# CYNAPSUS THERAPEUTICS INC.

# MANAGEMENT DISCUSSION AND ANALYSIS ("MD&A") OF OPERATING RESULTS AND FINANCIAL CONDITION FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2014

The following Management 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, 2014 and should be read in conjunction with the Company's Condensed Interim Consolidated Financial Statements for the three and nine months ended September 30, 2014 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, 2013. The condensed interim consolidated financial statements for the period ended September 30, 2014 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 10, 2014 unless otherwise indicated. All amounts are expressed in Canadian dollars, which is the functional currency of the Company, unless otherwise indicated.

#### **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 March 26, 2014, under the heading "Risks and Uncertainties" in the "Management Discussion and Analysis of Operating Results and Financial Condition" for the year ended December 31, 2013, 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.

# **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 ('CRO") in Asia, and a Phase 2 study is being conducted at multiple sites in the U.S. It is expected that CROs in Asia, the U.S. and/or Europe will be selected to assist in the management of Phase 3 clinical trials.

APL-130277 is being developed under Section 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 FDA accepted that APL-130277 could achieve approval either by demonstrating bioequivalence or through efficacy trials. The FDA noted in meeting minutes that labelling is not required to match that of the reference listed drug, but that any new claims would require adequate and controlled clinical trials. The FDA also noted that efficacy trials would need to be in patients that are similar to those for whom the treatment is intended.

In July 2014, Cynapsus announced that following communication from the United States Food and Drug Administration, Phase 2 clinical studies for APL-130277 commenced immediately. Specifically, clinical study CTH-105 was initiated per the proposal submitted to the FDA under the Company's Investigational New Drug application.

# **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 ("HCl") salt that is part of the API's 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 designed to facilitate the delivery of the drug through the oral mucosal route under the tongue. In this thin film format the strip dissolves in saliva maintaining "normal", near physiological pH, during absorption, thus obviating any issues with irritation. To date, short term administration of API-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 Corporation'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 had received favourable results from a second survey conducted, on behalf of the Corporation, by the same leading independent healthcare market research group. The survey results forecast favourable acceptance of APL-130277 by HMOs 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 their 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 as well as possible premiums based on additional clinical data.

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 the 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.

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 confirmed and expanded on the results of the smaller neurologist survey that was completed at the direction of the Corporation in July 2010.

In January 2012, Cynapsus announced positive data from the first human volunteer pilot proof-ofconcept study (CTH-101) of APL-130277. The study showed a pharmacokinetic ("PK") profile that compared favourably to historical PK data seen with injected apomorphine with a mean time post-administration when the maximum drug concentration in the blood is achieved ("Tmax") of 25 minutes and good tolerability. The successful completion of this first in-man study was an important de-risking event for APL-130277.

In August 2012, Cynapsus announced that it had been awarded a grant of USD\$947,925 from the Michael J. Fox Foundation for Parkinson's Research ("MJFF") to support clinical studies to develop APL-130277. 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-ofconcept 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 plasma concentrations reached with 8mg matched internal predictions and a potentially therapeutic concentration 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.

In September 2012, Cynapsus commenced activities for the Comparative Biostudy (CTH-103) of APL-130277. CTH-103 was 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 was 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 January 2014, Cynapsus announced the results of a Comparative Biostudy (CTH-103) of APL-130277. The CTH-103 study was planned as a three-dose (10mg, 15mg and 25mg) active comparator, placebo-controlled, randomized cross-over trial to examine the pharmacokinetic profile of sublingual administered APL-130277 compared to (2mg, 3mg and 4mg) subcutaneous injection of apomorphine in healthy volunteers. The 10mg and 15mg APL-130277 sublingual thin-film strips were crossed over to 2mg and 3mg subcutaneous injections, with N=15 and N=14 for the two cohorts, respectively. The intent in the CTH-103 study for the third cohort was to compare the 25mg sublingual thin film strip (APL-130277) to the 4mg subcutaneous injection, but this third cohort could not be dosed due to the dose-limiting adverse events experienced with the 3mg subcutaneous injection. The 15mg APL-130277 side effects were mild-to-moderate and not dose limiting. As a result, the Corporation completed the CTH-104 study, a single arm, healthy volunteer pharmacokinetic study to look at the 25mg APL-130277 sublingual strip (without a crossover to the injection).

In April 2014, Cynapsus announced the results of the CTH-104 study. The CTH-104 study was a single dose, single arm, placebo-controlled, healthy volunteer pharmacokinetic study, which was designed to examine the pharmacokinetic profile of the 25mg dose of APL-130277. In total, 13 subjects completed the study (11 active and 2 placebo). Key outcomes of the CTH-104 study, which were also compared to the results of the CTH-103 study, include: Dose Proportionality, Time to Maximum Concentration (Tmax), Maximum Concentration (Cmax), Minimum Efficacious Blood Level (Extrapolated Time-to-On), Duration Above Minimum Efficacious Blood Level (Extrapolated Time On), and No Dose Limiting Side Effects.

In May 2014, Cynapsus announced no irritation was observed when testing the APL-130277 sublingual apomorphine formulation in a 28-day buccal mucosal irritation model in hamsters, either macroscopically (clinician observation of oral cavity) or microscopically. The study was conducted in compliance with the Good Laboratory Practice for Nonclinical Laboratory Studies of the United States Food and Drug Administration, 21 CFR Part 58, and OECD Principles of Good Laboratory Practice (OECD, 1998). The data, coupled with clinical results to date, appear to validate the design of the Company's thin-film strip technology. This study is a required registration study by the FDA. The Company seeks to demonstrate similar results in upcoming human clinical trials planned over the next 24 months.

In July 2014, Cynapsus was awarded a new grant of US\$500,000 from the MJFF to support clinical studies to develop APL-130277. This second MJFF grant is being used to fund the Company's CTH-105 clinical study. As part of the MJFF grant agreement, Cynapsus has made a commitment to support further Parkinson's research by making up to US\$1 million in contributions to MJFF based on future sales of APL-130277.

In July 2014, Cynapsus announced that following communication from the United States Food and Drug Administration, Phase 2 clinical studies for APL-130277 commenced immediately. Specifically, clinical study CTH-105 was initiated per the proposal submitted to the FDA under the Company's Investigational New Drug application.

In October 2014, Cynapsus announced Thierry Bilbault, Ph.D., has been named Chief Scientific Officer (CSO) and Executive Vice President of Chemistry, Manufacturing and Controls (CMC). In this role, Dr. Bilbault will lead the strategic CMC activities related to the Company's APL-130277 drug candidate. Dr. Bilbault is a global pharmaceutical development and manufacturing operations leader with over 20 years of experience in the evaluation, development, partnering, transfer and manufacturing of API and Drugs (Rx, Generics, Switches, OTC) and Medical Device products. He has been involved with bringing more than 50 products to the market, including over 10 U.S. New Drug Applications. Dr. Bilbault joins Cynapsus from Galderma Pharma S.A. (part of Nestle Skin Health S.A.), where he has been a Technical and Industrial Development Director. Prior to Galderma, he served as Vice President New Technology and Product Innovation at Novartis, and held several product development leadership roles at Pfizer and Alcon Laboratories. At Pfizer, Dr. Bilbault developed and/or led the global launch activities for more than 30 products, including Listerine PocketPacks and Listerine Whitening Quick Dissolving thin films.

# APL-130277 Regulatory Plan

For development of APL-130277 in the United States, the Corporation will follow the 505(b)(2) regulatory pathway. Specifically, the Corporation is pursuing the reformulation of apomorphine from a subcutaneous injection to a convenient, more tolerable and safe sublingual thin film strip. The API 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, which is the description of the use of apomorphine in the current US approved label.

The 505(b)(2) pathway will require that the Corporation provide statistically sufficient clinical evidence that Parkinson's patients experience management of their "off" episodes, as a result of delivery of apomorphine via the sublingual thin film strip route. The primary end point would be based on the change in the Unified Parkinson's Disease Rating Scale Part III (UPDRS III) movement score. In addition, the Corporation would be required to provide in a separate study, statistically sufficient clinical evidence that administering apomorphine via a sublingual thin film route would result in the Parkinson's patients experiencing low to no oral irritation as a result of multiple daily exposures to the drug for an extended period.

To achieve this, the Corporation currently expects to complete the following clinical studies:

- 1. **CTH-105 Pilot Study.** A pilot study in patients with Parkinson's disease who are naïve to the use of apomorphine and who experience at least one daily "off" episode with a total duration of "off" in any 24-hour period of at least 2 hours. This study is planned to examine the effect of APL-130277 on relieving "off" episodes over a single day with a dose-titration used to determine dose strengths necessary for future clinical development.
- 2. **CTH-200 Bridging Study.** A single dose, crossover comparative bioavailability and PK study in healthy volunteers. This study is designed to provide the clinical "bridge" to the FDA's finding of safety and efficacy for the Reference Listed Drug (s.c. Apomorphine).
- 3. **CTH-300 Efficacy Study.** A double-blind, placebo-controlled, parallel-design study with Parkinson's patients who have at least one "off" episode every 24 hours, with total "off" time of at least 2 hours. The primary end point will be the change in the UPDRS III score.
- 4. **CTH-301 Safety Study.** A long-term safety study in apomorphine naïve Parkinson's patients who have at least one "off" episode every 24 hours, with total "off" time of at least 2 hours. The study will specifically look at the safety and tolerability of the new delivery route over a minimum period of 16 weeks.

In parallel to the studies, the Corporation 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 current Good Manufacturing Practices ("cGMP") methodology.

Upon completion of the efficacy and safety studies, as well as the CMC section, the Corporation will begin the preparation of a FDA 505(b)(2) NDA in 2016.

# **REVIEW OF OPERATING RESULTS:**

# Operating, General and Administrative ("OG&A") Expense

For the nine months ended September 30,

	2014 (\$)	2013 (\$)	\$ change in 2014	% change in 2014
Operating, general and administrative	2,858,317	1,788,240	1,070,077	59.8

For the three months ended September 30,

	2014 (\$)	2013 (\$)	\$ change in 2014	% change in 2014
Operating, general and administrative	1,005,843	736,636	269,207	36.5

The increase in OG&A expense for the nine months ended September 30, 2014 compared to September 30, 2013 is primarily attributed to the resumption of expenditures that were constrained in the prior years due to lack of financial resources. More specifically, following the closing of the financing in March 2013, there were increases in salaries and benefits associated with the hiring of new staff, investor and public relations activities, professional and legal fees, senior officers' base salaries, Board retainer and meeting fees (which commenced on July 1, 2013), and travel costs. In addition, there were one-time consulting fees associated with a comprehensive U.S. commercial assessment of APL-130277, which was completed in the first quarter of 2014. A bonus accrual of \$100,000 was also recorded during the third quarter of 2014. During the nine months ended September 30, 2014, the average monthly OG&A expenditures were: salaries and benefits excluding bonus (\$83,000), investor and public relations activities (\$81,000), consulting fees (\$40,000), professional and legal fees (\$39,000), office and administration (\$25,000), Board retainer and meeting fees (\$22,000), and travel (\$20,000).

The increase in OG&A expense for the three months ended September 30, 2014 compared to September 30, 2013 is primarily attributed to increases in salaries and benefits associated with the hiring of new staff, consulting fees, investor and public relations activities, and travel. During the three months ended September 30, 2014, the average monthly OG&A expenditures were: salaries and benefits excluding bonus (\$95,000), investor and public relations activities (\$95,000), professional and legal fees (\$38,000), office and administration (\$24,000), consulting fees (\$19,000), travel (\$16,000) and Board retainer and meeting fees (\$18,000).

# Research and Development ("R&D") Expense

For the nine months ended September 30,

	2014 (\$)	2013 (\$)	\$ change in 2014	% change in 2014
Research and development	2,859,912	715,572	2,144,340	299.7

For the three months ended September 30,

	2014 (\$)	2013 (\$)	\$ change in 2014	% change in 2014
Research and development	1,247,054	404,110	842,944	208.6

The increase in R&D expense for the nine months ended September 30, 2014 compared to September 30, 2013 is primarily due to increased expenditures in the second and third quarters of 2014 in consulting, formulation development, analytics, toxicology, and API related to the CTH-105 clinical study and scale-up CMC work. These expenditures followed the closing of the \$25 million financing in April 2014. In addition, in the first quarter of 2014, clinical research, consulting and analytical fees related to the CTH-104 Phase 1 clinical trial of APL-130277 were greater than the expenditures for the CTH-103 Phase 1 clinical trial of APL-130277 during the same period in 2013. The final results for the CTH-104 study were announced on April 24, 2014.

The increase in R&D expense for the three months ended September 30, 2014 compared to September 30, 2013 is primarily due to increases in consulting, formulation development, analytics, and toxicology, along with clinical study costs, data management related to the CTH-105 clinical study and scale-up CMC work.

# Other Expenses (Recoveries)

	2014 (\$)	2013 (\$)	\$ change in 2014	% change in 2014
Share-based payments	630,464	448,088	182,376	40.7
Amortization of intangible assets	44,240	44,240	-	-
Depreciation of equipment	5,358	1,391	3,967	285.2
Foreign exchange (gain) loss	(254,435)	27,789	(282,224)	(1,015.6)
Recovery on scientific research	(41,717)	(29,232)	(12,485)	42.7
Research grant	(351,969)	(211,601)	(140,368)	66.3
Other income	-	(2,200)	2,200	100.0
Severance and bonus	-	762,103	(762,103)	(100.0)
Debenture accretion and interest costs	_	187,975	(187,975)	(100.0)
Gain on debenture exchanges	-	(1,153,000)	1,153,000	(100.0)
Loss on disposal of equipment	-	1,325	(1,325)	(100.0)
Other interest (income) expense and related charges	(32,032)	1,543	(33,575)	(2,176.0)

For the nine months ended September 30,

For the three months ended September 30,

	2014 (\$)	2013 (\$)	\$ change in 2014	% change in 2014
Share-based payments	212,368	109,975	102,393	93.1
Amortization of intangible assets	14,747	14,747	-	-
Depreciation of equipment	2,923	658	2,265	344.2
Foreign exchange (gain) loss	(644,660)	6,415	(651,075)	(10,149.3)
Recovery on scientific research	(21,717	(15,000)	(6,717)	44.8
Research grant	(112,000)	-	(112,000)	(100.0)
Other interest (income) expense and related charges	(12,750)	83	(12,833)	(15,461.4)

There were several one-time transactions that occurred during the nine months ended September 30, 2013, which did not recur during the nine months ended September 30, 2014. Primarily, on March 1, 2013, debentures were exchanged for shares and warrants, resulting in a gain of \$1,153,000, and the elimination of further accretion and interest expenses associated with the debentures. The gain on the exchange of debentures for shares and warrants was recorded due to the \$4,030,244 carrying value of debt instruments extinguished exceeding the fair value of the shares and warrants issued in exchange. In addition, severance and bonus accruals that were triggered upon completion of the March 2013 prospectus offering did not recur in the nine months ended September 30, 2014.

Foreign exchange gains during the three and nine months ended September 30, 2014 were higher than the comparative periods ending September 30, 2013 due to unrealized gains on significantly higher U.S. dollar cash balances on hand at September 30, 2014, combined with a strengthening of the U.S. dollar, compared to both September 30, 2013 and December 31, 2013. As at September 30, 2014, the Company had cash of \$13,795,524 in U.S. dollars, compared to \$Nil as at September 30, 2013, and \$253,050 at December 31, 2013.

In addition, in the three months ended September 30, 2014 compared to September 30, 2013 there was an increase in share-based payments, as compensation expense was recognized on stock options granted in May 2014 to Officers, Directors, employees and consultants. In the third quarter of 2014 the Company also recognized a US\$100,000 milestone payment of a research grant from The Michael J. Fox Foundation.

# Loss and Loss Per Share

For the nine months ended September 30,

	2014 (\$)	2013 (\$)	\$ change in 2014	% change in 2014
Loss	5,718,138	2,582,233	3,135,905	121.4
Basic and diluted loss per share	0.09	0.08	0.01	12.5

For the three months ended September 30,

	2014 (\$)	2013 (\$)	\$ change in 2014	% change in 2014
Loss	1,691,808	1,257,624	434,184	34.5
Basic and diluted loss per share	0.02	0.03	(0.01)	(33.3)

The increased loss in the three and nine months ended September 30, 2014 compared to September 30, 2013 is primarily attributed to the resumption of OG&A and R&D expenditures that were constrained in the prior years due to lack of financial resources, but have substantially picked up following the completion of the two equity offerings in March 2013 (\$7 million) and April 2014 (\$25 million). Operating, general and administrative expenses that have increased include salaries associated with the hiring of new staff, base salaries for Officers and employees, investor and public relations activities, professional and legal fees, and Board retainer and meeting fees. In addition, there were one-time consulting fees associated with a comprehensive U.S. commercial assessment of APL-130277, which was completed in the first quarter of 2014. R&D expenses that increased include consulting, clinical research, formulation development, analytics, toxicology, and API purchases associated with the upcoming clinical studies and scale-up CMC work.

The decreased loss per share for the three months ended September 30, 2014 was a result of the dilutive effect resulting from the April 2014 prospectus offering, in which 38,461,538 shares were issued, resulting in a weighted average number of shares outstanding of 78,965,716 for the three months ended September 30, 2014, compared to 38,884,009 for the corresponding period in 2013.

# SUMMARY OF QUARTERLY RESULTS:

# (Numbers rounded to the nearest thousands)

	Q1	Q2	Q3
	(\$)	(\$)	(\$)
Total assets	2,398,000	21,540,000	20,397,000
Revenues	-	-	-
Operating, general and administrative	958,000	894,000	1,006,000
Research and development	449,000	1,164,000	1,247,000
Other operating expenses	45,000	775,000	(436,000)
Research grant	(240,000)	-	(112,000)
Other interest income and related charges	(2,000)	(17,000)	(13,000)
Net loss	1,210,000	2,816,000	1,692,000
Loss per share (basic and diluted)	0.03	0.04	0.02

For the nine months ended September 30, 2014

For the year ended December 31, 2013

	Corrected Q1(\$)	Q2(\$)	Q3(\$)	Q4(\$)	2013 Total (\$)
Total assets	7,002,000	5,383,000	4,301,000	3,149,000	
Revenues	-	-	-	-	
Operating, general and administrative	390,000	661,000	737,000	849,000	2,637,000
Research and development	143,000	169,000	404,000	915,000	1,631,000
Other operating expenses	144,000	231,000	117,000	85,000	577,000
Research grant	(121,000)	(91,000)	-	(212,000)	(424,000)
Other income	(2,000)	-	-	-	(2,000)
Severance and bonus accruals	762,000	-	-	215,000	977,000
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	-	(1,000)	1,000
Net loss*	352,000	972,000	1,258,000	1,851,000	4,433,000
Loss per share (basic and diluted)	0.02	0.03	0.03	0.04	0.13

\*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 condensed interim consolidated financial statements for the three months ended March 31, 2013, the amount of this gain was shown as \$Nil.

# 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	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

# LIQUIDITY AND CAPITAL RESOURCES

The cash and cash equivalents balance at September 30, 2014 was \$19,496,961 compared to \$2,289,046 at December 31, 2013. It is expected that the Company will not need to raise additional capital for 18 to 24 months.

Since inception, cash requirements have been financed primarily through issuances of securities and 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 \$1,183,967 at September 30, 2014, compared to \$2,315,082 at December 31, 2013.

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 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 three months ended September 30, 2014, operating activities used cash of \$1,762,223 compared to \$943,287 in the three months ended September 30, 2013. The increase is primarily attributed to the resumption of expenditures that were constrained in the prior years due to lack of financial resources. Cash used in operating activities for the three months ended September 30, 2014 reflects the net loss of \$1,591,808 for the three months ended September 30, 2014, adjusted for non-cash items including share-based payments, amortization of intangible assets, depreciation of equipment, changes in non-cash working capital (including prepaid expenses and other current assets, accounts payable and accrued liabilities, and deferred grant proceeds) and unrealized gain on foreign exchange.

#### **Investing Activities**

For the three months ended September 30, 2014, equipment of \$31,324 was purchased, compared to \$nil in the three months ended September 30, 2013.

# Financing Activities

For the three months ended September 30, 2014, net financing activities generated cash of \$9,804 arising from the exercise of share warrants, compared to \$nil for the three months ended September 30, 2013.

# Effect of Exchange Rate Changes

For the three months ended September 30, 2014, the effect of exchange rate changes on cash and cash equivalents was \$644,660 as result of the Canadian Dollar weakening relative to the U.S. Dollar. As at September 30, 2014, the Company had cash of \$13,795,524 and accounts payable and accrued liabilities of \$540,876 denominated in U.S. dollars (September 30, 2013 - \$Nil and \$185,241 respectively).

# 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	vember 10, 2014	
	Number of shares #	Number of shares issuable on exercise of options #	Number of shares issuable on exercise of warrants #	Total #
Common shares	79,068,867	-	-	79,068,867
Stock options	-	4,175,649	-	4,175,649
Common share purchase warrants	-		61,300,571	61,300,571
Total	79,068,867	4,175,649	61,300,571	144,545,087

#### **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. Research grants have been received to contribute toward these costs.

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**

On April 15, 2014, the Company announced that it completed its previously announced short form prospectus offering of units. Pursuant to the offering, the Company issued an aggregate of 38,461,538 units at a price of \$0.65 per unit for gross proceeds of \$25,000,000. Each unit consists of one common share in the capital of the Company and one common share purchase warrant of the Company. The units immediately separated on closing into common shares and warrants. Each warrant entitles the holder to purchase one common share at a price equal to \$0.81 per share for a period of 60 months after the closing of the offering, except that, subject to certain exceptions, the warrants will be cancelled if they are not exercised within 30 days after written notice from the Company that the closing price of its common shares on the principal stock exchange of the Company has been \$1.95 per common share or more for 20 consecutive trading days. The Company paid a Canadian agent a work fee in the amount of \$65,500, plus HST, and reimbursed the Canadian agent and the U.S. agent for certain expenses incurred in connection with the offering. In addition, the Company paid the Canadian agent and U.S. agent cash commissions equal to a total of 7% of the offering, and issued 2,676,923 non-transferable compensation warrants, each exercisable to purchase one common share on the same terms as the warrants issued in the offering.

Dexcel Pharma, a strategic pharmaceutical investor and significant shareholder of the Company, and which also has two directors on the Board of the Company, subscribed for 6,153,846 units having an aggregate subscription price of \$4,000,000.

# **Research Grant**

On August 8, 2012, the Company announced that it had been awarded a grant of US\$947,925 (\$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 US\$297,825 (\$289,516) was received on September 20, 2012 and was fully used by December 31, 2012. The second milestone payment of US\$412,087 (\$410,053) was received on January 30, 2013 and fully used by December 31, 2013. On December 16, 2013, the Company received the final milestone payment of US\$238,012 (\$254,102). As at September 30, 2014, all of the final milestone payment had been used, and \$Nil (December 31, 2013: \$239,968) is recorded as deferred grant proceeds.

On July 3, 2014, the Company was awarded a new grant of US\$500,000 from MJFF to support clinical studies to develop APL-130277, a sublingual thin film strip reformulation of apomorphine. This second MJFF grant will be used to fund the Company's CTH-105 clinical study. As part of the MJFF grant agreement, Cynapsus has made a commitment to support further Parkinson's research by making up to US\$1 million in contributions to MJFF based on future sales of APL-130277. The first milestone payment of US\$100,000 (\$112,000) was received on September 4, 2014 and was recognized as research grant income in the third quarter of 2014.

#### **Exercise of Warrants**

In January, February and March 2014, an aggregate of 1,242,602 warrants of the Company were exercised at an exercise price of \$0.575 to acquire 1,242,602 common shares for gross proceeds of \$714,495.

In February 2014, 10,000 warrants of the Company were exercised at an exercise price of \$1.00 to acquire 10,000 common shares for gross proceeds of \$10,000.

On April 22, 2014, 20,000 warrants of the Company were exercised at an exercise price of \$0.625 to acquire 20,000 common shares for gross proceeds of \$12,500.

On July 17, 2014, 17,051 warrants of the Company were exercised at an exercise price of \$0.575 to acquire 17,051 common shares for gross proceeds of \$9,804.

# **Exercise of Stock Options**

On May 20, 2014, 216,667 stock options held by a former officer of the Company with an exercise price of \$0.36 per share were exercised for \$78,000.

On June 4, 2014, 54,000 stock options held by a former director of the Company with an exercise price of \$0.36 per share were exercised for \$19,440.

On June 24, 2014, 63,000 stock options held by a former director of the Company with an exercise price of \$0.36 per share were exercised for \$22,680.

# **Expiry of Stock Options**

On January 21, 2014, 108,333 stock options held by a former officer of the Company were forfeited.

On May 21, 2014, 155,000 stock options held by a former officer of the Company expired unexercised.

On June 21, 2014, 34,667 stock options held by a former officer of the Company were forfeited.

On June 26, 2014, 95,000 stock options held by two former directors of the Company expired unexercised.

On August 31, 2014, 45,000 stock options held by one former director, one current director and an officer of the Company expired unexercised.

#### **Related Party Transactions**

Directors and key management are related parties to the Company. In accordance with IAS 24, key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company directly or indirectly, including any directors (executive and non-executive) of the Company.

The remuneration of directors and key executives is determined by the Board of Directors (through the Corporate Governance and Compensation Committee) having regard to the performance of individuals and market trends.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Salary and benefits to President and CEO	\$ 81,315	\$ 82,312	\$ 248,820	\$ 227,268
Salaries and benefits to other officers Salary and consulting fees to other key	44,751	113,998	121,769	312,186
management	52,212	11,250	160,289	25,020
Bonuses to officers and other key management	100,000	-	100,000	529,068
Director fees	53,000	58,750	197,428	84,100
	\$ 331,278	\$ 266,310	\$ 828,306	\$ 1,177,642

Related party transactions during the three and nine months ended September 30, 2014 and 2013 are as follows:

At September 30, 2014, included in accounts payable and accrued liabilities is \$102,122 (December 31, 2013: \$170,236) due to officers and directors of the Company. These amounts are unsecured and non-interest bearing with no fixed terms of repayment.

At September 30, 2014, also included in accounts payable and accrued liabilities is a bonus accrual to officers and other key management of \$100,000.

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, of which a total of \$529,068 was awarded to officers and other key management, 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. Following the closing of the \$25 million short form prospectus financing in April 2014, these bonuses owing were paid in full.

For the year ended December 31, 2013, the Company awarded bonuses of \$186,000, to officers and other key management. Following the closing of the \$25 million short form prospectus financing in April 2014, these bonuses owing were paid in full.

The grant date fair value of share-based payments issued to related parties during the three and nine month periods ended September 30, 2014 was \$Nil and \$791,300 (September 30, 2013: \$Nil and \$497,503), of which \$Nil and \$263,767 vested in the respective periods (September 30, 2013: \$Nil and \$219,344).

# **Commitments and Contingent Liabilities**

At September 30, 2014, the Company has research and development and other service contract commitments, as well as minimum future payments under operating leases for the periods presented as follows:

	Less than	1 - 2	
	1 year	years	Total
	\$	\$	\$
Purchase Obligations	975,000	344,000	1,319,000
Operating Leases	100,000	52,000	152,000
Total Contractual Obligations	1,075,000	396,000	1,471,000

Subsequent to September 30, 2014, the Company entered into additional research and other service contracts, resulting in additional purchase commitments of \$2,179,000 due within one year. As a result, the total current commitments are \$3,650,000. One of these additional commitments, amounting to \$186,000, related to a purchase obligation for equipment.

Of the total purchase obligations, one contract contains a change of control clause in which subject to certain conditions, the Company agrees to pay the vendor an amount equal to fees based on the minimum billable hours for the remainder of the agreement term. As a triggering event has not taken place, these contingent payments have not been recognized in these financial statements. The Company does not have a practicable estimate for the amount of this contingent liability due to the nature of the triggering event. As at September 30, 2014, the maximum amount of any contingent liability, based on a remaining term of 19 months, was \$764,000, which was included in the amount of unrecognized purchase obligations.

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 \$769,000 and are all payable 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 September 30, 2014; 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 September 30, 2014.

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 Toronto Venture Exchange (the "Exchange").

On July 3, 2014, as a condition of the MJFF grant agreement, the Company has made a commitment to support further Parkinson's research by making up to US\$1,000,000 in contributions to MJFF conditional on future sales of APL-130277.

#### **Subsequent Events**

On October 24, 2014, 100,000 warrants of the Company were exercised at an exercise price of \$0.81 to acquire 100,000 common shares for gross proceeds of \$81,000.

# 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, 2014.

# 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, 2014, the Company had cash and cash equivalents of \$19,496,961 (December 31, 2013 - \$2,289,046) to settle current liabilities of \$1,183,967 (December 31, 2013 - \$2,555,050). The Company's accounts payable and accrued liabilities have contractual maturities of less than 30 days and are subject to normal trade terms.

#### Market risk

#### (a) Interest rate risk

The Company had a cash and cash equivalents balance of \$19,496,961 as at September 30, 2014. The Company's current policy is to hold cash in business savings accounts or invest excess cash in investment-grade short-term deposit certificates issued by its banking institutions. The Company periodically monitors the investments it makes and is satisfied with the credit ratings of its banks. The Company considers interest rate risk to be minimal as investments are short term.

#### (b) Foreign currency risk

The Company's functional and presentation currency is the Canadian dollar and all amounts in the consolidated financial statements are expressed in Canadian dollars, unless otherwise noted. Most purchases are transacted in Canadian or U.S. dollars. The Company funds certain research and development expenses in the United States, Europe and Asia using the U.S. Dollar currency from its U.S. dollar bank account held in Canada. Management believes the foreign exchange risk derived from currency conversions is not significant and therefore does not hedge its foreign exchange risk. As at September 30, 2014, the Company had cash of \$13,795,524 and accounts payable and accrued liabilities of \$540,876 denominated in U.S. dollars (December 31, 2013 - \$253,050 and \$474,868, respectively). A plus or minus 10% change in foreign exchange rates could affect the Company's net loss by approximately \$1,400,000.

#### Market risk (continued)

#### (c) Price risk

The Company is exposed to price risk with respect to Active Pharmaceutical Ingredient ("API") prices used in research and development activities. The Company monitors API prices in the United States, Europe and Asia to determine the appropriate course of action to be taken by the Company. Management believes that the price risk concentration with respect to API is minimal.

# (d) Fair value

IFRS require that the Company disclose information about the fair value of its financial assets and liabilities. Fair value estimates are made at the statement of financial position date based on relevant market information and information about the financial instrument. These estimates are subjective in nature and involve uncertainties in significant matters of judgment and therefore cannot be determined with precision. Changes in assumptions could significantly affect these estimates.

The Company has designated its cash equivalents as held-for-trading, measured at fair value. Cash is classified as loans and receivables, which is measured at amortized cost. Accounts payable and accrued liabilities are classified as other financial liabilities, which are measured at amortized cost.

The carrying amounts for cash and accounts payable and accrued liabilities on the consolidated statement of financial position approximate fair value because of the limited term of these instruments.

The Company's financial instruments that are carried at fair value consist of cash equivalents that do not have quoted market prices. They have been classified as Level 2 within the fair value hierarchy.

# **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 those risks and uncertainties relating to Cynapsus' business disclosed under the heading "Risk Factors" in its latest Annual Information Form, 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 \$1,691,808 for the three months ended September 30, 2014 and expects to incur losses from continuing operations for the foreseeable future. As at September 30, 2014, the Company had cash and cash equivalents of \$19,496,961. The Company will require 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 possibility the Company may 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.

It is expected that the Company will not need to raise additional capital for 18 to 24 months.

#### **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 possible that even with further funding raised by issuing securities and debt financing that the Corporation may not be financially able to bring its product candidate to market. The Corporation has initiated its clinical and pre-clinical research programs for its product candidate with the intention that positive results may attract the attention of a well-financed pharmaceutical entity to enter into a partnership agreement and to sponsor product development. There is a risk that the Corporation 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 Corporation'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 may depend 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 March 26, 2014, and other documents filed on the System for Electronic Document Analysis and Retrieval at www.sedar.com.

# **Contact Information**

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