

# CYNAPSUS THERAPEUTICS INC.

MANAGEMENT DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED MARCH 31, 2015

# MANAGEMENT DISCUSSION AND ANALYSIS OF OPERATING RESULTS AND FINANCIAL CONDITION FOR THE THREE MONTHS ENDED MARCH 31, 2015

The following Management Discussion and Analysis ("MD&A") relates to the financial position and results of operations of Cynapsus Therapeutics Inc. ("Cynapsus", or the "Company") for the three months ended March 31, 2015 and should be read in conjunction with the Company's Condensed Interim Consolidated Financial Statements for the three months ended March 31, 2015 as well as the Company's Audited Annual Consolidated Financial Statements and related Notes and Management's Discussion and Analysis for the year ended December 31, 2014. The condensed interim consolidated financial statements for the period ended March 31, 2015 and related notes of Cynapsus have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board. Additional information, including its press releases, has been filed electronically through the System for Electronic Document Analysis and Retrieval ("SEDAR") and is available online under its profile at www.sedar.com.

The discussion and analysis within this Management Discussion and Analysis ("MD&A") are as of May 7, 2015.

In this MD&A, unless otherwise indicated, all dollar amounts are expressed in Canadian dollars. The term "dollars" and the symbols "\$" and "CDN\$" refer to Canadian dollars and the term "U.S. dollars" and the symbol "US\$" refer to United States dollars.

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

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 17, 2015, under the heading "Risk Factors" in the "Management Discussion and Analysis" for the year ended December 31, 2014, 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 PROFILE**

#### Overview

Cynapsus is a specialty central nervous system pharmaceutical company developing and preparing to commercialize a Phase 3, fast-acting, easy-to-use, sublingual thin film for the on-demand turning ON of debilitating OFF episodes associated with Parkinson's disease, or PD. PD is a chronic, progressive neurodegenerative disease characterized by motor symptoms including tremor at rest, rigidity and impaired movement as well as significant non-motor symptoms such as cognitive impairment and mood disorders. The re-emergence of PD symptoms is referred to as an OFF episode. The Company recently successfully completed a Phase 2 clinical trial for its product candidate, APL-130277, a sublingual formulation of apomorphine hydrochloride, or apomorphine. Apomorphine is the only molecule approved for acute, intermittent treatment to provide rapid turning ON and relief from OFF episodes, but is currently only approved in the United States as a subcutaneous injection, which poses a number of problems, APL-130277 is a "turning ON" medication designed to rapidly, safely and reliably convert a PD patient from the OFF to the ON state while avoiding many issues associated with subcutaneous delivery of apomorphine. It is designed to convert all types of OFF episodes, including morning OFF episodes, often considered the most difficult to treat. The Company has initiated its Phase 3 clinical program for APL-130277, relying on the abbreviated Section 505(b)(2) regulatory pathway in the United States, and intends to submit a New Drug Application ("NDA") in 2016.

PD is the second most common neurodegenerative disease worldwide. Over one million people in the United States and between four and six million people worldwide suffer from PD. There is no known cure or disease modifying treatment currently available for PD. Current medications and treatments only control the major symptoms of the disease, with most drugs becoming less effective over time as the disease progresses. Cells that die in PD produce dopamine, a neurotransmitter critical to the signaling for movement. These current drugs and therapies either aim to supplement dopamine levels in the brain, mimic the effect of dopamine in the brain by stimulating dopamine receptors, referred to as dopamine agonists, or prevent the enzymatic breakdown of dopamine, prolonging its effect. The standard of care for the treatment of symptoms of PD remains oral levodopa, a drug approved nearly 50 years ago. While oral levodopa is efficacious, there are significant challenges for physicians in creating a dosing regimen of oral levodopa that consistently maintains levodopa levels within a patient's therapeutic range. Over time, the response to levodopa becomes less reliable and predictable and levodopa often cannot turn a patient from the OFF to the ON state. As a result, the majority of PD patients experience OFF episodes despite taking PD medications.

OFF episodes are thought to occur when brain dopamine levels fall below a critical threshold to sustain relatively normal motor function, or ON. It can be a period of time when a patient's PD medication is not working adequately to alleviate the patient's PD symptoms, when the medication has a delayed effect or does not work at all. When experiencing an OFF episode, a PD patient is unable to perform simple daily tasks such as eating, bathing and dressing, thus becoming increasingly dependent on caregivers. OFF episodes are considered one of the greatest unmet medical needs facing PD patients. The Company believes the current addressable market for its product candidate, APL-130277, in the United States alone is approximately 400,000 patients.

Cynapsus has a substantial patent portfolio, including issued and pending patent applications in the United States and certain other jurisdictions that cover APL-130277 and its use in the treatment of PD. The Company also relies on significant know-how for the creation of an optimal and functional sublingual apomorphine strip system that combines key mechanical, chemical reaction and pharmacokinetic attributes.

#### APL-130277 Clinical and Regulatory Plan

On February 4, 2015, Cynapsus held an End-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA"). For development of APL-130277 in the United States, the Company will follow Section 505(b)(2) of the Food, Drug and Cosmetic Act. The drug substance (apomorphine) in APL-130277 is identical to the active pharmaceutical ingredient in the FDA approved subcutaneous injection, Apokyn®, and APL-130277 is designed for similar usage.

The Section 505(b)(2) regulatory pathway will require the Company to provide statistically significant clinical evidence that PD patients experience improvement in their motor function as a result of delivery of apomorphine via the sublingual thin film route.

To achieve this, the Company currently plan to complete the following clinical studies:

- CTH-200 Bridging Study. A single-dose, crossover comparative bioavailability and pharmacokinetic study in healthy volunteers. This study is designed to allow the Company to use the safety and efficacy data for Apokyn® in its NDA submission to the FDA. This study is planned to commence in the second quarter of 2015.
- CTH-300 Efficacy Study. A double-blind, placebo-controlled, parallel-design study with an estimated 126 PD patients who have at least one OFF episode every 24 hours, with total OFF time of at least two hours per day. The objective is to evaluate the efficacy and safety of APL-130277 versus placebo in patients with PD. Sites will recruit patients over several months. The 126 patients will each be observed for 12 weeks, with dosing at home and in clinic. Patients will be evaluated every four weeks in clinic. The primary end point will be measured at week 12 in clinic. The primary endpoint will be the mean change in the MDS-UPDRS Part III score at 30 minutes after dosing. This study was initiated in the second quarter of 2015.
- CTH-301 Safety Study. A long-term open-label, single arm safety study in PD patients who have at least one OFF episode every 24 hours, with total OFF time of at least two hours per day. The objective is to evaluate the safety and tolerability of APL-130277 in patients with PD over 6 months of treatment. Sites will recruit patients over several months, with each patient being evaluated for six months. An estimated 226 patients will be enrolled, including up to 126 who had been enrolled in the CTH-300 efficacy study and rolled over to this study, plus an additional 100 new patients. The CTH-301 protocol has a built-in adaptive component potentially allowing the open label titration procedure to be modified to at-home titration. This change will be based upon the safety assessment completed by a Drug Safety Monitoring Board in the CTH 300 study. This study is planned to commence in the third quarter of 2015.

In parallel, the Company will continue to perform the necessary development activities, including process validation and stability studies as part of the chemistry, manufacturing and controls, or CMC, requirements for the filing of the NDA. The Company expects that all development will be performed according to current Good Manufacturing Practices methodology.

Upon completion of the efficacy and safety studies, as well as the CMC requirements, the Company intends to prepare and submit a Section 505(b)(2) NDA to the FDA in 2016.

Additionally, the Company plans to apply for regulatory approval in Europe. The Company expects to use the United Kingdom as the reference country. Management is working with regulatory consultants and apomorphine key opinion leaders in the United Kingdom.

#### REVIEW OF OPERATING RESULTS – THREE MONTHS ENDED MARCH 31, 2015

## Loss and Loss Per Share

For the three months ended March 31,

	2015 (\$)	2014 (\$)	\$ change in 2015	% change in 2015
Loss	5,094,432	1,210,272	3,884,160	320.9
Basic and diluted loss per share	0.06	0.03	0.03	100.0

Net loss for the three months ended March 31, 2015 exceeded the loss for the three months ended March 31, 2014 due mainly to higher research and development program costs related to the APL-130277 program, higher personnel costs with the number of staff increasing from eight to 17 people, higher professional fees, investor relations and shareholder relations costs, higher share-based compensation expenses and acquisition milestone share-based payment.

Basic loss per share is calculated using the weighted average number of shares outstanding during the period. As a result of the losses in the respective periods, there was no dilutive loss per share calculation.

The weighted average number of shares outstanding for the three months ended March 31, 2015 was 83,740,263 (2014 - 39,459,170).

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

For the three months ended March 31,

	2015 (\$)	2014 (\$)	\$ change in 2015	% change in 2015
Salaries, benefits and bonuses	374,527	27,250	347,277	1,274.4
Other R&D	2,496,574	421,442	2,075,132	492.4
Total R&D	2,871,101	448,692	2,422,409	539.9

R&D expenses for the three months ended March 31, 2015 were substantially higher than for the three months ended March 31, 2014 due to increased activity associated with the APL-130277 program. Expenditures increased as a result of increases in salaries and benefits associated with additional staff, consulting, formulation development, packaging development, patent protection, analytics, and scale-up CMC work for APL-130277.

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

For the three months ended March 31,

	2015 (\$)	2014 (\$)	\$ change in 2015	% change in 2015
Salaries, benefits, bonuses and board fees	451,504	345,516	105,988	30.7
Other OG&A	1,326,646	612,847	713,799	116.5
Total OG&A	1,778,150	958,363	819,787	85.5

OG&A costs for the three months ended March 31, 2015 were higher than for the comparable period due mainly to increases in salaries and benefits associated with the addition of new staff, investor and public relations activities, professional fees, increases in employee base salaries, and travel costs.

## Other Expenses (Recoveries)

For the three months ended March 31,

	2015 (\$)	2014 (\$)	\$ change in 2015	% change in 2015
Share-based payments	274,068	17,076	256,992	1,505.0
Amortization of intangible assets	11,969	14,746	(2,777)	(18.8)
Depreciation of property, plant and equipment	8,287	659	7,628	1,157.5
Acquisition milestone share-based payment	1,500,000	1	1,500,000	100.0
Foreign exchange (gain) loss	(1,182,432)	22,898	(1,205,330)	(5,263.9)
Recovery on scientific research	(30,000)	(10,000)	(20,000)	200.0
Research grant	(127,710)	(239,969)	112,259	(46.8)
Interest income net of interest expense and related charges	(9,001)	(2,193)	(6,808)	310.4

Under the terms of the amended Adagio Share Purchase Agreement, the Company was required to pay the former shareholders contingent consideration upon the completion of certain operational milestones. On March 11, 2015, the Company announced the results of the end of Phase 2 meeting with the FDA, which triggered a milestone payment to former Adagio shareholders of 1,119,403 newly issued common shares. The fair value of these shares, in the amount of \$1,500,000, was recorded as an expense during the three months ended March 31, 2015.

Foreign exchange gains for three months ended March 31, 2015 were \$1,182,432 compared to a loss of \$22,898 in the three months ended March 31, 2014 due to unrealized gains on significantly higher U.S. dollar cash balances on hand at March 31, 2015, combined with a strengthening of the U.S. dollar, compared to March 31, 2014. As at March 31, 2015, the Company had cash of \$30,635,493 denominated in U.S. dollars, compared to \$253,039 as at March 31, 2014.

Share-based payments increased to \$274,068 for the three months ended March 31, 2015 from \$17,076 for the three months ended March 31, 2014, as compensation expense was recognized over the vesting period for stock options previously granted.

Research grants for the three months ended March 31, 2015 represent the final installment of the second Michael J. Fox Foundation ("MJFF") for Parkinson's Research grant received, while research grants recognized in the three months ended March 31, 2014 relate to amounts previously deferred from the first MJFF grant. MJFF grants were awarded to support clinical research activities and have been recognized in accordance with IFRS accounting standards.

# SUMMARY OF QUARTERLY RESULTS

## FINANCIAL INFORMATION (IN DOLLARS):

(Numbers rounded to the nearest thousands)

	Q1 2015	Q4 2014	Q3 2014	Q2 2014
	(\$)	(\$)	(\$)	(\$)
Total assets	38,434,000	18,551,000	20,397,000	21,540,000
R&D	2,871,000	3,333,000	1,247,000	1,164,000
OG&A	1,778,000	2,148,000	1,006,000	894,000
Other operating expenses	582,000	(22,000)	(436,000)	775,000
Research grant	(128,000)	(343,000)	(112,000)	-
Interest income net of interest expense and related charges	(9,000)	(16,000)	(13,000)	(17,000)
Loss and comprehensive loss	5,094,000	5,100,000	1,692,000	2,816,000
Loss per share (basic and diluted)	0.06	0.07	0.02	0.04

	Q1 2014	Q4 2013	Q3 2013	Q2 2013
	(\$)	(\$)	(\$)	(\$)
Total assets	2,398,000	3,149,000	4,301,000	5,383,000
R&D	449,000	946,000	404,000	169,000
OG&A	958,000	1,033,000	737,000	661,000
Other operating expenses	45,000	85,000	117,000	232,000
Research grant	(240,000)	(213,000)	-	(91,000)
Interest income net of interest expense and related charges	(2,000)	(1,000)	-	1,000
Loss and comprehensive loss	1,210,000	1,851,000	1,258,000	973,000
Loss per share (basic and diluted)	0.03	0.04	0.03	0.03

#### LIQUIDITY AND CAPITAL RESOURCES

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 PD research, or a combination of the above.

The development of pharmaceutical products is a process that requires significant investment. Cynapsus expects to incur increased R&D expenses, including expenses related to completing Phase 3 clinical trials, NDA submission with the FDA, commercialization studies, and preparation for a U.S. product launch. The Company also expects that its general and administrative expenses will increase in the future as it adds infrastructure, including personnel costs, investor relations activities and professional fees.

The Company's future capital requirements will depend on a number of factors, including the continued progress of its R&D for its APL-130277 drug candidate, the timing and outcome of clinical trials and regulatory approvals, payments received or made under licensing or other collaborative agreements, if any, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, defending against patent infringement claims, the acquisition of licenses or technologies, the status of competitive products and the success of the Company in developing and maintaining markets for its product.

The cash balance was \$36,661,012 at March 31, 2015 compared to \$17,448,497 at December 31, 2014. Accounts payable and accrued liabilities as at March 31, 2015 was \$2,431,677 compared to \$3,080,631 at December 31, 2014.

The Company believes that it has sufficient resources available to support its activities for up to the next 12 to 18 months. Based on the Company's current operating plan, the Company would need to raise additional capital to fund completion of its preparation for commercial launch, and activities related to European registration. There are a significant number of warrants and options outstanding, some of which are in-the-money and may provide future sources of capital.

# **Operating Activities**

For the three months ended March 31, 2015, operating activities used cash of \$5,689,901 compared to \$1,676,386 in the three months ended March 31, 2014. 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 March 31, 2015 reflects the net loss of \$5,094,432 for the three months ended March 31, 2015, adjusted for non-cash items including share-based payments, amortization of intangible assets, depreciation of property, plant and equipment, changes in non-cash working capital (including prepaid expenses and other current assets, and accounts payable and accrued liabilities), acquisition milestone share-based payment and unrealized gain on foreign exchange.

## **Investing Activities**

For the three months ended March 31, 2015, \$133,146 of computer equipment and leasehold improvements was purchased, compared to nil in the three months ended March 31, 2014.

#### Financing Activities

For the three months ended March 31, 2015, net financing activities generated cash of \$23,853,130, compared to \$669,266 for the three months ended March 31, 2014. During the first quarter of 2015, the Company raised \$20,981,579 through a private placement of common shares, less transaction costs of \$1,468,029. In addition, during the three months ended March 31, 2015, the Company generated \$4,253,874 in proceeds from the exercise of warrants, and \$85,706 in proceeds from the exercise of share-based payments, while in the three months ended March 31, 2014, the Company generated \$724,495 in proceeds from the exercise of warrants.

## Effect of Exchange Rate Changes

For the three months ended March 31, 2015, the effect of exchange rate changes on cash and cash equivalents was \$1,182,432 as result of the Canadian dollar weakening relative to the U.S. dollar. As at March 31, 2015, the Company had cash of \$30,635,493 and accounts payable and accrued liabilities of \$878,796 denominated in U.S. dollars (December 31, 2014 - \$12,370,423 and \$1,539,496, respectively).

## Commitments and Contingent Liabilities

As at March 31, 2015, the Company had R&D and other service contract commitments, as well as minimum future payments under operating leases for the periods presented as follows:

	Less than 1 year (\$)	1 - 2 Years (\$)	Total (\$)
Purchase Obligations	2,150,000	137,000	2,287,000
Operating Leases	110,000	18,000	128,000
Total Contractual Obligations	2,260,000	155,000	2,415,000

Subsequent to March 31, 2015, the Company entered into additional research and development contracts, resulting in additional purchase obligations of \$1,422,000 within one year. As a result, the total current purchase obligations as at May 7, 2015 are \$3,709,000.

Of the total purchase obligations, one consulting 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 expected value of this contingent liability due to the nature of the triggering event. As at March 31, 2015, the maximum amount of any contingent liability, based on a remaining term of 15 months, was \$535,000, which was included in the amount of unrecognized purchase obligations.

The Company is a party to certain management contracts for its executive officers. Minimum management contract termination commitments remaining under the agreements, for termination without cause, are approximately \$1,252,325 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. On January 28, 2015, the Company and the former Adagio shareholders, whom are substantially represented by key management and therefore are related parties, signed an amendment to the Adagio Share Purchase Agreement to better reflect the contemplated agreement between the parties. Adagio shareholders are entitled to 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 had not been started as of March 31, 2015. With respect to the payment, the VWAP of the common shares may not be less than the "discounted market price" as defined in the policies of the Exchange.

On July 3, 2014, as a condition of the MJFF grant agreement, the Company is required 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.

## Off-Balance Sheet Arrangements

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

## March 31, 2015 Private Placement

On March 31, 2015, the Company announced the completion of a private placement of 22,039,472 common shares of the Company for gross proceeds of \$20,981,579. The issue price of \$0.952 per share represents a 20% discount to the 5-day volume-weighted average price per common share on the TSX as of the close of business on March 27, 2015. The common shares issued are subject to a hold period, which will expire four months plus one day from the date of issue.

## **SHARE CAPITAL**

Since the three months ended March 31, 2015, the following changes have occurred to Common Shares, stock options and warrants:

	As at May 7, 2015			
	Number of shares	Number of shares issuable on exercise of options	Number of shares issuable on exercise of warrants	Total
	#	#	#	#
As at March 31, 2015	110,311,428	5,324,316	53,343,218	168,978,962
Warrants exercised	324,795	-	(324,795)	1
Options issued	-	3,980,000	-	3,980,000
As at May 7, 2015	110,636,223	9,304,316	53,018,423	172,958,962

On April 2, 2015, the Company granted stock options to acquire 3,980,000 common shares. The stock options were granted to officers, directors and employees of the Company at an exercise price equal to \$1.36 per share and expire 5 years from the date of grant. The closing price of the shares of the Company on the Toronto Stock Exchange (CTH: TSX) on the day prior to the grant was \$1.36.

## **Exercised Warrants**

Summary of warrants exercised since the three months ended March 31, 2015 are as follows:

Number of Warrants #	Cash Proceeds \$	Exercise Price \$	Expiry Date
108,695	62,500	0.575	March 1, 2018
216,100	175,041	0.810	April 15, 2019
324,795	237,541		

#### TRANSACTIONS WITH RELATED PARTIES

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company, including directors and senior executives. Compensation paid or payable to key management was composed of the following during the three months ended March 31, 2015 and March 31, 2014:

	2015	2014	
	\$	\$	
Short-term salaries, benefits and bonuses to executives	297,122	207,655	
Director fees	126,130	70,428	
	423,252	278,083	

As at March 31, 2015, included in accounts payable and accrued liabilities was \$201,299 (December 31, 2014 - \$128,713) due to officers and directors of the Company. These amounts are unsecured and non-interest bearing with no fixed terms of repayment. As at March 31, 2015, \$100,000 was accrued as bonuses to related parties (December 31, 2014 - \$508,710).

The Company's executive agreements provide for additional payments in the event of termination without cause.

On March 11, 2015, the Company announced the results of the end of Phase 2 meeting with the FDA, which triggered a milestone payment to former Adagio shareholders of 1,119,403 common shares. Of the total, 602,442 shares were issued to the Company's President and Chief Executive Officer.

As part of the March 31, 2015 private placement, the Dexcel Pharma group, a strategic pharmaceutical investor and significant shareholder of Cynapsus, and which also has two directors on the Board of Directors of the Company, subscribed for 4,342,105 common shares having an aggregate subscription price of \$4,133,684.

#### SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS

A summary of significant accounting policies is included in Note 6 of the Company's 2014 audited financial statements. Critical accounting estimates require management to make judgments, estimates and assumptions that affect the application of accounting policies and reported amounts of assets and liabilities at the date of the consolidated financial statements and reported amounts of revenue and expenses during the reporting period. Actual outcomes could differ from these estimates. Changes in management's accounting estimates can have a material impact on the financial results of the Company. The Company's significant accounting judgments, estimates and assumptions are included in Note 5 of the Company's 2014 audited financial statements.

The estimates and underlying assumptions are reviewed on a regular basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised and in any future periods affected. The areas involving a higher degree of judgment or complexity, or areas where the assumptions and estimates are significant to the financial statements were the same as those applied to the Company's consolidated financial statements as at and for the year ended December 31, 2014.

#### 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 three months ended March 31, 2015.

#### 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 March 31, 2015, the Company had cash of \$36,661,012 and other current assets of \$828,186 (December 31, 2014 - \$17,448,479 and \$269,779, respectively) to settle current liabilities of \$2,431,677 (December 31, 2014 - \$3,080,631). 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 balance of \$36,661,012 as at March 31, 2015. The Company's current policy is to invest excess cash in a business savings account and 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 condensed interim consolidated financial statements are expressed in Canadian dollars, unless otherwise noted. Most purchases are transacted in Canadian dollars. The Company funds the majority of research and development expenses in the United States from its US dollar bank account held in Canada and certain expenses in Europe on a cash call basis using the euro converted from its Canadian dollar bank accounts 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 March 31, 2015, the Company had cash of \$30,635,493 and accounts payable of \$878,796 denominated in US dollars (December 31, 2014 - \$12,370,423 and \$1,539,496). A plus or minus 10% change in foreign exchange rates could affect the Company's net loss by approximately \$3,000,000.

# (c) Price risk

The Company is exposed to price risk with respect to active pharmaceutical ingredient, or 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.

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 short term of these instruments.

#### RISK FACTORS

While the Company remains optimistic about its long-term outlook, the Company is subject to a number of risks and uncertainties in carrying out its activities. In order to address the Company's business risks and effectively manage them, the Company has developed a process for managing risk with the Company's strategic plan. The Company provides regular updates to the Audit Committee to identify, measure, and prioritize the critical risks facing the company and manage these risks by ensuring that they are adequately addressed through mitigating procedures where appropriate. The objectives of the risk-management function include developing a common framework for understanding what constitutes principal business risks, ensuring that risk management activities are aligned with business strategies, and providing an effective mechanism for governance in the area of risk management.

A list of the primary risks and uncertainties facing the Company is found below. A more detailed description of the Company's risk factors is disclosed in its most recently filed Annual Information Form, as well as other information which is available at <a href="https://www.cynapsus.ca">www.cynapsus.ca</a> and at the System for Electronic Document Analysis and Retrieval ("SEDAR") at <a href="https://www.sedar.com">www.sedar.com</a>.

## Risks Related to the Company's Financial Position and Need for Additional Capital

- The Company has incurred net losses since its inception and anticipate that it will continue to incur substantial operating losses for the foreseeable future. The Company may never achieve or sustain profitability.
- The Company will require substantial additional financing to achieve its goals, and a failure to obtain this necessary capital when needed could force it to delay, limit, reduce or terminate its product development or commercialization efforts.
- Raising additional capital may cause dilution to the Company's existing shareholders, restrict its
  operations or require it to relinquish rights to its product candidate on unfavorable terms to the
  Company.

## Risks Related to Regulatory Review and Approval of the Company's Product Candidate

- Clinical failure may occur at any stage of clinical development, and the Company may never succeed in developing marketable products or generating product revenue.
- Delays in the commencement, enrollment or completion of clinical trials of the Company's drug candidate could result in increased costs to the Company as well as a delay or failure in obtaining regulatory approval, or prevent the Company from commercializing its product candidate on a timely basis, or at all.
- Clinical development, regulatory review and approval of the FDA and comparable foreign
  authorities are lengthy, time consuming, and inherently unpredictable. If the Company is ultimately
  unable to obtain regulatory approval for its drug candidate, its business will be substantially
  harmed.
- The Company currently has only one drug candidate, APL-130277, in clinical trials and is substantially dependent on this single drug candidate. A failure of this drug candidate in clinical development would significantly adversely affect the Company's business.
- If the Company fails to obtain regulatory approval in jurisdictions outside the United States, the Company will not be able to market the Company's products in those jurisdictions.

- Even if the Company receives regulatory approval for its drug candidate, its product will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, the Company's product, if approved, could be subject to labeling and other restrictions, and the Company may be subject to penalties if the Company fails to comply with regulatory requirements or experience unanticipated problems with the Company's product.
- The Company's drug candidate may cause undesirable side effects or have other properties that delay or prevent its regulatory approval or limit its commercial potential.

# Risks Related to Development and Manufacturing of the Company's Drug Candidate and Its Reliance on Third-Parties

- The Company relies on third parties to supply APIs and manufacture its sublingual thin filmstrip formulation of apomorphine. The Company does not have long-term contracts with such manufacturers or suppliers.
- The Company is subject to a number of risks relating to its third party service providers, any of which could substantially increase its costs and limit supply of its products.
- The ability of the Company's third party manufacturers to continue manufacturing and supplying its drug candidate depends on their continued adherence to cGMP regulations.
- If the Company changes the manufacturers of its drug candidate, the Company may be required to conduct comparability studies evaluating the manufacturing processes of the drug candidate.
- The Company relies on third parties to conduct preclinical studies and clinical trials for APL-130277, and if they do not properly and successfully perform their obligations to the Company, the Company may not be able to obtain regulatory approvals for APL-130277.
- The Company may not be successful in establishing and maintaining strategic partnerships, which could adversely affect its ability to develop and commercialize products, negatively impacting its operating results.

#### Risks Related to Commercialization of the Company's Drug Candidate

- The Company's future commercial success depends upon attaining significant market acceptance of its drug candidate, if approved, among physicians, patients and health care payors.
- The market for the Company's drug candidate may not be as large as the Company expects.
- The Company currently has no sales and marketing staff and no product distribution network. If
  the Company is unable to establish sales and marketing arrangements, the Company will not be
  successful in commercializing its products.
- Reimbursement may be limited or unavailable in certain market segments for the Company's drug candidate, which could make it difficult for the Company to sell its product profitably.
- Price controls may be imposed in foreign markets, which may adversely affect the Company's future profitability.
- The impact on the Company of health care reform legislation and other changes in the health care industry and in health care spending is currently unknown, and may adversely affect its business model.
- The Company faces substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, the Company does.

#### Risks Related to the Company's Intellectual Property

- If the Company is unable to obtain or protect intellectual property rights related to its drug candidate, the Company may not be able to compete effectively.
- The Company may become involved in lawsuits to protect or enforce its intellectual property, which could be expensive, time consuming and unsuccessful.
- Third party claims of intellectual property infringement or misappropriation may prevent or delay the Company's development and commercialization efforts.
- Confidentiality agreements with employees and third-parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

## Risks Related to the Company's Business and Industry

- If the Company fails to attract and keep senior management and key scientific personnel, the Company may be unable to successfully develop its drug candidate, conduct its clinical trials and commercialize its drug candidate.
- The Company may encounter difficulties in managing its growth and expanding its operations successfully.
- The Company's relationships with health care professionals, institutional providers, principal investigators, consultants, customers (actual and potential) and third party payors are, and will continue to be, subject, directly and indirectly, to health care fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, and health information privacy and security laws. If the Company is unable to comply, or has not fully complied, with such laws, the Company could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other government health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of the Company's operations.
- The Company may experience a security breach that could lead to the loss of critical information.
- The Company's employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.
- If product liability lawsuits are brought against the Company, it may incur substantial liabilities and may be required to limit commercialization of its drug candidate.
- The Company and its third party contract manufacturers must comply with environmental, health and safety laws and regulations, and failure to comply with these laws and regulations could expose the Company to significant costs or liabilities.

#### Risks Related to the Company's Common Shares

- If the Company is a passive foreign investment company for U.S. federal income tax purposes in any year, certain adverse tax rules could apply to U.S. Holders of the Company's Common Shares
- The market price of the Company's Common Shares may be highly volatile.
- The Company does not expect to pay any cash dividends for the foreseeable future.
- If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research about the Company's business, its share price and trading volume could decline.
- As the Company is a Canadian company, it may be difficult for U.S. shareholders to effect service on the Company or to realize on judgments obtained in the United States.

#### DISCLOSURE CONTROLS AND INTERNAL CONTROL OVER FINANCIAL REPORTING

The Company conducted an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures. The evaluation was conducted under the supervision and with the participation of management, including the Company's President and Chief Executive Officer, and Chief Operating Officer and Chief Financial Officer, as of December 31, 2014. Based on the evaluation, the Company's President and Chief Executive Officer, and Chief Operating Officer and Chief Financial Officer, concluded that such disclosure controls and procedures – as defined in Canada under National Instrument 52-109 – *Certification of Disclosure in Issuers' Annual and Interim Filings*, are effective as at December 31, 2014.

It should be noted that while the Company's disclosure controls and procedures are designed to provide a reasonable level of assurance of achieving their objectives, the Company's Chief Executive Officer and Chief Financial Officer do not expect that the Company's disclosure controls and procuedres or internal control over financial reporting will prevent all errors and fraud. A control system, no matter how well conceived or operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

There were no changes in the Company's internal control over financial reporting during the period ended March 31, 2015 that materially affected or are reasonably likely to materially affect its internal control over financial reporting.

#### ADDITIONAL INFORMATION

Additional information about the Company, including its most recent Annual Information Form, is available on the Company's website at <a href="www.cynapsus.ca">www.cynapsus.ca</a>, or on the Canadian Securities Administrators' electronic filing website at <a href="www.sedar.com">www.sedar.com</a>.

## **Contact Information**

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