

## **CYNAPSUS THERAPEUTICS INC.**

### **MANAGEMENT DISCUSSION AND ANALYSIS (“MD&A”) OF OPERATING RESULTS AND FINANCIAL CONDITION FOR THE YEAR ENDED DECEMBER 31, 2012**

The following Management’s Discussion and Analysis (“MD&A”) relates to the financial condition and results of operations of Cynapsus Therapeutics Inc. (“Cynapsus”, or the “Company”) for the year ended December 31, 2012 and should be read in conjunction with the Company’s consolidated financial statements for the year ended December 31, 2012. The financial statements and related notes of Cynapsus have been prepared in accordance with International Financial Reporting Standards (“IFRS”). Additional information, including our press releases, has been filed electronically through the System for Electronic Document Analysis and Retrieval (“SEDAR”) and is available online under our profile at [www.sedar.com](http://www.sedar.com).

This MD&A reports our activities through April 24, 2013 unless otherwise indicated. All amounts are expressed in Canadian (CDN) dollars, which is the functional currency of the Company, unless otherwise indicated.

Subsequent to December 31, 2012, the Company completed a share consolidation of the Company’s issued and outstanding common shares on the basis of one (1) new common share for every ten (10) common shares issued and outstanding. As required under IFRS, all common shares, option, warrants and per share amounts have been restated to give retrospective effect to the share consolidation.

#### **Cautionary Statement Regarding Forward-Looking Information**

Some of the statements contained in this MD&A constitute forward-looking statements within the meaning of applicable Canadian securities legislation. Generally, these forward-looking statements can be identified by the use of forward-looking terminology such as "plans", "expects" or "does not expect", "is expected", "budget", "scheduled", "estimates", "forecasts", "intends", "anticipates" or "does not anticipate", or "believes" or variations of such words and phrases or state that certain actions, events or results "may", "could", "would", "might" or "will be taken", "occur" or "be achieved". Forward-looking statements are subject to known and unknown risks, uncertainties and other factors that may cause the actual results, level of activity, performance or achievements of Cynapsus to be materially different from those expressed or implied by such forward-looking statements, including but not limited to those risks and uncertainties relating to Cynapsus’ business disclosed under the heading “Risk Factors” in the Company’s Annual Information Form dated November 1, 2012, under the heading “Risk and Uncertainties” in this “Management's Discussion and Analysis of Operating Results and Financial Condition” for the year ended December 31, 2012, and its other filings with the various Canadian securities regulators which are available online at [www.sedar.com](http://www.sedar.com). Although Cynapsus has attempted to identify important factors that could cause actual results to differ materially from those contained in forward-looking statements, there may be other factors that cause results not to be as anticipated, estimated or intended. There can be no assurance that such statements will prove to be accurate, as actual results and future events could differ materially from those

anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements. Cynapsus does not undertake to update any forward-looking statements, except in accordance with applicable securities laws.

## **Company Overview**

Cynapsus is a specialty pharmaceutical company developing the only non-injectable (i.e. sublingual) delivery of the only approved drug (apomorphine) to be used as a rescue therapy for “off” motor symptoms of Parkinson’s disease. Over one million people in the U.S. and an estimated 5 million people globally suffer from Parkinson’s disease. Parkinson’s disease is a chronic and progressive neurodegenerative disease that impacts motor activity, and its prevalence is increasing with the aging of the population. Based on a recent study and the results of the Company’s Global 500 Neurologists Survey, it is estimated that between 25 percent and 50 percent of patients experience “off” episodes in which they have impaired movement or speaking capabilities. Current medications only control the disease’s symptoms, and most drugs become less effective over time as the disease progresses.

Cynapsus’ drug candidate, APL-130277, is an easy-to-administer, fast-acting reformulation of apomorphine, which is approved in an injection formulation to rescue patients from “off” episodes. Cynapsus is focused on maximizing the value of APL-130277 by completing pivotal studies in advance of a New Drug Application (“NDA”) expected to be submitted in 2015. Cynapsus anticipates a trade sale or out-licensing to an appropriate global pharmaceutical partner before such an application is submitted.

## **Drug Development**

Cynapsus is currently focused on clinical development and maximizing the commercialization potential of APL-130277, primarily through a semi-virtual outsourcing business model integrating a leading team of formulation developers, active pharmaceutical ingredient (“API”) suppliers, regulatory and intellectual property experts, neuroscientists and central nervous system researchers. To date, pilot proof-of-concept Phase 1 human volunteer clinical trials have been conducted by a Contract Research Organization in Asia. It is expected that CROs in Asia, the U.S. and/or Europe will be selected to manage future clinical trials.

APL-130277 is being developed under 505(b)(2) of the Federal Food, Drug and Cosmetic Act (“FFDCA”) of the United States. In April 2011, the Company met with the U.S. Food and Drug Administration (“FDA”) in a pre-IND (“Investigational New Drug”) meeting to propose a regulatory strategy toward achieving approval of APL-130277. The results and meeting minutes reflect the FDA’s guidance on a two-step process: first, demonstrate bioequivalence to the approved subcutaneous injectable form of apomorphine (Apokyn®); and, second, demonstrate safety and tolerability of APL-130277’s sublingual thin film strip dosage form in an appropriate patient population.

## **Parkinson's Disease**

Parkinson's disease is a chronic, progressive, neurodegenerative disease that results from the death of neurons in the region of the brain that control movement. This degeneration creates a shortage of an important brain signalling chemical, or neurotransmitter, known as dopamine, rendering patients unable to initiate movements in a normal manner. Parkinson's disease is characterized by a number of symptoms, including tremors, rigidity, slowness of movement, impaired balance and difficulty swallowing, as well as significant non-motor disturbances, including mood disorders, fatigue and dementia. The severity of Parkinson's disease symptoms progressively worsens over time.

Patients with Parkinson's disease have trouble dressing, walking, talking or completing simple tasks that require coordinated muscle movement. Treatment paradigms exist to account for the progression of the disease and wearing-off phenomena that eventually leave patients with disabling motor and non-motor fluctuations, as well as involuntary movements. In general, 30-50% experience wearing off 5 years after initiating levodopa therapy and this number increases by about 5-10% per year after initiating levodopa to reach upwards of 70% after 9 or more years. The cause of Parkinson's disease remains undetermined. There is no cure, and the need for improvement over the current treatments for symptoms is significant.

Parkinson's disease typically affects people 60 years of age or older. Parkinson's disease affects more than 1 million patients in the U.S. and an estimated 5 million worldwide. The Company expects the Parkinson's disease drug market to grow significantly during the next several decades because of the aging "baby-boomer" worldwide population and the prolonged survival of Parkinson's disease patients.

Currently there are several approaches to the treatment of Parkinson's disease: dopamine stimulation, dopamine replacement, and drugs that inhibit the breakdown of dopamine. Dopamine stimulation strategies, referred to as dopamine agonists, seek to stimulate the dopamine receptor in place of naturally released dopamine. Dopamine replacement strategies are designed to supplement normally produced levels of dopamine. This is accomplished through the use of levodopa, a dopamine prodrug which is broken down in the body to produce dopamine, the natural neurotransmitter involved in motor function. Drugs that inhibit the breakdown of dopamine include dopamine decarboxylase inhibitors ("DDIs"), catechol-O-methyl transferase ("COMT") inhibitors, and monoamine oxidase B ("MAO-B") inhibitors.

In addition to the above approaches, neurosurgery, brain stimulation devices or cell implants, are reserved for late-stage Parkinson's patients that no longer respond to pharmacotherapy.

Existing therapeutic approaches have a number of limitations. Dopamine replacement is the leading therapy for the treatment of Parkinson's disease. Levodopa's effectiveness is hampered by its low water-solubility and limited absorption in the small intestine of the Parkinson's patient. Dopamine agonists have limited benefits due to the fewer number of neurons in that part of the brain of the patient. DDI, COMT and MAO-B inhibitors are limited in their effect due to the reduced levels of dopamine in the brain of the patient.

Notwithstanding the limitations, the combination of levodopa and carbidopa, the latter being a DDI, is the current standard of care for Parkinson's patients. Unstable levodopa levels in the blood and brain are believed to lead to variable, unpredictable efficacy and side-effects, including involuntary movements and psychological disorders. Spikes and troughs in the blood profile of the drug are often cited as one of the key factors leading to refraction, a condition where the drug becomes less effective over time (lesser activity and shorter duration of action). This leads patients to supplement their dose of levodopa with more levodopa, in hopes of achieving efficacy, only to further exacerbate the refraction problem. As a result, Parkinson's patients increasingly experience periods without the ability to move regardless of the amount of drug consumed (i.e., "off" time).

## **Apomorphine**

Apomorphine hydrochloride has been known since the 1960s to be effective in Parkinson's disease. An injectable form of apomorphine hydrochloride was developed in the 1990's to treat mid-to-late stage Parkinson's disease patients suffering from motor fluctuations, and is known to be efficacious, safe and well-tolerated. Motor fluctuations are most common during end-of-dose deterioration in mobility known as "wearing off". These periods are a result of reduced duration of levodopa effectiveness, usually requiring increases in dose frequency of levodopa with less clinical benefit. This results in a "never on" phenomena and an eventual extension of "off" symptoms including tremors, bradykinesia, and rigidity.

Apomorphine by injection is the only approved form of apomorphine hydrochloride, sold in approximately 40 markets world-wide. Apomorphine is currently marketed as a hydrochloride injection in the U.S. under the trade name Apokyn, and outside the U.S. as ApoGo, ApokinON or Apomin, by a pharmaceutical company with partners in Europe, the Americas and Asia-Pacific.

In 2004, Apokyn was approved in the U.S. with Orphan Drug Status. In April 2011, the Orphan Drug Status expired.

Since the early 1990s, several groups have attempted to conceive and develop new drug delivery forms of apomorphine to avoid the injection route. Apomorphine cannot be formulated for oral ingestion because swallowing results in almost complete inaction as a result of liver metabolism. These included primarily unsuccessful attempts to develop drug products delivered via nasal, inhaled, sublingual tablet and transdermal routes. As almost all of these developments occurred prior to Apokyn® approval in 2004, they were new drug product developments and required full Phase 3 clinical trials. More recent sublingual, nasal and inhaled developments are more loosely aligned with the pharmacokinetic properties of the drug and an approval pathway that benefits from prior approval and known efficacy and safety record of Apokyn®.

In most cases, where the drug has been delivered either by injection, nasally or sublingually, clinicians have observed irritation. Cynapsus believes that irritation resulting from absorption of the drug is related to release of the hydrochloride salt ("HCl") that is part of the API's (active pharmaceutical ingredient) chemical structure. To remain stable for extended periods of time, apomorphine must be formulated as an acid (HCl) salt, but during absorption into the blood

stream that HCl is released, causing a lowering of the local pH and, irritation. After repeat administration, this results in what is essentially a chemical (acid) burn. It is believed that inhaled delivery will equally result in irritation and that regulatory agencies will be very vigilant and request extensive clinical testing to demonstrate non-irritance and safety.

### **APL-130277**

Cynapsus' drug candidate, APL-130277, is an easy-to-administer, fast-acting reformulation of apomorphine, being developed to rescue patients from "off" episodes. APL-130277 is a bilayer film that incorporates a neutralizing agent. The neutralizing agent is maintained in a separate layer from the API to avoid any reaction between the two before administration, as the neutral form of the drug is unstable to air oxidation. In a thin film format the neutralizing agent reacts immediately upon dissolving in saliva with the API and maintains a "normal", near physiological pH, during absorption, thus obviating any issues with irritation. To date, short term administration of APL-130277 in animal and human studies has not shown any macroscopic or microscopic signs of irritation.

In July 2010, Cynapsus announced the results of a survey of neurologists and movement disorder specialists relating to Parkinson's practices and treatments, specifically targeted at analyzing the use of apomorphine products. An independent, experienced, medical survey company in the U.S. questioned 50 neurologists in the United States and Europe, who collectively treat approximately 12,000 Parkinson's patients for motor fluctuations. The results of the survey validated the APL-130277 product concept and showed that neurologists would value an approved drug using the Company's sublingual delivery system and would use the APL-130277 product to treat several categories of Parkinson's patients.

In November 2010, Cynapsus announced that it received favourable results from a second survey conducted, on behalf of the Company, by the same leading independent healthcare market research group. The survey results forecast favourable acceptance of APL-130277 by HMO's and insurers as well as an attractive range of pricing for the product from a reimbursement perspective. This survey of 11 large U.S. payors gauged the opinion and acceptance of APL-130277. The results indicate that APL-130277 may be readily accepted by payors and reimbursed at price levels at or near the level at which apomorphine injection is currently reimbursed.

In December 2010, Cynapsus announced the completion of results of pre-clinical animal model studies of APL-130277. The results demonstrated that the APL-130277 sublingual thin film strip system was able to deliver apomorphine into the bloodstream of rabbits in a similar manner as injection, in the proper quantity and over the required period of time.

In April 2011, Cynapsus met with the FDA in a pre-IND meeting. Cynapsus reviewed the drug product concept, data obtained to date and proposed a 505(b)(2) type regulatory pathway for approval of APL-130277. As described in minutes from that meeting, the FDA agreed that a demonstration of bioequivalence of APL-130277 to Apokyn® subcutaneous injection would provide sufficient proof of PK equivalence of the new drug product. Bioequivalence is a Phase 1 pharmacokinetic clinical study where serum levels of a single dose of a test product are

compared to a single dose of approved (reference) drug in an appropriately designed crossover study using healthy human volunteers. Statistical analysis of the maximum serum level (C<sub>max</sub>) and the total exposure, as measured by the area under the curve (AUC) should be between 80% and 125% with a confidence interval of 95%. In addition, the FDA will require an additional study in naïve Parkinson's patients over a minimum of 12 weeks to demonstrate safety and tolerability of the drug that is administered via this new route of administration.

In December 2011, Cynapsus announced the results of the Global 500 Neurologists Survey. Collectively, the professionals surveyed treat approximately 62,000 Parkinson's patients per year with approximately 41.4% classified as mild-moderate in severity, 42.2% as moderate-severe, and 16.4% as severe. The results of this survey confirm and expand on the results of the smaller neurologist survey that was completed at the direction of the Company in July 2010.

In January 2012, Cynapsus announced positive data from the first human volunteer pilot proof-of-concept study (CTH-101) of APL-130277. The study showed a pharmacokinetic ("PK") profile that compared favourably to injected apomorphine with a mean T<sub>max</sub> of 25 minutes and good tolerability. The successful completion of this first in man study was an important de-risking event for APL-130277.

The pharmacokinetics and safety/tolerability of APL-130277 were demonstrated in 15 healthy volunteers with 12 of 15 subjects receiving drug product and 3 subjects receiving placebo. Patients were dosed in a two period crossover with APL-130277 placing the drug in a different orientation under the tongue. The study determined that the sublingual orientation does impact the T<sub>max</sub> and PK of APL-130277. In the majority of subjects, maximum blood levels were reached within 20 minutes of administration. Pharmacokinetic parameters mirrored those seen with a subcutaneous injection of apomorphine after an expected dose adjustment. The study showed that APL-130277 was safe and showed good local tolerability (no irritation). Adverse events were mostly mild in intensity with one subject having moderate nausea and dizziness post dosing. In placebo treated subjects, 33% had at least one adverse event during the treatment period, with 17% of subjects having at least one adverse event in the APL-130277 treatment group. The adverse effects were typical of those commonly observed with apomorphine injection.

In August 2012, Cynapsus announced that it had been awarded a grant of USD\$947,925 from the The Michael J. Fox Foundation ("MJFF") for Parkinson's Research to support clinical studies to develop APL-130277, a sublingual thin film strip reformulation of apomorphine. The grant was awarded under the MJFF's The Edmond J. Safra Core Programs for Parkinson's Research, Clinical Intervention Award, aimed at supporting human clinical trials testing promising Parkinson's therapies that may significantly and fundamentally improve treatment for people with Parkinson's.

In August 2012, Cynapsus announced the results of a second human volunteer pilot proof-of-concept clinical trial (CTH-102) of APL-130277. The results of the first study (CTH-101) were reported on January 10, 2012. This second pilot study was closed out in August 2012 after it was determined that the goal of finding a therapeutic dose had been reached. The first dose evaluated in the study was deemed to be dose proportional to the dose evaluated in the CTH-101 clinical

pilot study and achieved a pharmacokinetic profile (C<sub>max</sub>, AUC and T<sub>max</sub>) that was sufficiently similar to subcutaneous injectable apomorphine. Management decided that it was unnecessary to proceed with a second dose, and then began preparations for a Comparative Biostudy (CTH-103) to be funded by the MJFF.

The pharmacokinetics and safety/tolerability of APL-130277 were demonstrated in the second Phase 1 pilot study in 12 healthy volunteers with 10 of 12 subjects receiving active drug product and 2 receiving placebo. Patients were dosed in a two period crossover with APL-130277 placing the drug in a different orientation under the tongue. The study determined that the sublingual orientation does impact the T<sub>max</sub> and PK of APL-130277. The dose was deemed to be dose proportional to the dose evaluated in CTH101 and achieved a pharmacokinetic profile (C<sub>max</sub>, AUC and T<sub>max</sub>) that was sufficiently similar to subcutaneous injectable apomorphine that management decided to begin preparations for the Comparative Biostudy (CTH-103).

In September 2012, Cynapsus commenced activities for the CTH-103, a Comparative Biostudy of APL-130277. CTH-103 will be a placebo-controlled, randomized cross-over Phase 1 trial in healthy volunteers to examine the pharmacokinetic profile of three dose strengths of APL-130277 as compared to equivalent doses of apomorphine subcutaneous injection. The objective of this study is to directly compare the pharmacokinetic profile of APL-130277 to subcutaneous apomorphine in healthy subjects to more precisely design the subsequent bio-equivalent registration trial to support an FDA 505(b)(2) NDA in 2015.

### **APL-130277 Regulatory Plan**

For development of APL-130277 in the United States, the Company will follow the 505(b)(2) regulatory pathway. Specifically, the Company is pursuing the reformulation of apomorphine from a subcutaneous injection to a convenient and more tolerable and safe sublingual thin film strip. The drug being delivered (apomorphine) is identical to the drug used in the injection, and its use will be intended as an acute rescue therapy for Parkinson's patients experiencing acute, intermittent hypomobility (i.e. "off" episodes) associated with advanced Parkinson's disease.

Based on a pre-IND meeting with the CNS division at the FDA in April 2011, as well as the extensive experience of the Company's regulatory consultant (a former FDA Director) and its Chief Medical Officer, the Company will pursue a 505(b)(2) bioequivalence pathway for regulatory and clinical development.

This pathway will require that the Company provide statistically sufficient clinical evidence that the pharmacokinetic parameters (i.e. the amount of drug in a specified time period accumulates in the blood stream of a person) are sufficiently similar to those of the injection to be bioequivalent and provide for the fast "on" that Parkinson's patients experience with the injectable form of apomorphine. To achieve this, the Company will be required to complete a minimum of two clinical studies: (1) a pharmacokinetic study in healthy volunteers; and (2) a study in Parkinson's patients to determine that this new method of delivery is safe and tolerable.

The Bioequivalence PK Study (CTH-201) is expected to begin in early 2014, subsequent to the filing and approval of an IND application by the FDA. Based on the FDA's 505(b)(2)

regulations, this study will be required to demonstrate that the C<sub>max</sub> (maximum concentration of drug in the blood stream after administration) and AUC (area under the curve, i.e. total exposure to drug as calculated by integration of the pharmacokinetic profile of concentration of drug in the blood versus time) is within 80% to 125% of the values achieved by the reference drug, Apokyn® injection. Further, based on the guidance provided during the pre-IND meeting with the FDA, it will be important that the T<sub>max</sub> (the time that which C<sub>max</sub> is achieved) be within the range of 10 to 60 minutes (as per information from the prescribing information of Apokyn®).

Upon successful completion of the Bioequivalence PK study, the Company will provide the results to the FDA. The Company will then request a meeting to confirm the results and their interpretation with the FDA and seek final guidance on the structure and end points, both primary and secondary, for the Safety Study (CTH-301). The Safety Study is expected to start in the second half of 2014 and be completed in 2015. Based upon our initial interaction with the FDA, the study is expected to administer the drug to approximately 150 to 250 Parkinson's patients diagnosed and in need of apomorphine, but have never used it before. The FDA has indicated that this study must specifically look at the safety and tolerability and safety of the new delivery route over a minimum period of 12 weeks. The Company currently plans to run this study for at least 16 weeks.

The Company currently does not expect to be required to conduct any efficacy studies for U.S. approval, because the drug's efficacy has been proven in the past and is well-understood by the FDA.

In Europe, the Company and its experienced European regulatory consultants currently expect to be required to complete a Safety/Efficacy Study with 75 Parkinson's patients over a duration of 16-20 weeks and with an open label safety extension out to at least 30 weeks in total. The Company does not plan on completing this European study using internal resources. This study is expected to be undertaken after a partnering event, either as a post-transaction commitment or as a means of earning into the value of the project, or possibly as a result of access to non-dilutive capital, such as a grant.

In parallel to the BioEquivalence PK and Safety Studies, the Company will be performing the necessary scale-up, process validation and stability as part of the Chemistry, Manufacturing and Controls (CMC) requirements for the filing of the NDA. Accordingly, all development will be performed according to Good Manufacturing Practices (GMP) methodology.

Upon completion of the PK and Safety studies, as well as the CMC section, the Company will begin the preparation of a FDA 505(b)(2) NDA in 2015. This dossier will be shared with several potential Global Pharmaceutical Companies under confidentiality, in order to gauge their interest in completing a licensing or purchase transaction.

The Company may consider completing the application for submission to the FDA as a modified New Drug Approval application if it is judged by the Board and management to be cost effective.



## REVIEW OF OPERATING RESULTS:

### *Operating, General and Administrative (“OG&A”) Expense*

For the year ended December 31,

	2012 (\$)	2011 (\$)	\$ change in 2012	% change in 2012
Operating, general and administrative	1,373,192	1,236,297	136,895	11.1

For the three months ended December 31,

	2012 (\$)	2011 (\$)	\$ change in 2012	% change in 2012
Operating, general and administrative	380,109	168,932	211,177	125.0

The increase in OG&A expense in the year ended December 31, 2012 compared to December 31, 2011 is primarily attributed to Board approved increases in senior officers’ salaries starting January 1, 2012, which were being accrued, not paid, until an equity financing of \$3 million or more was completed. The increases in base salaries were approved by the Board to compensate for several years without salary increases. Other increases in OG&A expense in 2012 compared to 2011 related to increased corporate finance and marketing efforts, which mostly offset the absence of one-time professional fees that occurred in the first and second quarters of 2011 due to the acquisition of Adagio Pharmaceuticals Ltd. and the transition to International Financial Reporting Standards (IFRS).

The increase in OG&A expense in the three months ended December 31, 2012 compared to December 31, 2011 is primarily attributed to increased corporate finance and legal fees, as well as senior officers’ salaries which were being accrued, not paid.

### *Research and Development (“R&D”) Expense*

For the year ended December 31,

	2012 (\$)	2011 (\$)	\$ change in 2012	% change in 2012
Research and development	814,716	907,483	(92,767)	(10.2)

For the three months ended December 31,

	2012 (\$)	2011 (\$)	\$ change in 2012	% change in 2012
Research and development	336,186	519,184	(182,998)	(35.2)

The decrease in R&D expense for the year ended December 31, 2012 compared to December 31, 2011 is primarily due to the lower costs of the second Phase 1 human volunteer study (CTH102) compared to the costs of the first Phase 1 human volunteer study (CTH101). In particular, the formulation development, consulting and analytics expenses related to CTH101 study completed in 2011, were higher than the formulation development, consulting and analytics expenses related to the CTH102 study completed in 2012. The lower costs of the CTH102 study were partially offset by the expenses related to The Michael J. Fox Foundation funded CTH103 study, which commenced in September 2012.

The decrease in R&D expense for the three months ended December 31, 2012 compared to December 31, 2011 is primarily due to higher consulting, analytics and clinical expenses related to the CTH101 study completed in the fourth quarter of 2011, which were greater than the expenses related to The Michael J. Fox Foundation funded CTH103 study in the fourth quarter of 2012.

### *Other Operating Expenses*

For the year ended December 31,

	2012 (\$)	2011 (\$)	\$ change in 2012	% change in 2012
Other operating expenses				
Share-based payments	335,497	87,348	248,149	284.1
Amortization of intangible assets	58,986	11,110	47,876	430.9
Depreciation of equipment	2,002	2,762	(760)	(27.5)
Foreign exchange (gain) loss	(9,572)	23,094	(32,666)	(141.4)
(Recovery) on scientific research	(86,219)	(51,467)	(34,752)	67.5
Total other operating expenses	300,694	72,847	227,847	312.8

For the three months ended December 31,

	2012 (\$)	2011 (\$)	\$ change in 2012	% change in 2012
Other operating expenses				
Share-based payments	36,480	8,331	28,149	337.9
Amortization of intangible assets	14,746	2,777	11,969	431.0
Depreciation of equipment	500	690	(190)	(27.5)
Foreign exchange (gain) loss	7,554	(3,954)	11,508	(291.1)
(Recovery) on scientific research	(20,000)	17,500	(37,500)	(214.3)
Total other operating expenses	39,280	25,344	13,936	55.0

The increase in other operating expenses in the year ended December 31, 2012 compared to December 31, 2011 is primarily attributed to increases in share-based payments resulting from the issuance of 667,250 stock options to directors, officers, employees and other service providers following the closing of the debenture financing in March 2012 (2011 – 115,000 stock options).

The increase in other operating expenses in the three months ended December 31, 2012 compared to December 31, 2011 is attributed to increases in share-based payments, amortization of intangible assets and foreign exchange loss, which were partially offset by the increase in recovery on scientific research.

*Other Loss (Income)*

For the year ended December 31,

	2012 (\$)	2011 (\$)	\$ change in 2012	% change in 2012
Other loss (income)				
Research grant	(289,516)	-	(289,516)	-
Other income	(13,200)	(9,300)	(3,900)	41.9
Debenture accretion and interest costs	1,097,552	631,980	465,572	73.7
(Gain) on extension of debenture maturity dates	(225,263)	-	(225,263)	-
Other interest and related charges	5,631	7,940	(2,309)	(29.1)
Total other loss (income)	575,204	630,620	(55,416)	(8.8)

For the three months ended December 31,

	2012 (\$)	2011 (\$)	\$ change in 2012	% change in 2012
Other loss (income)				
Research grant	(227,916)	-	(227,916)	-
Other income	(3,300)	(3,300)	-	-
Debenture accretion and interest costs	298,625	245,521	53,104	21.6
(Gain) on extension of debenture maturity dates	-	-	-	-
Other interest and related charges	4,173	131	4,042	3,085.5
Total other loss (income)	71,582	242,352	(170,770)	(70.5)

The decrease in other loss (income) in the year ended December 31, 2012 compared to December 31, 2011 is primarily attributed to the receipt in September 2012 of the first milestone payment of the research grant from The Michael J. Fox Foundation. This income was partially offset by the increase in accretion and interest expenses associated with the Series E5 debentures issued on March 9, 2012, net of the impact of the extension of the maturity dates of the Series A-E debentures to February 28, 2013, which occurred in conjunction with the closing of Series E5 debentures.

The decrease in other loss (income) in the three months ended December 31, 2012 compared to December 31, 2011 is primarily attributed receipt research grant from The Michael J. Fox Foundation, which was partially offset by the increase in accretion and interest expenses associated with debentures.

*Loss and Loss Per Share*

For the year ended December 31,

	2012 (\$)	2011 (\$)	\$ change in 2012	% change in 2012
Loss	3,063,806	2,847,247	216,559	7.6
Basic and diluted loss per share	0.22	0.28	0.06	(21.4)

The loss per share for year ended December 31, 2012 compared to December 31, 2011 increased as increases in senior officer compensation, corporate finance, marketing, share-based payments, and debenture accretion and interest expenses, more than offset the decreases in research and development expenses, a one-time gain on the extension of the maturity dates of the Series A-E debentures to February 28, 2013, and the impact of the first milestone payment of the research grant received from The Michael J. Fox Foundation.

## SUMMARY OF QUARTERLY RESULTS:

### Annual Statements of Income:

	2012 (\$)	2011 (\$)
Total assets	1,169,000	1,202,000
Revenues	-	-
Interest income	-	-
Operating, general and administrative	1,373,000	1,236,000
Research and development	815,000	907,000
Other	876,000	704,000
Net loss	3,064,000	2,847,000
Loss per share (basic and diluted)	0.22	0.28

For the year ended December 31, 2012

	Q1(\$)	Q2(\$)	Q3(\$)	Q4(\$)	2012 Total (\$)
Total assets	1,403,000	948,000	1,137,000	1,169,000	
Revenues	-	-	-	-	-
Interest income	-	-	-	-	-
Operating, general and administrative	395,000	384,000	214,000	380,000	1,373,000
Research and development	122,000	252,000	105,000	336,000	815,000
Other operating expenses	111,000	63,000	87,000	39,000	300,000
Research grant		-	(61,000)	(229,000)	(290,000)
Other income	(4,000)	(2,000)	(3,000)	(4,000)	(13,000)
Debenture accretion and interest costs	206,000	295,000	299,000	298,000	1,098,000
(Gain) on extension of debenture maturity dates	(225,000)	-	-	-	(225,000)
Other interest and related charges	-	-	2,000	4,000	6,000
Net loss	603,000	992,000	641,000	828,000	3,064,000
Loss per share (basic and diluted)	0.05	0.07	0.05	0.05	0.22

For the year ended December 31, 2011

	Q1(\$)	Q2(\$)	Q3(\$)	Q4(\$)	2011 Total (\$)
Total assets	563,000	439,000	657,000	1,202,000	
Revenues	-	-	-	-	-
Interest income	-	-	-	-	-
Operating, general and administrative	345,000	510,000	212,000	169,000	1,236,000
Research and development	147,000	190,000	51,000	519,000	907,000
Other operating expenses	112,000	111,000	213,000	268,000	704,000
Net loss	604,000	811,000	476,000	956,000	2,847,000
Loss per share (basic and diluted)	0.06	0.08	0.05	0.09	0.28

## **LIQUIDITY AND CAPITAL RESOURCES**

The cash balance at December 31, 2012 was \$50,401 compared to \$294,812 at December 31, 2011. Due to continuing operating losses and a working capital deficiency, the application of the going concern basis of accounting is dependent upon the Company achieving profitable operations to generate sufficient cash flows to fund continuing operations, or in the absence of adequate cash flows from operations, obtaining additional financing to support operations for the foreseeable future. It is not possible to predict whether financing efforts will be successful or if the Company will attain profitable levels of operations. Notwithstanding the above, subsequent to December 31, 2012, there have been several positive changes to the Company's cash position. In particular, the Company completed two closings of a short form prospectus financing for total gross proceeds of \$7,317,160.

Since inception, cash requirements have been financed primarily through issuances of securities. In the past two years, the Company has also raised capital through the issuance of secured debentures. Cynapsus anticipates future funding requirements to be met primarily through additional securities issuances, debentures, research and development tax credits, other potential sources of government funding, grants from foundations that support Parkinson's research, or a combination of the above.

The balance of accounts payable and accrued liabilities was \$2,119,438 at December 31, 2012, compared to \$1,389,004 at December 31, 2011.

The balance of Series A to Series E debentures payable was \$4,059,693 at December 31, 2012, compared to \$2,646,446 at December 31, 2011. Subsequent to December 31, 2012, on February 28, 2013, the total debentures outstanding was \$4,238,717. On March 1, 2013, holders of \$4,031,406 in Series A to Series E debentures agreed to an exchange of debt for shares and warrants, with the remaining \$207,311 repaid.

The development of pharmaceutical products is a process that requires significant investment. Cynapsus expects to incur losses from operations for the foreseeable future. R&D expenses are expected to increase, including the expenses related to additions of personnel and clinical trials. General and administrative expenses are expected to increase in the future as the Company adds infrastructure and incurs additional costs.

Future cash requirements will depend on a number of factors, including the continued progress of R&D for the APL-130277 drug candidate, the timing and outcome of clinical trials and regulatory approvals, the ability to out-license drug candidates to partners, the timing of payments received or made under licensing or other agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, defending against patent infringement claims, the status of competitive products and the success of the Company in developing and maintaining markets for its products.

### *Operating Activities*

For the year ended December 31, 2012, operating activities used cash of \$1,337,821 compared to \$1,720,200 used in operations for the year ended December 31, 2011. Cash used in operating activities reflects the net loss of \$3,063,806 for the year ended December 31, 2012, adjusted for non-cash items including share-based payments, depreciation of equipment, amortization of intangible assets, debenture accretion expense, accrual of debenture interest expense, a gain on extension of debenture maturity dates, and changes in non-cash working capital (including deferred financing costs).

### *Investing Activities*

For the year ended December 31, 2012, investing activities were \$nil compared to \$44,999 for the year ended December 31, 2011. The amount for the year ended December 31, 2011 was paid expenses related to the acquisition of Adagio and the associated intellectual property.

### *Financing Activities*

For the year ended December 31, 2012, net financing activities were \$1,092,870 compared to \$1,866,527 for the year ended December 31, 2011.

Shareholders' deficiency increased to \$5,010,201 at December 31, 2012 from \$2,833,804 at December 31, 2011, as the value of the private placement shares and warrants issued, value of the debenture bonus shares issued and share-based payments issued, were insufficient to offset the net loss for the year ended December 31, 2012.

## **Share Capital**

The Company has authorized an unlimited number of common shares with no par value.

A summary of common shares, stock options and common share purchase warrants issued is as follows:

	As at April 24, 2013			
	Number of shares #	Number of shares issuable on exercise of options #	Number of shares issuable on exercise of warrants #	Total #
Common shares	38,884,011	-	-	38,884,011
Stock options	-	1,573,066	-	1,573,066
Common share purchase warrants	-	-	21,551,763	21,551,763
<b>Total</b>	<b>38,884,011</b>	<b>1,573,066</b>	<b>21,551,763</b>	<b>62,008,840</b>



## **Off-Balance Sheet Arrangements**

The Company does not have any off-balance sheet arrangements.

## **Revenue and Expenses**

Revenue has historically been generated from interest received from short term deposits. Cynapsus expects longer-term revenues and profits to be generated from the commercialization of pharmaceutical products. These revenues are considered long-term as a result of the long lead times required to complete clinical trials and to receive regulatory approvals.

Research and development expenses consist primarily of vendor, personnel and related costs associated with the formulation development and clinical testing of the Company's pharmaceutical product candidates.

Operating, general and administration costs consist of personnel and related costs associated with management, administration and finance functions, as well as professional fees, office rent, insurance and other corporate expenses.

## **Debenture Financings and Share Issuances**

On March 9, 2012 the Company completed a financing of secured Series E5 debentures in the aggregate principal amount of \$1,075,865. As part of the financing, the Company issued 374,400 common shares to the debenture holders at a price of \$0.60 per share. The share price was estimated based on the trading price of a common share on the date of the issuance. As part of the Series E5 debenture financing, the due dates for all the other Series A-E debentures were extended to February 28, 2013.

## **Private Placements**

On July 18, 2012 the Company announced that it closed a non-brokered private placement of units. The Company issued an aggregate of 200,000 units at a price of \$0.50 per unit raising gross proceeds of \$100,000. Each unit consisted of one common share and one common share purchase warrant. Each warrant entitles the holder to acquire one common share at a price of \$1.00 for a period ending on the earlier of 5 years from the closing date, and a period ending 20 days after prior written notice from the Company that the closing price of its common shares on the principal stock exchange of the Company has been at least \$1.50 per share for 20 consecutive trading days. The common shares issued under the private placement were subject to a hold period of four months which expired on November 19, 2012. Related parties including the President and Chief Executive Officer, Chief Scientific Officer, and Chief Operating Officer/Chief Financial Officer participated on the same terms in the private placement, for an aggregate of 5% of the issued units.

On October 24, 2012 the Company announced that it closed a brokered private placement of 340,000 units at a price of \$0.50 per unit raising gross proceeds of \$170,000. Each unit consisted of one common share and one share purchase warrant. Each warrant entitles the holder to acquire one additional common share at an exercise price of \$0.625 per share. The warrants are exercisable by the holder thereof on any business day during the period ending 60 months following the closing date. The Company paid to Northern Securities Inc. cash commissions of \$5,200 and issued 10,400 non-transferable compensation warrants, each exercisable to purchase one common share on the same terms as the warrants issued in the private placement. The common shares issued under the private placement were subject to a hold period of four months expiring on February 24, 2013.

On November 23, 2012 the Company announced that it closed a brokered private placement of 126,200 units at a price of \$0.50 per unit raising gross proceeds of \$63,100. Each unit consisted of one common share and one share purchase warrant. Each warrant entitles the holder to acquire one additional common share at an exercise price of \$0.625 per share. The warrants are exercisable by the holder thereof on any business day during the period ending 60 months following the closing date. The Company paid to Northern Securities Inc. cash commissions of \$648 and issued 1,296 non-transferable compensation warrants, each exercisable to purchase one common share on the same terms as the warrants issued in the private placement. The common shares issued under the private placement were subject to a hold period of four months expiring on March 23, 2013.

### **Research Grant**

On August 8, 2012, the Company announced that it had been awarded a grant of USD \$947,925 (CDN \$942,977) from The Michael J. Fox Foundation (MJFF) for Parkinson's Research to support clinical studies to develop APL-130277. The grant was awarded under the Foundation's The Edmond J. Safra Core Programs for Parkinson's Research, Clinical Intervention Awards aimed at supporting human clinical trials testing promising Parkinson's therapies that may significantly and fundamentally improve treatment for people with Parkinson's. Funds awarded by MJFF are to be used solely for the project and are conditioned by meeting certain milestones and deliverables.

The first milestone payment of USD \$297,825 (CDN \$289,516) was received on September 20, 2012. The second milestone payment of USD \$412,087 (CDN \$411,057) was received on January 30, 2013, subsequent to December 31, 2012. The Company expects to receive the final milestone payment of USD \$238,012 and complete this research in Q3 2013.

### **Grant of Stock Options**

On March 23, 2012, the Company granted stock options to acquire 467,500 common shares. The stock options were granted to directors, officers and employees at an exercise price of \$1.00 per share for a term of 5 years from the date of grant, and shall vest on the basis of 207,500 options immediately, 130,000 after 6 months, and 130,000 options after 12 months. Of the total,

95,000 stock options were granted to each of Andrew Williams (COO/CFO) and Nathan Bryson (CSO), 70,000 to Albert Agro (CMO), 40,000 to Rochelle Stenzler (Director), and 20,000 to each of Ron Hosking (Director), Julia Levy (Director), Alan Ryley (Director) and Alan Torrie (Director).

On May 17, 2012, the Company granted stock options to purchase up to 46,250 common shares. The stock options were granted to an employee at an exercise price of \$1.00 per share for a term of 5 years from the date of grant, and shall vest in equal amounts quarterly over a 12 month period.

On May 30, 2012, the Company granted stock options to acquire 26,000 common shares. The stock options were granted to a director and an employee at an exercise price of \$1.00 per share for a term of 5 years from the date of grant, and shall vest on the basis of 12,666 options immediately, 6,667 in 6 months, and 6,667 options in 12 months.

On August 29, 2012, the Company granted stock options to acquire 46,250 common shares. The stock options were granted to an employee at an exercise of \$1.00 per share for a period of 5 years from the date of grant, and shall vest in equal amounts quarterly over a 12 month period.

On August 29, 2012, the Company granted stock options to acquire 35,000 common shares. The stock options were granted to directors and an officer at an exercise of \$1.00 per share for a period of 5 years from the date of grant, with all options vesting immediately. Of the total, 10,000 stock options were granted to each of Rochelle Stenzler (Director), Alan Ryley (Director) and Alan Torrie (Director), and 5,000 were granted to Andrew Williams (COO/CFO).

On November 14, 2012, the Company granted stock options to acquire 46,250 common shares. The stock options were granted to an employee at an exercise of \$1.00 per share for a period of 5 years from the date of grant, and shall vest in equal amounts quarterly over a 12 month period.

### **Expiry of Stock Options**

On March 22, 2012, 65,000 options held by a former board member expired unexercised.

On May 24, 2012, 26,000 options held by a current employee and a former employee expired unexercised.

On May 31, 2012, 50,000 options held by a former board member expired unexercised.

On June 25, 2012, 30,000 options held by current board members expired unexercised.

On June 30, 2012, 1,667 options held by an officer representing 5,000 common shares issuable on exercise of those options expired unexercised.

On August 31, 2012, 5,000 options held by current board members representing 15,000 common shares issuable on exercise of those options expired unexercised.

## **Related Party Transactions**

At December 31, 2012, included in accounts payable and accrued liabilities is \$649,504 (December 31, 2011: \$439,877) due to officers and directors of the Company. These amounts are unsecured, non-interest bearing with no fixed terms of repayment.

The value of share-based payments issued to related parties during the year ended December 31, 2012 is \$213,500 (December 31, 2011: \$34,000).

On September 29, 2011, the Company completed a financing of secured debentures in the aggregate amount of \$488,503 (See Note 12). Included in this total, was a \$28,735 debenture from a former director who also received 10,000 common shares at a price of \$0.30 per share.

As at December 31, 2012, \$125,915 (December 31, 2011: \$84,472) of the interest-bearing debentures are due to a former director of the Company. Subsequent to December 31, 2012, these debentures were exchanged for shares and warrants.

## **Commitments and Contingencies**

The Company is party to certain management contracts for its executive officers. Minimum management contract termination commitments remaining under the agreements, for termination without cause, are approximately \$441,000 plus any earned bonus amounts owing, and are all payable within one year.

The Company is subject to additional termination and stock option commitments, contingent upon the Company raising a cumulative amount of \$5 million in equity after November 16, 2009. Once raised, the Company will be required to issue 373,316 stock options priced at the then fair market value, but not less than \$0.10 per share, and will have additional management contract termination commitments of \$97,368. On March 1, 2013, the Company raised \$6,008,000 as part of a short form prospectus offering, triggering the issuance of these stock options.

On November 15, 2009, the former CEO resigned and is due \$216,500 over a twelve month period, contingent upon the Company raising additional equity and at the discretion of the Board. As Board approval has not yet been provided, the contingent payment has not been reflected in these consolidated financial statements. Subsequent to December 31, 2012, the Company completed two closings of a short form prospectus offering for gross proceeds \$7,317,160 (See Note 19, Subsequent Events). As a result, this amount became payable at that time.

During the years ended December 31, 2012, 2011 and 2010 the Company awarded bonuses of \$177,201, \$189,350 and \$179,052, respectively, to certain officers and employees of the Company, with payment being contingent upon the Company raising additional equity and at the discretion of the Board. As Board approval has not yet been provided, the contingent payments have not been reflected in these consolidated financial statements. Subsequent to December 31, 2012, the Company completed two closings of a short form prospectus offering for gross

proceeds \$7,317,160 (See Note 19, Subsequent Events). As a result, these amounts became payable at that time.

The Company and the principal shareholders of Adagio entered into a share purchase agreement dated December 22, 2011 providing for the purchase by the Company of all the issued and outstanding shares of Adagio. Upon closing, the Adagio shareholders were issued 2,600,000 common shares. In addition, the Adagio shareholders are entitled to the following payments pursuant to the transaction:

- (a) a payment of \$1,500,000 conditional upon the successful completion of the APL-130277 Phase 1 bioequivalence studies, to be satisfied by the issuance of common shares at a deemed value equal to the 30 day volume weighted average trading price (“VWAP”) immediately prior to the first public announcement of the results of such studies; and
- (b) a payment of \$2,500,000 conditional upon the successful completion of the APL-130277 final safety study, to be satisfied by the issuance of common shares at a deemed value equal to the 30 day VWAP immediately prior to the first public announcement of the results of such study.

With respect to the payments described in (a) and (b) above, the VWAP of the common shares may not be less than the “discounted market price” as defined in the policies of the Exchange.

### **Subsequent Events**

- (a) On February 2, 2013, warrants to acquire 580,000 common shares of the Company expired unexercised.
- (b) On March 1, 2013 the Company announced that it completed its short form prospectus offering (“the Offering”) of 13,061,688 units at a price of \$0.46 per unit for aggregate gross proceeds of \$6,008,000. Each unit consisted of one common share and one share purchase warrant. Each warrant entitles the holder to acquire one additional common share at an exercise price of \$0.575 per share from the closing date for a period of 60 months, except that the warrants will be cancelled if they are not exercised within 30 days after prior written notice from the Company that the closing price of its common shares on the principal stock exchange of the Company has been \$1.38 or greater for 20 consecutive trading days. The Company paid the Agent a work fee of \$87,500 plus applicable taxes and has agreed to reimburse the Agent for certain expenses incurred in connection with the Offering. The Company also paid the Agent a cash commission of \$47,088 and issued 102,365 non-transferable compensation warrants, each exercisable to purchase one common share on the same terms as the warrants issued in the Offering. In addition, the Company paid other registered dealers and brokers cash commissions of \$117,500 and issued 255,434 non-transferable compensation warrants, each exercisable to purchase one common share on the same terms as the warrants issued in the Offering.

In addition, the Company completed a share consolidation of the Company's issued and outstanding common shares concurrent on the basis of one (1) new common share for every ten (10) common shares issued and outstanding.

Concurrent with the closing of the Offering, the Company and holders of the Series A to E debentures agreed to convert \$4,031,406 in debt for common shares and warrants. This resulted in 8,761,399 common shares and 4,380,700 debenture warrants being issued. Each debenture warrant entitles the holder to acquire one common share at a price of \$0.575 for a period of 24 months after the closing date. The 8,761,399 common shares issued are subject to a hold period to July 2, 2013.

- (c) Effective March 1, 2013, the Company granted stock options to acquire 373,316 common shares. The stock options were granted to the President and CEO of the Company at an exercise price of \$0.46 per share for a period of 5 years from the date of the grant, and vested immediately.
- (d) On March 21, 2013 the Company announced that it completed a second closing of the Offering. The Company issued 2,846,000 units at a price of \$0.46 per unit for aggregate gross proceeds of \$1,309,160. Each unit consisted of one common share and one share purchase warrant. Each warrant entitles the holder to acquire one additional common share at an exercise price of \$0.575 per share from the closing date for a period of 60 months, except that the warrants will be cancelled if they are not exercised within 30 days after prior written notice from the Company that the closing price of its common shares on the principal stock exchange of the Company has been \$1.38 for 20 consecutive trading days. The Company paid to the Agent a cash commission of \$33,064 and issued 71,880 non-transferable compensation warrants, each exercisable to purchase one common share on the same terms as the warrants issued in the Offering. In addition, the Company paid other registered dealers and brokers cash commissions of \$71,668 and issued 155,800 non-transferable compensation warrants, each exercisable to purchase one common share on the same terms as the warrants issued in the Offering. The total gross proceeds from the first and second closings of the Offering is \$7,317,160. Additional closings of the Offering may occur as the Offering will be discontinued on the earlier of the date that the maximum offering of \$8,000,000 has been subscribed for and May 21, 2013.

Following the close of the Offering, the Company released from escrow 1,512,794 common shares to Adagio shareholders. As at April 24, 2013, a total of 699,530 common shares remain in escrow.

- (e) On April 4, 2013, 60,000 stock options held by current and former officers, directors and employees of the Company expired unexercised.

## **FINANCIAL RISK MANAGEMENT**

In the normal course of business, the Company is exposed to a number of financial risks that can affect its operating performance. These risks are: credit risk, liquidity risk and market risk. The Company's overall risk management program and prudent business practices seek to minimize any potential adverse affects on the Company's financial performance. There were no changes in the Company's approach to risk management during the years ended December 31, 2012 and 2011.

### **Credit Risk**

The Company's cash balance is on deposit with a Canadian chartered bank. The Company has no significant concentration of credit risk arising from operations. Management believes that the credit risk concentration with respect to these financial instruments is remote.

### **Liquidity Risk**

The Company's approach to managing liquidity risk is to ensure that it will have sufficient liquidity to meet liabilities when due (See Note 2). As at December 31, 2012, the Company had cash of \$50,401 and other current assets of \$325,916 (December 31, 2011 - \$294,812 and \$53,233) to settle current liabilities of \$6,179,131 (December 31, 2011 - \$4,035,450). The Company's accounts payable and accrued liabilities have contractual maturities of less than 30 days and are subject to normal trade terms; however, some accounts payable have been outstanding for more than one year. The terms of the debentures payable are disclosed in Note 12. The Company believes movement in interest rates is reasonably possible over the next 12 months. Since cash has varying terms and rates, sensitivity to a plus or minus 1% change in rates could affect the Company's net loss by approximately \$500.

## **RISKS AND UNCERTAINTIES**

An investment in the Company involves significant risks and must be considered speculative due to the nature of the Company's business. Investors should carefully consider the risks and uncertainties described below. This list of risks and uncertainties below is not exhaustive. Furthermore, additional risks and uncertainties not presently known to Cynapsus or that Cynapsus believes to be immaterial may also adversely affect Cynapsus' business. Prospective purchasers of securities in the capital of the Company should carefully consider the following risk factors, as well as other information which is available at [www.cynapsus.ca](http://www.cynapsus.ca) and at the System for Electronic Document Analysis and Retrieval ("SEDAR") at [www.sedar.com](http://www.sedar.com).

### **Availability of Additional Capital**

The Company incurred a net loss of \$3,063,806 for the year ended December 31, 2012 and expects to incur losses from continuing operations for the foreseeable future. As at December 31, 2012, the Company had cash of \$50,401. In addition, the Company had \$4,059,693 in secured debentures due on February 28, 2013. Subsequent to December 31, 2012, in March 2013, the Company completed two closings of a short form prospectus financing for total gross proceeds \$7,317,160. In addition, holders of \$4,031,406 in debentures agreed to a shares-for-debt exchange. There are no more debentures outstanding as at April 24, 2013.

The Company will require significant additional financing and it may not have access to sufficient capital. The Company anticipates it will need additional financing in order to fund its ongoing research and development activities and for general corporate requirements. The Company may choose to seek additional funding through public or private offerings, debentures, corporate collaborations, partnership arrangements or grants. The amount of financing required will depend on many factors including the financial requirements of the Company to fund its research and clinical trials, and the ability of the Company to secure partnerships and achieve partnership milestones as well as to fund other working capital requirements. The Company's ability to access the capital markets or to enlist partners is mainly dependent on the progress of its research and development and regulatory approval of its product. There is no assurance that additional funding will be available on acceptable terms, if at all.

### **Recent and Anticipated Future Losses**

The Company has a history of losses, and it has not generated any product revenue to date. It may never achieve or maintain profitability. Since inception, the Company has incurred significant losses each year and expects to incur significant operating losses as the Company continues product research and development and clinical trials. There is no assurance that the Company will ever successfully commercialize or achieve revenues from sales of its pharmaceutical product, if they are successfully developed, or that profitability will ever be achieved or maintained. Even if profitability is achieved, the Company may not be able to sustain or increase profitability.



## **Achievement of Development Goals in Time Frames Announced and Expected**

The Company sets goals for and makes public statements regarding the timing of the accomplishment of objectives material to its success, such as the commencement and completion of clinical trials, anticipated regulatory submission and approval dates and time of product launch. The actual timing of these events can vary dramatically due to factors such as delays or failures in the Company's clinical trials, or the uncertainties inherent in the arrangements sufficient to commercialize its product. There can be no assurance that the Company's clinical trials will be completed, that the Company will make regulatory submissions or receive regulatory approvals as planned. If the Company fails to achieve one or more of these milestones as planned, the price of the Common Shares would likely decline.

## **Strict Regulatory Environment**

The Company's product candidate has not received regulatory approval for commercial sale. Numerous statutes and regulations govern human testing and the manufacture and sale of human pharmaceutical products in Canada, the U.S. and other countries where the Company intends to market its product. Such legislation and regulation bears upon, among other things, the approval of protocols and human testing, the approval of manufacturing facilities, testing procedures and controlled research, review and approval of manufacturing, preclinical and clinical data prior to marketing approval including adherence to GMP during production and storage as well as regulation of marketing activities including advertising and labelling.

The completion of the clinical testing of the Company's product candidate and the obtaining of required approvals are expected to take approximately three years and require the expenditure of substantial resources. There can be no assurance that clinical trials will be completed successfully within any specified period of time, if at all. Furthermore, clinical trials may be delayed or suspended at any time by the Company or by regulatory authorities if it is determined at any time that patients may be or are being exposed to unacceptable health risks, including the risk of death, or that compounds are not manufactured under acceptable GMP conditions or with acceptable quality. Any failure or delay in obtaining regulatory approvals would adversely affect the Company's ability to utilize its technology thereby adversely affecting operations. No assurance can be given that the Company's product candidate will prove to be safe and effective in clinical trials or that it will receive the requisite protocol approval or regulatory approval. Furthermore, no assurance can be given that current regulations relating to regulatory approval will not change or become more stringent.

There are no assurances the Company can scale-up, formulate or manufacture sufficient quantities with acceptable specifications for the regulatory agencies to grant approval or not require additional changes or additional trials be performed. The agencies may also require additional trials be run in order to provide additional information regarding the safety, efficacy or equivalency of any drug candidate for which the Company seeks regulatory approval. Similar restrictions are imposed in foreign markets other than the U.S. and Canada. Investors should be aware of the risks, problems, delays, expenses and difficulties which may be encountered by the Company in light of the extensive regulatory environment in which the Company's business

operates. Even if a product candidate is approved by the U.S. FDA or any other regulatory authority, the Company may not obtain approval for an indication whose market is large enough to recoup its investment in that product candidate. The Company may never obtain the required regulatory approvals for its product candidate.

### **Patent Applications**

The Company's success will depend, in part, on its ability to obtain patents, protect trade secrets and operate without infringing upon the exclusive rights of third parties. Although the Company intends to file patent applications in the U.S., Europe and other jurisdictions, there is no guarantee that it will obtain such patents or that it will develop a patentable product. Moreover, there is no proof that any patent that is granted to the Company will make the product more competitive, that its patent protection will not be contested by third parties or that the patents of others will not be detrimental to the Company's commercial activities. It cannot be assured that other companies will not independently develop products similar to the Company's product, that they will not imitate its product, or that, if the Company obtains its patents, its competitors will not manufacture products designed to circumvent the exclusive patent rights granted to it.

### **Dependency on Securing a Pharmaceutical Partner**

It is unlikely that even with further funding raised by issuing securities and debt financing that the Company will be financially able to bring its product candidate to market. The Company has initiated its clinical and pre-clinical research programs for its product candidate with the intention that positive results will attract the attention of a well-financed pharmaceutical entity willing to enter into a partnership agreement to sponsor product development. There is a risk that the Company will not find such an entity, either at all or in sufficient time to support the research and clinical program. Failure to locate a pharmaceutical partner within a reasonable time frame could result in the cessation of the Company's product development programs and result in a failure to bring any product candidate to market.

If a pharmaceutical partner is secured, there is no guarantee that the terms of the partnership agreement will be competitive or favourable for the Company and there is a risk that such an agreement could have a negative impact on the Company's operations including, but not limited to:

- relinquishment of key managerial decisions;
- partial or complete loss of rights to intellectual properties;
- costly and hindering changes to clinical and research programs;
- alterations to third-party contracts; and
- unprofitable or inferior share of profits from any marketed product.

Such an event would have a material adverse effect on the Company's profits and pose a risk to shareholder value.

## **Dependence on Strategic Partnerships and Licenses**

The Company's success depends, in large measure, on its ability to conclude development, manufacturing and marketing and distribution agreements with other pharmaceutical companies.

Factors that may affect the success of the Company's collaborative efforts with pharmaceutical company partners include the following:

- the Company's partners may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with the product as to which they are collaborating with the Company, which could affect their commitment to the Company's product development efforts;
- the Company's technology partners may not be able to adequately supply its product in commercial quantities, which would adversely affect revenues;
- decreases in marketing or sales efforts or a discontinuation of marketing or sales of the Company's product by its commercial partners may reduce future revenues, which will be based on a percentage of net sales by these partners; and
- the Company's partners may terminate their collaborations with the Company, which could make it difficult for the Company to attract new partners or adversely affect how the Company is perceived in the business and financial communities.

The development of pharmaceutical products is a process that requires large investments and can take years to complete. Projects can be abandoned along the way or regulatory authorities can refuse to approve new products.

With respect to projects the Company initiates, the Company will attempt to minimize risk through the judicious selection of product candidates and by focusing on improving products that have already been marketed.

## **Dependency on Management and Key Consultants and Employees**

The Company's operations are dependent on the abilities, experience and efforts of its management, consultants, advisors and other key employees. Should any of these persons be unable or unwilling to continue in their employment or arrangement with the Company, this could have a material adverse effect on the Company's business, financial condition and results of operations. The Company does not have key man insurance on the lives of these personnel. In addition, substantial competition exists for qualified technicians and personnel in the pharmaceutical drug development industry, and the Company may be unable to attract or retain highly qualified personnel in the future to meet its needs. It is possible that additional incentives may be required and that some initiatives may be jeopardized if skill shortages occur. Any failure to attract qualified personnel may materially adversely affect the business, financial condition or results of operations of the Company.

## **Competition**

Competition within the pharmaceutical drug development industry is intense and is expected to increase in the future. The Company's competitors have long operating histories and greater financial, technical and marketing resources than the Company. The introduction of new drugs similar to those being developed by the Company by such competitors could materially and adversely affect the Company's business, results of operations and financial condition. There can be no assurance that the Company will be able to respond effectively, or in a timely manner, to the various competitive factors affecting its industry.

## **Market Price of Common Shares**

As the common shares are currently listed on the Exchange, factors such as announcements of quarterly variations in operating results, or new initiatives or contracts by competitors of the Company, as well as market conditions in the pharmaceutical drug development industry, may have a significant impact on the market price of the common shares of the Company. The stock market has from time to time experienced extreme price and volume fluctuations, which have often been unrelated to the operations of particular companies. Share prices for companies in the pharmaceutical drug development industry have experienced wide fluctuations that have been often unrelated to the operations of the companies themselves, such as changes in financial estimates by securities analysts or other events or factors, many of which will be beyond the Company's control. In addition, there can be no assurance that an active public market will develop or be sustained for the common shares.

## **Securities are Subject to Market Price Volatility**

Market prices for the securities of pharmaceutical and biotechnology companies have historically been highly volatile and the market has, from time to time, experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in the Company's operating results, the aftermath of any public announcements made by the Company, concern as to the safety of any drugs developed by the Company, and general market conditions, can have an adverse effect on the market price of the Company's securities.

## **Additional Information**

For additional information with respect to certain of these and other factors, please refer to the Annual Information Form filed on November 1, 2012, and other documents filed on the System for Electronic Document Analysis and Retrieval at [www.sedar.com](http://www.sedar.com).

## **Contact Information**

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