

ProtoX

THERAPEUTICS

2010 Q1 report



***Management's Discussion and Analysis***  
***Quarter Ended March 31, 2010***

**DATE OF REPORT: May 13, 2010**

**CORPORATE OFFICE:**

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**SYMBOL: PRX** (Toronto Stock Exchange - TSX)

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

The following management's discussion and analysis ("MD&A") has been prepared as of May 13, 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 31, 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 diseases of the Prostate via our PORxin platform lead candidate, PRX302, has now completed three clinical trials for the treatment of benign prostatic hyperplasia ("BPH", which is commonly known as enlarged prostate) as well as localized prostate cancer. To date, we have enrolled a total of 155 subjects in five clinical trials with PRX302. 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 is expected to occur once partners or collaborators have been secured to fund further development activities. To date, a total of 86 subjects have been treated with PRX321 in four clinical trials. The HUMxin platform is in pre-clinical development and is expected to advance 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.

### **PORxin Platform**

#### *License agreement for commercialization of PRX302*

The Company obtained strong third-party validation of its PORxin platform in April 2010 with the signing of its first license agreement for the commercialization of PRX302. The agreement with Kissei Pharmaceutical Co., Ltd., one of Japan's leading pharmaceutical companies, covers the development and commercialization of PRX302 in Japan for the treatment of BPH, prostate cancer and other diseases of the prostate. Under the terms of this agreement, Kissei assumes all responsibilities and costs of development, regulatory approval, commercialization and marketing of PRX302 in Japan for prostate disease. Protox retains exclusive rights to PRX302 in all other jurisdictions.

Under the terms of the agreement, Protox will receive an upfront payment of \$3 million and is eligible to receive a near term payment of \$5 million as well as additional progressive payments of \$67 million on achievement of specific development, regulatory and commercial milestones. In addition, Protox will receive a drug supply fee and double digit royalty payments based on product sales.

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*Placebo controlled BPH Study:*

During the three months ended March 31, 2010, the Company continued to advance its program for the treatment of benign prostatic hyperplasia. On January 11, 2010, the Company's released its top level results from its 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.

The study achieved its primary clinical endpoint of a statistically significant improvement in International Prostate Symptom Score (IPSS) at day 90 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.

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 Jarislawsky 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.

**INxin**

Based on encouraging Phase 1 and 2a study results of PRX321, the Company had anticipated initiating a multi-centre Phase 2b (pre-pivotal) clinical trial in patients with recurrent malignant glioblastoma multiforme ("GBM"). Although the preparations for the study have been completed, including FDA approval to proceed, patient enrolment has been deferred until a suitable partner has been identified to fund further clinical development. 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 clinical research and development agreement (CRADA) to further investigate IL-4R-directed agents such as PRX321 on various human tumours.

The Company has recently entered into a CRADA with the Veterans Administration to develop PRX321 for the targeting of cancer stem cells derived from patients with tumors of the gastrointestinal tract (GIT).

**HUMxin**

HUMxin, a next-generation platform technology in-licensed in 2007, is being developed in collaboration with the U.S. National Institute of Neurological Disease and Stroke ("NINDS") 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.

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

On February 26, 2010, Dr. Samuel Denmeade, Chief Scientific Officer at Protox, spoke at the Third International Symposium on Focal Therapy and Imaging of Prostate and Kidney Cancer. Dr. Denmeade's talk was entitled "*PRX302: A Targeted PSA-activated Pore Forming Toxin for the Treatment of Benign and Malignant Diseases of the Prostate*".

**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.

Patents and patent applications covering the PORxin technology licensed or owned by the Company are covered by issued patents and patent applications 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.

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 European Medicines Agency, the market exclusivity of PRX321 will be extended by seven and ten years, respectively, if the drug candidate is approved.

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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.

**ACHIEVEMENTS & HIGHLIGHTS**

The following are the achievements and highlights since 1<sup>st</sup> January, 2010:

- Positive top line results were released on January 11, 2010 from the Company's multi-centre, double-blinded placebo controlled Phase 2b study of PRX302 (study name: TRIUMPH) in patients with moderate to severe benign prostatic hyperplasia. The results indicated that the TRIUMPH study achieved its primary clinical endpoint of a statistically significant improvement in International Prostate Symptom Score at day 90 for patients treated with PRX302 versus subjects receiving placebo.
- 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 Prottox and one-half of a common share purchase warrant. Each whole warrant entitles the holder to purchase one common share of Prottox 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.
- On April 29, 2010, the Company announced that it had entered into a US \$75 million license agreement with Kissei Pharmaceutical Co., Ltd. for the development and commercialization of PRX302 in Japan for BPH, prostate cancer and other diseases of the prostate.

**SELECTED FINANCIAL INFORMATION**

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

<b>Years ended December 31:</b>	<b>2009 (audited)</b>	<b>2008 (audited)</b>	<b>2007 (audited)</b>
Net loss (in thousands)	\$ (7,944.5)	\$ (8,919.0)	\$ (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

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Summary of quarterly results for the eight quarters to March 31, 2010 (unaudited, in thousands, except per share data):

Three months ended:	<b>March 31 2010</b>	<b>December 31 2009</b>	<b>September 30 2009</b>	<b>June 30 2009</b>
Interest income	\$ 0.5	\$ 1.3	\$ 3.3	\$ 10.4
Total expenses	1,638.0	1,719.3	2,191.7	1,814.7
Net loss	(1,637.5)	(1,717.9)	(2,189.9)	(1,812.2)
Loss per share	(0.02)	(0.02)	(.03)	(.02)
Three months ended:	<b>March 31 2009</b>	<b>December 31 2008</b>	<b>September 30 2008</b>	<b>June 30 2008</b>
Interest income	\$ 32.5	\$ 63.9	\$ 90.8	\$ 50.0
Total expenses	2,296.0	2,555.6	2,587.0	1,936.9
Net loss	(2,263.5)	(2,491.7)	(2,496.1)	(1,886.7)
Loss per share	(0.03)	(0.03)	(.03)	(0.03)

**RESULTS OF OPERATIONS**

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.

Expenses, in particular R&D 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. G&A expenses will be dependent on the personnel and infrastructure required to support the corporate, clinical and business development objectives and initiatives of the Company.

Total expenses for the three months ended March 31, 2010 ("2010-Q1") decreased over the comparative quarter in 2009 as the Company had significantly reduced clinical activity in 2010-Q1 compared to the comparative quarter as the double-blinded placebo controlled TRIUMPH study had completed enrolment and there were no other on-going clinical trials enrolling subjects during this period.

The Company reported a net and comprehensive loss of \$1.6 million or \$0.02 per share in 2010-Q1 compared to \$2.3 million or \$0.03 per share for the three months ended March 31, 2009 ("2009-Q1"). The decrease of \$0.6 million in net loss over the comparative period in 2009 was primarily driven by the decrease in research and development activity due primarily to the completion of enrolment in the TRIUMPH study, as well as the impact of our efforts to reduce costs across all areas of the Company, including general and administration. This was partially offset by an increase in stock-based compensation during 2010-Q1 which resulted from the issuance of 2,405,000 options in the latter half of 2009.

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Research and Development Costs

Research and development ("R&D") costs of \$1.0 million were incurred during 2010-Q1: a decrease of \$606,000 (38%) from \$1.6 million incurred in the 2009-Q1 comparative period. The decrease for the period reflects the effect of the consolidation of our research and development programs to focus on our lead BPH program and the completion of enrolment in the double-blinded placebo controlled TRIUMPH study.

Direct costs incurred in 2010-Q1 for our PRX302 clinical programs for the treatment of BPH and prostate cancer as well as activities associated with maintaining our PRX321 program totaled \$748,000 compared to \$1.4 million for 2009-Q1.

General and Administrative Costs

2010-Q1 general and administrative costs of \$567,000 decreased slightly from \$619,000 in the 2009-Q1 comparative period. 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 2010-Q1 were reduced as a result of the measures implemented through 2009 to consolidate and focus available resources on our lead clinical BPH program, TRIUMPH, offset by the higher level of activities in 2010-Q1 relating to the successful pursuit of additional financing and our first licensing agreement.

Stock-Based Compensation

Stock-based compensation increased significantly over 2009-Q1 as a result of the Company issuing 2,405,000 options between September and November 2009. This issuance resulted in a sharp increase in stock based compensation over the first quarter of 2009.

Interest Income

During 2010-Q1, the Company earned only minimal interest income, compared to \$33,000 in the corresponding 2009 period. Interest income earned during a particular period or between periods 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 lower returns available in the market.

Foreign Exchange Gain

During 2010-Q1, the Company recorded a foreign exchange gain of \$51,000 compared to a foreign exchange gain during 2009-Q1 of \$8,000. This increase was caused by the rise in the Canadian dollar against the US dollar during the respective quarters.

## **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 \$40 million as of March 31, 2010. With current revenues only consisting of interest earned on excess cash, losses are expected to continue while the Company's R&D programs are further advanced, in particular active and planned clinical trials.

At March 31, 2010, the Company had cash and cash equivalents of \$5.2 million, representing a net increase of \$3.4 million from December 31, 2009. The Company had working capital of \$4.2 million at March 31, 2010, an increase of \$3.4 million from December 31, 2009.

The Company consumed cash of \$1.4 million during 2010-Q1 to finance continuing operations compared to \$1.8 million for 2009-Q1. These expenditures principally related to funding the continuing operations and license agreements, or collaborative research commitment payments by the Company. The Company's average monthly consumption of cash for operating and investing activities during 2010-Q1 was \$462,000 compared to \$596,000 during 2009-Q1.

As a result of the challenging global economic and capital market conditions, the Company undertook 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 with the addition of the upfront payment from our agreement with Kissei, cash resources should enable the Company to execute its core business plan / priority initiatives and meet its projected cash requirements for at least the next twelve months. 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 future commitments of \$97,000.

### *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 and drug manufacturing milestones and generally may be cancelled with written notice. Total commitments amount to approximately \$2 million.

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*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 March 31, 2010, the Company has paid milestone payments of \$122,000.

*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 up to \$1.2 million on the achievement of certain clinical and regulatory milestones and to pay royalties on commercial sales of resulting products. To March 31, 2010, 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 March 31, 2010, the company has future annual commitments remaining of US\$125,000 per year until 2012.

**TRANSACTIONS WITH RELATED PARTIES**

During the three month ended March 31, 2010, certain directors provided business advisory services to the Company amounting to \$20,000 compared to nil for 2009-Q1. These transactions were incurred during 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.

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.

## **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 record an impairment charge against of our long-lived assets. The amount of impairment would

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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 global economic crisis, capital markets uncertainty and the decrease in our stock price, events in 2008 warranted an impairment test on definite lived intangible assets. 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.

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

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- 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 Company does not expect the changeover to IFRS to have a significant impact on its information and data systems. The Company has recently purchased new software to manage stock-based compensation requirements in accordance with IFRS 2 share-based payments. Internal and disclosure controls will be adopted to ensure appropriate identification and application of new and ongoing IFRS requirements. The Company’s financial reporting staff participated in several educational seminars on IFRS adoption, obtained guidance provided by various professional advisory firms and reviewed disclosure and guidance publicly available from companies that have early adopted or already report in accordance with IFRS.

The Company expects to complete the assessment phase in fiscal Q2 2010. Analysis and quantification of adjustments in accordance with IFRS1 will begin in fiscal Q3 2010 and will include the review of proposed and recommended accounting policy changes by the audit committee of the Board of Directors. Adoption in fiscal Q1 2011, will result in the interim financial statements being prepared in accordance with the new accounting policies under IFRS and the Company will continue to monitor and maintain appropriate accounting in accordance with IFRS thereafter.

## **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 third quarter of 2011. Funding requirements may vary depending on a number of factors including progress in research and development, the cost

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associated with conducting clinical trials and the regulatory approval process and the costs of enforcing and prosecuting patent claims and other intellectual property rights.

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 and Chief Financial Officer have designed our disclosure controls and procedures, or caused them to be designed under their supervision, as of March 31, 2010 to 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 Chief Executive Officer and Chief Financial Officer are responsible for the design of internal controls over financial reporting, or for causing them to be designed under their supervision, 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 Chief Executive Officer and Chief Financial Officer have evaluated the design of the Company's internal controls and procedures over financial reporting as of the end of the period covered by this filing, and believe the design to be sufficient to provide such reasonable assurance. There were no changes that occurred during 2010-Q1 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**

As at the date of this report, the Company has 96,301,477 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 6,919,015 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. 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 March 31, 2010, refer to Note 7 (b) and (d) in our unaudited interim financial statements for the three months ended March 31, 2010.



# Protox Therapeutics Inc.

## Interim Statements of Operations, Comprehensive Loss and Deficit (unaudited)

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	For the three months ended March 31,	
	2010	2009
	\$	\$
<b>Expenses</b>		
Research and development	999,660	1,605,559
General and administrative	567,396	619,242
Stock-based compensation (Note 7(d))	115,090	57,062
Amortization of property and equipment	7,097	22,368
	<u>1,689,243</u>	<u>2,304,231</u>
<b>Other income</b>		
Interest income	549	32,466
Foreign exchange gain	51,247	8,241
	<u>51,796</u>	<u>40,707</u>
<b>Net and comprehensive loss for the period</b>	<b>(1,637,447)</b>	<b>(2,263,524)</b>
<b>Deficit accumulated during development stage, beginning of period</b>	<b>(38,343,669)</b>	<b>(30,399,136)</b>
<b>Deficit accumulated during development stage, end of period</b>	<b>(39,981,116)</b>	<b>(32,662,660)</b>
<b>Basic and diluted loss per share</b>	<b>(0.02)</b>	<b>(0.03)</b>
<b>Weighted average number of outstanding shares</b>	<b>86,556,672</b>	<b>75,894,044</b>

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

# Protox Therapeutics Inc.

## Interim Statements of Cash Flows (unaudited)

	For the three months ended March 31,	
	2010	2009
	\$	\$
<b>Cash flows from operating activities</b>		
Loss and comprehensive loss for the period	(1,637,447)	(2,263,524)
Items not affecting cash:		
Stock-based compensation (Note 7(d))	115,090	57,062
Amortization of property and equipment	7,097	22,368
Amortization of intangible assets	49,835	49,835
Change in non-cash working capital:		
Other receivables	(59,026)	93,271
Prepaid expenses	12,460	2,949
Accounts payable	90,938	716,831
Accrued liabilities	35,952	(463,977)
	<b>(1,385,101)</b>	<b>(1,785,185)</b>
<b>Cash flows from investing activities</b>		
Proceeds on sale of short-term investments	-	612,412
Purchase of property and equipment	(883)	(3,084)
	<b>(883)</b>	<b>609,328</b>
<b>Cash flows from financing activities</b>		
Issuance of common shares from private placement		
- net of cash costs (Note 7)	4,609,890	-
Issuance of common shares on exercise of warrants	204,537	-
Capital lease payments	(1,204)	(1,141)
	<b>4,813,223</b>	<b>(1,141)</b>
<b>Net increase in cash equivalents</b>	<b>3,427,239</b>	<b>(1,176,998)</b>
<b>Cash and cash equivalents - beginning of period</b>	<b>1,768,305</b>	<b>6,652,810</b>
<b>Cash and cash equivalents - end of period</b>	<b>5,195,544</b>	<b>5,475,812</b>
<b>Supplemental cash flow information</b>		
Interest received	549	37,540

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

# **Protox Therapeutics Inc.**

Notes to the Interim Financial Statements (unaudited)

For the three months ended March 31, 2010 and 2009

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## **1 Nature of operations and going concern**

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 is 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 amalgamated under the Company’s Act of British Columbia and commenced operations on January 11, 2002.

Management believes that current cash resources should enable the Company to execute its core business plan and meet its projected cash requirements for at least the next twelve months. 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 and/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 Basis of presentation and significant accounting policies**

### **a) Interim Statements**

The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in Canada (“Canadian GAAP”) for interim financial statements and do not include all the information required for annual audited financial statements. They are consistent with the policies outlined in the Company’s audited financial statements for the year ended December 31, 2009 except as described in Note 3 below. The interim financial statements and related notes should be read in conjunction with the Company’s audited financial statements for the year ended December 31, 2009. When necessary, the financial statements include amounts based on informed estimates and best judgments of management. The results of operations and comprehensive loss for the interim periods reported are not necessarily indicative of results for the full year.

# Protox Therapeutics Inc.

Notes to the Interim Financial Statements (unaudited)

For the three months ended March 31, 2010 and 2009

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## Basis of presentation and significant accounting policies (continued)

### b) 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".

### 3 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 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.

### 4 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 the Interim Financial Statements (unaudited)  
For the three months ended March 31, 2010 and 2009

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## 5 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	
			March 31, 2010 \$	December 31, 2009 \$
Cash and cash equivalents	Held-for-trading	Fair value Level 1	5,195,544	1,768,305
Other receivables	Loans and receivables	Amortized cost using the effective interest method	235,897	176,871
Accounts payable and accrued liabilities	Other financial liabilities	Amortized cost using the effective interest method	1,338,933	1,212,043

*(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 three months ended March 31, 2010 (December 31, 2009-nil)

### 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. At March 31, 2010, the Company had \$954,000 (December 31, 2009-\$1,103,850) invested in highly rated money market funds.

# Protox Therapeutics Inc.

Notes to the Interim Financial Statements (unaudited)

For the three months ended March 31, 2010 and 2009

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## Financial instruments and financial risk management (continued)

### *Liquidity risk*

The 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 aggregate accounts payable outstanding totalling \$1,086,777 as at March 31, 2010, \$674,000 is payable within ninety days and the balance of \$413,000 is payable within one year.

### *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 March 31, 2010, US dollar denominated cash and cash equivalents totalled US\$6,000 (December 31, 2009 - US\$139,000) and foreign denominated accounts payable and accrued liabilities included US\$321,000 (December 31, 2009 - US\$182,000) and €297,000 (December 31, 2009 - €297,000). Based on the US dollar and Euro balance sheet exposure at March 31, 2010, 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*

Interest rate risk relates primarily to cash and cash equivalents and short term investments. At March 31, 2010, with other variables unchanged, a 1% absolute change in interest rates would not have had a significant impact on net and comprehensive loss.

# Protox Therapeutics Inc.

Notes to the Interim Financial Statements (unaudited)  
For the three months ended March 31, 2010 and 2009

## 6 Intangible assets

Intangible assets consist of patents and technology rights

	Cost \$	Accumulated amortization \$	Net book value \$
Balance at December 31, 2009	1,395,368	675,218	720,150
Balance at March 31, 2010	1,395,368	725,053	670,315

## 7 Shareholders' equity

### a) Common shares

Authorized: Unlimited (2009 - unlimited) common shares without par value

Issued: 96,195,585 (2009 - 84,493,875)

	Number of shares	Amount \$
Balance December 31, 2008	75,894,044	32,628,223
Issuance of common shares from private placement at \$0.27 per share - net of share issuance cash costs of \$311,953	8,554,004	1,997,628
Less 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 at December 31, 2009	84,493,875	34,571,941
Issuance of common shares on exercise of warrants	416,322	301,144
Issuance of common shares and common share purchase warrants at \$0.45 per unit - net of share issuance cash costs of 468,535	11,285,388	4,609,890
Less ascribed value of common share purchase warrants	-	(1,122,859)
Less fair value of warrants issued as finance fee on private placement	-	(200,045)
Balance - March 31, 2010	96,195,585	38,160,071

In March 2010, the Company completed a brokered private placement financing. The financing resulted in the issuance of 11,285,388 units at a price of \$0.45 consisting of one common share and one-half common share purchase warrant amounting for gross proceeds of \$5,078,425. In conjunction with the financing, the Company issued 756,296 agents' warrants as a finder's fee with a fair value of \$200,045.

The relative fair value of the share purchase warrants attached to the unit offering and the agents' warrant values were derived using the Black-Scholes method using the following fair value assumptions: dividend yield of 0%; volatility of 69%; expected life of 5 years and a risk-free interest rate of 2.75%.

# Protox Therapeutics Inc.

Notes to the Interim Financial Statements (unaudited)

For the three months ended March 31, 2010 and 2009

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## Shareholders' equity (continued)

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.

### b) Warrants

At March 31, 2010, the Company had warrants outstanding to purchase 7,024,907 common shares at a weighted average exercise price of \$0.64 per share.

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

	Number outstanding	Weighted average exercise price \$	Fair value at date of grant \$
Balance at 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 at December 31, 2009	1,042,239	0.52	224,452
Issued with private placement shares	5,642,694	0.65	1,122,859
Issued as part of private placement commission	756,296	0.65	200,045
Exercised warrants	(416,322)	0.49	(204,537)
Balance at March 31, 2010	7,024,907	0.64	1,342,819

The following table summarizes warrants outstanding and exercisable at March 31, 2010:

Exercise price \$	Number outstanding	Expiry date
0.71	375,026	May 23, 2010
0.27	250,891	May 20, 2011
0.65	6,398,990	March 16, 2015
0.64	7,024,907	

# Protox Therapeutics Inc.

Notes to the Interim Financial Statements (unaudited)  
For the three months ended March 31, 2010 and 2009

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## Shareholders' equity (continued)

### c) Other equity

At March 31, 2010, the Company had other equity recorded as follows:

	Amount \$
Balance outstanding - December 31, 2008	4,780,754
Stock-based compensation	338,927
Balance outstanding - December 31, 2009	5,119,681
Stock-based compensation	115,090
Balance outstanding - March 31, 2010	5,234,771

### 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 March 31, 2010, the Company had 96,195,585 common shares issued and outstanding resulting in a maximum of 9,619,559 options issuable.

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

	Number of options	Weighted average exercise price \$
Balance outstanding at 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 at December 31, 2009	6,647,500	0.69
Options expired	(39,000)	1.00
Options forfeited	(300,000)	0.76
Balance at March 31, 2010	6,308,500	0.68

# Protox Therapeutics Inc.

Notes to the Interim Financial Statements (unaudited)  
For the three months ended March 31, 2010 and 2009

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## Shareholders' equity (continued)

The following table summarizes stock options outstanding and exercisable at March 31, 2010:

Exercise price	Number outstanding	Weighted average remaining contractual life (years)	Weighted average exercise price	Number	Weighted average remaining contractual life (years)	Weighted average exercise price
0.40 - 0.50	2,155,000	4.4	0.50	602,500	4.4	0.50
0.51 - 0.60	940,000	2.1	0.53	681,667	1.2	0.52
0.61 - 0.70	225,000	1.9	0.64	225,000	1.9	0.64
0.71 - 0.80	1,443,500	2.1	0.77	1,303,500	2.1	0.77
0.81 - 0.90	670,000	2.8	0.88	521,666	2.8	0.88
0.91 - 1.00	875,000	0.2	1.00	875,000	0.2	1.00
	6,308,500	2.7	0.68	4,209,333	1.9	0.77

## 8 Related party transactions

During the quarter ended March 31, 2010, certain directors provided business advisory and scientific consulting services to the Company pursuant to consulting agreements. The Company incurred expenses of \$20,000 under such agreements. These transactions were incurred in the normal course of business and recorded at their exchange amounts.

## 9 Research agreements and commitments

### a) Operating leases

The Company has operating lease agreements for the rental of office and laboratory facilities until April 30, 2011 and June 30, 2010, respectively, amounting to total commitments of \$97,000.

# **Protox Therapeutics Inc.**

Notes to the Interim Financial Statements (unaudited)  
For the three months ended March 31, 2010 and 2009

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## **Research agreements and commitments (continued)**

### **b) PORxin license agreement for prostate cancer**

In 2004, the Company signed an exclusive license agreement with John Hopkins University and the University of Victoria with respect to the use of PORxin 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 license 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 March 31, 2010, the Company has paid milestone payments of \$122,000.

### **c) PORxin license agreement for benign prostate hyperplasia**

In 2009, the company signed an exclusive license agreement with John Hopkins University and the University of Victoria with respect to the use of PORxin 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 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 March 31, 2010, the Company has paid milestone payments of \$125,000.

### **d) INxin license and acquisition**

On July 20, 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 has committed to pay Neurocrine and PHS up to US\$2.0 million over three years for the INxin license, regulatory assets and product related assets, of which US\$1.4 million had been paid as of December 31, 2009. Protox 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 paying royalties on commercial sales of resulting products.

### **e) HUMxin license agreement**

During 2008, the Company entered into a license agreement with PHS for an exclusive license 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 license 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 certain successful clinical and regulatory milestones and the compound receiving FDA approval for at least three indications, as well as paying royalties on commercial sales of resulting products.

# **Protox Therapeutics Inc.**

Notes to the Interim Financial Statements (unaudited)

For the three months ended March 31, 2010 and 2009

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## **Research agreements and commitments (continued)**

### **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 March 31, 2010, the Company has commitments to these third parties amounting to approximately \$2 million.

## **10 Subsequent events**

On April 29, 2010, the Company announced that it had entered into a US \$75 million license agreement with Kissei Pharmaceutical Co., Ltd. for the development and commercialization of its PSA-activated pro-drug, PRX302, in Japan for Benign Prostate Hyperplasia, prostate cancer and other diseases of the prostate. Protox retains exclusive rights to PRX302 in all other territories.

Under the terms of the agreement, Protox received an upfront payment of US \$3 million and is eligible to receive progressive payments of up to US \$72 million upon achievement of specific development, regulatory and commercial milestones. In addition Protox will receive a double-digit royalty fee plus a drug supply fee based on product sales. Kissei will be responsible for all costs associated with further development, regulatory approvals, commercialization and marketing of PRX302 in Japan.