#### CYNAPSUS THERAPEUTICS INC.

# MANAGEMENT DISCUSSION AND ANALYSIS ("MD&A") OF OPERATING RESULTS AND FINANCIAL CONDITION FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2013

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 three and nine months ended September 30, 2013 and should be read in conjunction with the Company's Condensed Interim Consolidated Financial Statements for the three and nine months ended September 30, 2013 as well as the Company's Audited Annual Consolidated Financial Statements and related Notes and Management's Discussion and Analysis for the twelve months 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.

This MD&A reports our activities through November 20, 2013 unless otherwise indicated. All amounts are expressed in Canadian (CDN) dollars, which is the functional currency of the Company, unless otherwise indicated.

On February 28, 2013, 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 August 30, 2013, 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. 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 a convenient and easy to use sublingual (oral) thin film strip for the acute rescue of "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 the only approved drug (in the United States, Europe, Japan and other countries) to rescue patients from "off" episodes. Apomorphine is currently primarily available as an injection, which can be inconvenient and painful. 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 2016. 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, two pilot proof-of-concept Phase 1 human volunteer clinical trials have been conducted. 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. A two-step process would be required: first, demonstration of bioequivalence to the approved subcutaneous injectable form of apomorphine (Apokyn®); and, second, demonstration of 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-Omethyl 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 thin film strip system that has been optimized to deliver apomorphine to the blood stream in a similar quantity and time as the injection. In this delivery format the dissolution of the strip ingredients in saliva is designed to maintain a "normal" pH (i.e. 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 (Cmax)

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 Tmax of 25 minutes and good tolerability. The successful completion of this first in man study was an important derisking 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 Tmax 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 (Cmax, AUC and Tmax) 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 Tmax and PK of APL-130277. The dose was deemed to be dose proportional to the dose evaluated in CTH-101 and achieved a pharmacokinetic profile (Cmax, AUC and Tmax) 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 2016. The CTH-103 study is expected to be completed in December 2013.

#### 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 may 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 Q3 2014, subsequent to the filing of an IND application. Based on the FDA's 505(b)(2) regulations, this study will be required to demonstrate that the Cmax (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 Tmax (the time that which C-max 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 late 2014 or early 2015 and be completed in late 2015 or early 2016. Based upon our initial interaction with the FDA, the study is expected to administer the drug to approximately 150 to 200 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 16 to 24 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 2016. 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 nine months ended September 30,

	2013 (\$)	2012 (\$)	\$ change in 2013	% change in 2013
Operating, general and administrative	1,788,240	993,083	795,157	80.1

For the three months ended September 30,

	2013 (\$)	2012 (\$)	\$ change in 2013	% change in 2013
Operating, general and administrative	736,636	214,310	522,326	243.7

The increase in OG&A expense for the nine months ended September 30, 2013 compared to September 30, 2012 is primarily attributed to the resumption of expenditures that were constrained in the prior year due to lack of financial resources. More specifically, following the closing of the financing in March 2013, there has been increases in investor and public relations activities, professional and legal fees, senior officers' base salaries, and Board retainer and meeting fees (commencing July 1, 2013). In addition, there were also one-time listing, professional and legal fees associated with the United States OTCQX listing. On July 18, 2013, the Company's common shares were approved for trading in the United States on the OTCQX marketplace ("OTCQX"). Trading commenced immediately on the OTCQX International under the symbol CYNAF. The Company continues to trade on the TSX Venture Exchange under its existing symbol CTH.

The increase in OG&A expense for the three months ended September 30, 2013 compared to September 30, 2012 is primarily attributed to Board approved increases in senior officers' base salaries, increases in investor and public relations activities, and increases in Board retainer and meeting fees commencing July 1, 2013. During the period, the average monthly OG&A expenditures were: salaries and benefits (\$80,000), investor and public relations activities (\$45,000), professional and legal fees (\$40,000), office and administration (\$30,000), corporate finance (\$20,000), Board retainer and meeting fees (\$20,000), and travel (\$10,000).

Research and Development ("R&D") Expense

For the nine months ended September 30,

	2013 (\$)	2012 (\$)	\$ change in 2013	% change in 2013
Research and development	715,572	478,530	237,042	49.5

For the three months ended September 30,

	2013	2012	\$ change in	% change in
	(\$)	(\$)	2013	2013
Research and development	404,110	104,731	299,379	285.9

The increase in R&D expense for the nine months ended September 30, 2013 compared to September 30, 2012 is primarily due to the fact that consulting, formulation development, analytical and clinical expenditures in the first nine months of 2013 related to the CTH-103 Phase 1 clinical trial of APL 130277, were greater than the expenditures for the CTH-102 Phase 1 clinical trial of APL 130277 during the same period in 2012.

The increase in R&D expense for the three months ended September 30, 2013 compared to September 30, 2012 is primarily due to the fact that formulation development and analytical related to the CTH-103 Phase 1 clinical trial of APL 130277, were greater than the expenditures for the CTH-102 Phase 1 clinical trial of APL 130277 during the same period in 2012.

# Other Operating Expenses

For the nine months ended September 30,

	2013 (\$)	2012 (\$)	\$ change in 2013	% change in 2013
Other operating expenses				
Share-based payments	448,088	299,017	149,071	49.9
Amortization of intangible assets	44,240	44,240	-	0.0
Depreciation of equipment	1,391	1,502	(111)	(7.4)
Foreign exchange loss (gain)	27,789	(17,126)	44,915	(262.3)
(Recovery) on scientific research	(29,232)	(66,219)	36,987	(55.9)
Total other operating expenses	492,276	261,414	230,862	88.3

#### For the three months ended September 30,

	2013 (\$)	2012 (\$)	\$ change in 2013	% change in 2013
Other operating expenses				
Share-based payments	109,975	98,886	11,089	11.2
Amortization of intangible assets	14,747	14,748	(1)	(0.0)
Depreciation of equipment	658	501	157	31.3
Foreign exchange loss (gain)	6,415	(17,072)	23,487	(137.6)
(Recovery) on scientific research	(15,000)	(10,000)	(5,000)	50.0
Total other operating expenses	116,795	87,063	29,732	34.2

The increase in other operating expenses in the nine months ended September 30, 2013 compared to September 30, 2012 is primarily attributed to the increases in share-based payments, as stock options were granted in March and May 2013 to officers, directors, employees and consultants following the closing of the \$7.3 million short form prospectus financing in March 2013. In addition, there was an increase in foreign exchange loss in the nine months ended September 30, 2013 due to the change in the US-Canadian exchange rate, as well as a decrease in expected recovery on scientific research, due to the fact that much of the R&D spending is being funded by the grant from the Michael J. Fox Foundation, which was not the case in the same period in 2012.

No significant changes in other operating expense occurred in the three months ended September 30, 2013.

# Other Loss (Income)

# For the nine months ended September 30,

	2013 (\$)	2012 (\$)	\$ change in 2013	% change in 2013
Other loss (income)				
Research grant	(211,601)	(61,600)	(150,001)	243.5
Other income	(2,200)	(9,900)	7,700	(77.8)
Severance and bonus accruals	762,103	-	762,103	100.0
Debenture accretion and interest costs	187,975	798,927	(610,952)	(76.5)
(Gain) on extension of debenture maturity dates	-	(225,263)	225,263	(100.0)
(Gain) on debentures exchange	(1,153,000)	1	(1,153,000)	100.0
Loss on disposal of fixed asset	1,325	-	1,325	100.0
Other interest and related charges	1,543	1,458	85	5.8
Total other loss (income)	(413,855)	503,622	917,477	182.2

#### For the three months ended September 30,

	2013 (\$)	2012 (\$)	\$ change in 2013	% change in 2013
Other loss (income)				
Research grant	-	(61,600)	61,600	(100.0)
Other income	-	(3,300)	3,300	(100.0)
Debenture accretion and interest costs	-	298,625	(298,625)	(100.0)
Other interest and related charges	83	1,294	(1,211)	(93.6)
Total other loss (income)	83	235,019	(234,936)	(100.0)

The increase in other loss (income) in the nine months ended September 30, 2013 compared to September 30, 2012 is primarily attributed to the one-time gain on the exchange of debentures for shares and warrants, the research grant from The Michael J. Fox Foundation, and a decrease in accretion and interest expenses associated with debentures. These increases were offset by, and a decrease in, the reclassification of severance and bonus contingent liabilities that became payable upon closing the short form prospectus financing on March 1, 2013.

Regarding the one-time gain on the exchange of debentures for shares, the primary reason there was recorded gain to the Company relates to the fair values of the units in the short form prospectus financing and the calculated grant date fair values of the warrants in the debenture exchanges. More specifically, even though both transactions were priced at \$0.46 per unit, the unit values of each were different due to fact that the Black-Scholes calculated value of the 5 year full warrants issued in the March 1, 2013 financing was higher, compared to the value of the 2 year half warrants issued in the March 1, 2013 debenture exchanges.

The decrease in other loss (income) in the three months ended September 30, 2013 compared to September 30, 2012 is primarily attributed to the 2012 research grant from The Michael J. Fox Foundation and the elimination of accretion and interest expenses associated with debentures that were exchanged for shares and warrants on March 1, 2013.

#### Loss and Loss Per Share

For the nine months ended September 30,

	2013 (\$)	2012 (\$)	\$ change in 2013	% change in 2013
Loss	2,582,233	2,236,649	345,584	15.5
Basic and diluted loss per share	0.08	0.17	(0.09)	

#### For the three months ended September 30,

	2013	2012	\$ change in	% change in
	(\$)	(\$)	2013	2013
Loss	1,257,624	641,123	616,501	96.2
Basic and diluted loss per share	0.03	0.05	(0.02)	

The increase in loss per share for the three and nine months ended September 30, 2013 compared to September 30, 2012 is primarily attributed to the gain on the exchange of debentures for shares and warrants, which offset the reclassification of severance and bonus contingent liabilities that became payable upon closing the short form prospectus financing on March 1, 2013, as well as increases in professional and legal fees associated with the United States OTCQX listing application, investor and public relations activities, senior officer's base salaries and Board fees.

# **SUMMARY OF QUARTERLY RESULTS:**

# **Quarterly Statements of Income:**

For the nine month period ended September 30, 2013

	Corrected			2013 YTD
	Q1 2013 (\$)	Q2 2013 (\$)	Q3 2013 (\$)	TOTAL (\$)
Total assets	7,002,000	5,383,000	4,301,000	
Revenues	-	-	-	-
Operating, general and administrative	390,000	661,000	737,000	1,788,000
Research and development	143,000	169,000	404,000	716,000
Other operating expenses	144,000	231,000	117,000	492,000
Research grant	(121,000)	(91,000)	-	(212,000)
Other income	(2,000)	-	-	(2,000)
Severance and bonus accruals	762,000	-	-	762,000
Debenture accretion and interest costs	188,000	-	-	188,000
(Gain) on debentures exchange*	(1,153,000)	-	-	(1,153,000)
Loss on disposal of equipment	-	1,000	-	1,000
Other interest and related charges	1,000	1,000	-	2,000
Net loss*	352,000	972,000	1,258,000	2,582,000
Loss per share (basic and diluted)	0.07	0.03	0.03	0.07

<sup>\*</sup>Note: The net loss for Q1 2013 has been corrected to include the one-time gain of \$1,153,000 from the exchange of debentures on March 1, 2013. In the Company's financial statements for the three months ended March 31, 2013, the amount of this gain was shown as \$Nil. The Company has adjusted the figure for both the six months ended June 30, 2013 and the nine months ended September 30, 2013 in order to correct this error.

# 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	-	ı	-	-	-
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)	1	ı	-	(225,000)
Other interest and related charges	-	-	2,000	4,000	6,000
Net loss	605,000	992,000	643,000	824,000	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 September 30, 2013 was \$3,409,766 compared to \$50,401 at December 31, 2012. Since inception, cash requirements have been financed primarily through issuances of securities. In the previous two years, the Company 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 \$1,725,065 at September 30, 2013, compared to \$2,119,438 at December 31, 2012.

The balance of Series A to Series E debentures payable was \$Nil at September 30, 2013, compared to \$4,059,693 at December 31, 2012. On February 28, 2013, the total debentures outstanding were \$4,247,668. On March 1, 2013, holders of \$4,030,244 in Series A to Series E debentures agreed to an exchange of debt for shares and warrants, with the remaining \$217,424 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 nine months ended September 30, 2013, operating activities used cash of \$3,063,444 compared to \$873,224 used in operations for the nine months ended September 30, 2012. The increase is primarily attributed to the resumption of expenditures that were severely constrained in the prior year due to lack of financial resources. Cash used in operating activities reflects the net loss of \$2,582,233 for the nine months ended September 30, 2013, adjusted for non-cash items including share-based payments, amortization of intangible assets, depreciation of equipment, debenture accretion expense, accrual of debenture interest expense, gain on debentures exchange, and changes in non-cash working capital (including severance and bonus accruals included in accounts payable and accrued liabilities, and deferred grant proceeds).

#### **Investing Activities**

For the nine months ended September 30, 2013, net investing activities were \$10,117 compared to \$Nil for the nine months ended September 30, 2012.

#### Financing Activities

For the nine months ended September 30, 2013, net financing activities generated cash of \$6,432,926 compared to \$865,600 for the nine months ended September 30, 2012.

Shareholders' equity increased to \$2,376,887 at September 30, 2013 from a shareholder's deficiency of \$5,010,201 at December 31, 2012, as the value of the shares and warrants issued in the short form prospectus offering and the debenture exchange for shares and warrants in March 2013 significantly offset the net loss for the nine month period ended September 30, 2013.

# **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 No		
	Number of shares #	Number of shares issuable on exercise of options #	Number of shares issuable on exercise of warrants #	Total #
Common shares	38,884,009	-	-	38,884,009
Stock options	-	2,691,316	-	2,691,316
Common share purchase warrants	-	-	21,551,763	21,551,763
Total	38,884,009	2,691,316	21,551,763	63,127,088

#### **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.

## Prospectus Offering, Share Consolidation and Debenture Exchange

(a) 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 reimbursed 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 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 \$4,030,244 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.

(b) 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.

#### **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 and was fully used by December 31, 2012. The second milestone payment of USD \$412,087 (CDN \$411,057) was received on January 30, 2013. As at September 30, 2013, CDN \$211,601 of the second milestone payment has been used, and CDN \$199,456 is recorded as deferred grant proceeds. The Company expects to receive the final milestone payment of USD \$238,012 and complete this research in Q4 2013.

## **Expiry of Warrants**

On February 2, 2013, warrants to acquire 580,000 common shares of the Company expired unexercised.

#### **Grant of Stock Options**

On 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.

On May 1, 2013, the Company granted stock options to acquire 1,392,000 common shares. The stock options were granted to officers, directors, employees and consultants of the Company at an exercise price equal to \$0.36 per share and expire 5 years from the date of grant. One third of the options granted vested immediately, one-third will vest in 6 months and one-third will vest in 12 months.

On May 28, 2013, the Company granted stock options to acquire 25,000 common shares. The stock options were granted to a director of the Company at an exercise price equal to \$0.31 per share and expire 5 years from the date of grant. One third of the options granted vested immediately, one-third will vest in 6 months and one-third will vest in 12 months.

## **Expiry of Stock Options**

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

On June 25, 2013, 50,000 stock options held by current and former directors of the Company expired unexercised.

On June 30, 2013, 214,062 stock options held by a former officer, employee and consultants of the Company expired unexercised.

# **Related Party Transactions**

At September 30, 2013, included in accounts payable and accrued liabilities is \$725,453 (December 31, 2012: \$649,504) due to officers and directors of the Company.

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. In March 2013, the Company completed two closings of a short form prospectus offering for gross proceeds of \$7,317,160. As a result, these bonus amounts became payable at that time, and have been accrued in these condensed interim consolidated financial statements. These amounts are unsecured, non-interest bearing with no fixed terms of repayment.

The Company had a stock option commitment to the President and CEO, contingent upon the Company raising a cumulative amount of \$5 million in equity after November 16, 2009. Once raised, the Company was required to issue 373,316 stock options priced at the then fair market value, but not less than \$0.10 per share. 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.

The grant date fair value of share-based payments issued to related parties during the three and nine months periods ended September 30, 2013 was \$Nil and \$497,503 (September 30, 2012: \$21,000 and \$259,000), of which \$Nil and \$219,344 vested in the respective periods (September 30, 2012: \$21,000 and \$216,833).

#### **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 \$770,000 and are all payable within one year.

The Company is committed to a minimum rental under a lease for its premises, which will expire on April 30, 2014. As at September 30, 2013, minimum rental commitments remaining under this lease are \$70,875, all due within one year.

On December 22, 2011, the Company completed the acquisition of 100% of the outstanding common shares of Adagio and certain indebtedness of Adagio (the "Transaction"). The Transaction was structured as a share exchange with Adagio shareholders receiving newly issued common shares of the Company in exchange for all of the issued and outstanding shares of Adagio. Adagio shareholders are entitled to the following remaining 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 study. This study has not been started as of November 20, 2013; 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. This study has not been started as of November 20, 2013.

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.

#### 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 effects on the Company's financial performance. There were no changes in the Company's approach to risk management during the nine months ended September 30, 2013.

#### **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. As at September 30, 2013, the Company had cash and cash equivalent of \$3,409,766 and other current assets of \$134,543 (December 31, 2012 - \$50,401 and \$325,916) to settle current liabilities of \$1,924,521 (December 31, 2012 - \$6,179,131). 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 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 \$34,000.

#### 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 and at the System for Electronic Document Analysis and Retrieval ("SEDAR") at www.sedar.com.

#### **Availability of Additional Capital**

The Company incurred a net loss of \$2,582,233 for the nine months ended September, 2013 and expects to incur losses from continuing operations for the foreseeable future. As at September 30, 2013, the Company had cash of \$3,409,766. 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, concerns 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.

# **Contact Information**

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