)	1.00
Options forfeited	(90,000)	0.71
Balance outstanding - December 31, 2009	6,647,500	0.69

The following table summarizes stock options outstanding and exercisable at December 31, 2009:

Exercise price \$	Options outstanding			Options exercisable	
	Number outstanding	Weighted average remaining contractual life (years)	Weighted average exercise price \$	Number exercisable	Weighted average exercise price \$
0.50	2,155,000	4.7	0.50	699,971	0.50
0.52	640,000	1.3	0.52	640,000	0.52
0.56	250,000	4.9	0.56	20,821	0.56
0.60	50,000	2.8	0.60	20,833	0.60
0.64	225,000	2.2	0.64	200,000	0.64
0.75	347,500	2.3	0.75	144,167	0.75
0.76	300,000	2.3	0.76	216,667	0.76
0.77	1,076,000	2.3	0.77	775,667	0.77
0.80	20,000	2.9	0.80	13,333	0.80
0.87	520,000	3.2	0.87	223,334	0.87
0.90	150,000	2.8	0.90	75,000	0.90
1.00	914,000	0.4	1.00	914,000	1.00
	6,647,500	2.8	0.69	3,943,793	0.69

# Protox Therapeutics Inc.

## Notes to Financial Statements

### December 31, 2009 and 2008

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During the year ended December 31, 2009, the Company granted 2,155,000 (2008 - 910,000) options to employees (including directors and officers) and granted 250,000 (2008 - 75,000) options to non-employees.

Stock-based compensation expense relating to stock options for the year ended December 31, 2009 was \$330,516 (2008 - \$368,504) for employees, directors and officers and \$8,411 (2008 - \$47,817) for others for a combined amount of \$338,927 (2008 - \$416,321).

The fair value of each stock option granted to employees and non-employees was estimated using the Black-Scholes option pricing model with the following assumptions:

<b>December 31,</b>	<b>2009</b>	<b>2008</b>
Expected life of the option	3 years	2 - 4 years
Volatility	68%	49% - 73%
Dividend yield	0%	0%
Risk-free interest rate	2.57%	2.74% - 3.75%

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## 9 Income taxes

As at December 31, 2009, the Company has unused non-capital losses of \$25,245,759 and accumulated scientific research and experimental development expenditures in the amount of \$9,357,205 that are available to reduce taxable income of future years. The non-capital losses expire as follows:

<b>Non-capital losses</b>	<b>Amount</b>
	<b>\$</b>
2010	499,786
2014 - 2015	4,967,715
2026 - 2029	19,778,258
	<b>25,245,759</b>

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In addition, the Company has unused investment tax credits in the amount of \$2,925,621 which may be applied to reduce future income taxes payable. The investment tax credits expire as follows:

	<b>Amount</b>
	<b>\$</b>
2014	58,373
2015	95,383
2016	84,173
2017	148,655
2018	212,330
2019	211,983
2024 - 2029	2,114,724
	<b>2,925,621</b>

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# Protox Therapeutics Inc.

## Notes to Financial Statements

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Future income tax assets and liabilities comprise the following:

Years ended December 31,	2009	2008
	\$	\$
Future income tax assets		
Non-capital losses	6,311,440	5,185,203
Share issue costs	187,198	239,932
Scientific research and development	2,339,301	1,671,576
Investment tax credits	2,384,412	1,713,736
Other	493,930	388,652
	11,716,281	9,199,099
Less: Valuation allowance	(11,716,281)	(9,199,099)
	-	-

A reconciliation of the statutory income tax rate applied to the loss before income taxes to the income tax recovery is as follows:

Years ended December 31,	2009	2008
Statutory income tax rate	30.00%	31.00%
	\$	\$
Income tax recovery based on statutory rate	(2,383,360)	(2,764,909)
Increase in valuation allowance	2,517,182	2,754,665
Change in income tax rates	379,566	914,718
Increase in investment tax credits	(615,851)	(488,292)
Income tax effect on expiry of non-capital loss	72,206	2,643
Increase in share issuance costs	(77,988)	(160,071)
Return to provision and other permanent differences	108,245	(258,754)
	-	-

## 10 Related party transactions

During the year ended December 31, 2009, certain directors provided business advisory and scientific consulting services to the Company pursuant to consulting agreements. The Company incurred expenses of \$93,864 (2008 - \$131,670) under such agreements. These transactions were incurred in the normal course of business and recorded at their exchange amounts.

# Protox Therapeutics Inc.

Notes to Financial Statements

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## 11 Segmented information

The Company identifies its operating segments based on business activities, management responsibility and geographical location. The Company operates within a single operating segment, being the research and development of receptor targeted fusion proteins, and operates in one geographic area, being Canada. All of the Company's assets are located in Canada.

## 12 Research agreements and commitments

### a) Operating leases

The Company has operating lease agreements for the rental of office and laboratory facilities until April 2011 and June 2010, respectively, amounting to total commitments of \$108,200.

### b) PRX302 licence agreement for prostate cancer

In 2004, the Company signed an exclusive licence agreement with John Hopkins University and the University of Victoria with respect to the use of the lead drug, PRX302, for the treatment of prostate cancer. Pursuant to the terms of this agreement, the Company paid upfront cash and share consideration valued at \$260,000. The licence agreement requires the Company to make payments of up to \$2.9 million on the achievement of certain clinical and regulatory milestones and to pay royalties on commercial sales of resulting products. To December 31, 2009, the Company has paid milestone payments of \$103,000.

### c) PRX302 licence agreement for benign prostate hyperplasia

In 2009, the Company signed an exclusive licence agreement with John Hopkins University and the University of Victoria with respect to the use of PRX302 for the treatment of benign prostate hyperplasia and other non-cancer diseases and conditions of the prostate. Pursuant to the terms of this agreement, the Company paid upfront licensing fees of \$45,000. The licence agreement requires the Company to make payments of \$1.2 million on the achievement of certain clinical and regulatory milestones and to pay royalties on commercial sales of resulting products. To December 31, 2009, the Company has paid milestone payments of \$125,000.

# Protox Therapeutics Inc.

Notes to Financial Statements

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## **d) INxin licence and acquisition**

In 2006, the Company acquired a Phase 2 clinical stage program for the treatment of cancer from Neurocrine Biosciences, Inc. (“Neurocrine”) and US Public Health Services (“PHS”). Protox paid Neurocrine and PHS \$1.4 million for the INxin licence, regulatory assets and product related assets, and will pay PHS up to US\$4.0 million in future milestone payments - based on the compound receiving US Food and Drug Administration (“FDA”) approval for at least three indications - as well as low single digit royalties on commercial sales of resulting products.

## **e) HUMxin licence agreement**

During 2008, the Company entered into a licence agreement with PHS for an exclusive licence related to the HUMxin technology. The patents licensed under this agreement cover fully human anti-apoptotic fusion proteins comprising GM-CSF and Bcl-xL. Pursuant to the terms of the agreement, the Company paid an initial upfront licence fee of US\$12,500 and a second instalment of US\$12,500 was paid in 2009. The Company will make future payments to PHS of up to US\$4.8 million based on the achievement of specific successful clinical and regulatory milestones and the compound receiving FDA approval for at least three indications, as well as pay royalties on commercial sales of resulting products.

## **f) Cooperative research and development agreements**

The Company is party to two multi-year Collaborative Research and Development Agreements (“CRADAs”) relating to its INxin and HUMxin technology with aggregate commitments of US\$800,000 over the term of the two CRADAs. As of December 31, 2009, the Company has future annual commitments remaining of US\$125,000 per year until 2012.

## **g) Clinical trial programs**

The Company has agreements with clinical sites, contract research organizations and other service providers related to the conduct of active clinical trials and programs. These commitments are performance based with payment subject to the achievement of clinical trial milestones and generally may be cancelled with written notice. At December 31, 2009, the Company has commitments to these third parties amounting to approximately \$532,000.

# Protox Therapeutics Inc.

Notes to Financial Statements

December 31, 2009 and 2008

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## 13 Supplemental cash flow information

For the years ended December 31,	2009 \$	2008 \$
<b>Interest received</b>	52,716	238,586
<b>Interest paid</b>	353	607
<b>Non-cash financing activities</b>		
Issuance of common shares for agent's corporate finance fee	-	67,600
Issuance of warrants as part of private placement commission	72,918	158,169

## 14 Subsequent events

On March 16, 2010, the Company closed a brokered private placement raising net proceeds of \$4.8 million from the issuance of 11,285,388 units at a price of \$0.45 per unit. Each Unit comprises of one common share of Protox and one-half of a common share purchase warrant. Each whole warrant entitles the holder to purchase one common share of Protox at a price of \$0.65 for a five-year period from the closing date subject to an acceleration of the expiry date in certain circumstances.