

# FORM 51-102F1 MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED DECEMBER 31, 2015 AND 2014

# **ESSA Pharma Inc.**

**ESSA Pharmaceuticals Corp.** 

900 West Broadway – Suite 720 Vancouver, BC V5Z 1K5 Canada 2130 West Holcombe Blvd – Suite 900 Houston, TX 77030 USA

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED DECEMBER 31, 2015 AND 2014

This management's discussion and analysis ("MD&A") of ESSA Pharma Inc. (the "Company" or "ESSA") for the three months ended December 31, 2015 and 2014 is as of February 12, 2016.

This MD&A has been prepared with reference to National Instrument 51-102 "Continuous Disclosure Obligations" of the Canadian Securities Administrators. This MD&A should be read in conjunction with the unaudited condensed consolidated interim financial statements for the three months ended December 31, 2015 and 2014 and the related notes thereto. The consolidated financial statements are prepared in accordance with International Financial Reporting Standards ("IFRS"). Financial information presented in this MD&A is presented in United States dollars ("\$" or "US"), unless otherwise indicated.

This MD&A may contain certain "forward-looking statements" and certain "forward-looking information" as defined under applicable Canadian securities laws. Please refer to the discussion of forward-looking statements set out under the heading "Forward-Looking and Other Statements", located at the end of this document. As a result of many factors, our actual results may differ materially from those anticipated in these forward-looking statements.

The Company's common shares trade on the Toronto Stock Exchange ("TSX") under the symbol "EPI" and the NASDAQ under the symbol "EPIX".

# **OVERVIEW OF THE COMPANY**

ESSA is a clinical-stage pharmaceutical company focused on developing novel and proprietary therapies for the treatment of prostate cancer in patients whose disease is progressing despite treatment with current therapies, including abiraterone and enzalutamide. We believe our product candidate, EPI-506, can significantly expand the interval of time in which patients suffering from castration-resistant prostate cancer ("CRPC") can benefit from hormone-based therapies. Specifically, EPI-506 acts by disrupting the androgen receptor ("AR") signaling pathway, which is the primary pathway that drives prostate cancer growth. EPI-002, the primary metabolite of EPI-506, prevents AR activation by binding selectively to the N-terminal domain ("NTD") of the AR. A functional NTD is essential for activation of the AR. Blocking the NTD prevents activation of the AR by all of the known mechanisms of activation. In pre-clinical studies, blocking the NTD has demonstrated the capability to prevent AR activation and overcome the known AR-dependent mechanisms of CRPC.

The Company's Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for EPI-506 to begin a Phase 1/2 clinical trial was accepted in September 2015 with the first clinical patient enrolled in November 2015. We will explore the safety, tolerability, maximum tolerated dose and pharmacokinetics of EPI-506, in addition to tumor response rates in asymptomatic or minimally symptomatic patients who are no longer responding to either abiraterone or enzalutamide treatments, or both. Efficacy endpoints include prostate specific antigen ("PSA") reduction, as well as other progression criteria.

According to the American Cancer Society, in the United States, prostate cancer is the second most frequently diagnosed cancer among men, behind skin cancer. Approximately one-third of all prostate cancer patients who have been treated for local disease will subsequently have rising serum levels of PSA, which is an indication of recurrent or advanced disease. Patients with advanced disease often undergo androgen ablation therapy using analogues of luteinizing hormone releasing hormone ("LHRH") or surgical castration. Most advanced prostate cancer patients initially respond to androgen ablation therapy, however many experience a recurrence in tumor growth despite the reduction of testosterone to castrate levels, and at that point are considered to be suffering from CRPC. Following diagnosis of CRPC, patients are often treated with anti-androgens, which block the binding of androgens to the AR.

The growth of prostate tumors is mediated by an activated AR. Generally, there are three means of activating the AR. First, androgens such as dihydrotestosterone can activate AR by binding to its ligand-binding domain ("LBD"). Second, CRPC can be driven by constitutively-active variants of AR ("vAR") that lack a LBD and do not require androgen for activation. The third mechanism involves certain signaling pathways that activate AR independent of androgen activity. Current drugs for the treatment of prostate cancer work by focusing on the first mechanism and preventing androgen from binding to LBD, but this approach eventually fails and may not block the other two mechanisms of AR activation. By directly and selectively blocking all known means of activating the AR, we believe EPI-506 holds the potential to be effective in cases where current therapies have failed.



According to the Decision Resources Group, in 2014, there were approximately 213,000 prevalent cases of CRPC, and that prevalence is expected to increase to approximately 235,000 in 2023. The Company expects that EPI-506 could be effective for many of those patients. For the following reasons, the Company intends to first focus on patients who have failed abiraterone or enzalutamide therapies:

- CRPC treatment remains the prostate cancer market segment with the greatest unmet need and is therefore a potentially large market;
- we believe that the unique mechanism of action of our product candidate is well suited to treat patients who have failed LBD focused therapies; and
- we expect the large number of patients with unmet therapeutic needs in this area will facilitate timely enrollment in our clinical trials.

EPI-506 is a potent pro-drug of EPI-002, a stereoisomer of the discovery compound, EPI-001. A pro-drug is a drug which after administration is converted into an active form through a normal metabolic process. Pro-drugs are typically utilized to administer and more efficiently deliver another drug, which in this case is EPI-002. The Company believes that EPI-506 can deliver higher concentrations of EPI-002 to the target tissue than EPI-002 itself. In pre-clinical studies, EPI-001 has been shown to shrink benign prostate tissue in mice. The pro-drug EPI-506 has demonstrated similar biological effects at doses that are lower than those required for EPI-002.

The NTD of AR is flexible with a high degree of intrinsic disorder making it extremely difficult to be used for crystal structure-based drug design. To the Company's knowledge, no crystal structure has been identified in the AR NTD that could facilitate development of drugs which interact with this domain. The Company is not currently aware of any success by other drug development companies in finding drugs that bind to this drug target.

The Company has initiated a Phase 1/2 clinical trial that will enroll approximately 150 patients, 30 in the Phase 1 dose-escalation group and 120 in the Phase 2 dose expansion group. Key enrollment criteria are progressive, metastatic CRPC for patients who are no longer responding to abiraterone or enzalutamide. Efficacy endpoints include PSA response and radiographic progression criteria. The Company will also assess biomarkers of resistance including the splice variant status of patients. A biomarker is a measurable biological or chemical change that is believed to be associated with the severity or presence of a disease or condition. If the Phase 1/2 trial is successful, we expect FDA approval would be sought to commence a Phase 3 trial in a similar patient population.

The British Columbia Cancer Agency ("BCCA") and the University of British Columbia ("UBC") are joint owners of the intellectual property that constitutes our primary asset. The Company has entered into a joint agreement with those two institutions which provides them with exclusive access to the patent and patent applications to our EPI-series compounds, including EPI-506.

# **Our Strategy**

The Company's therapeutic goal is initially to provide a safe and effective therapy for prostate cancer patients who have failed current therapies, and ultimately to treat all AR-dependent forms of recurrent or advanced prostate cancer. The Company intends to accomplish those objectives while maximizing shareholder value. Specific components of our strategy include:

Rapidly advancing EPI-506 through clinical development and regulatory approval in CRPC patients

The Company has initiated a Phase 1/2 trial to determine the safety, tolerability, maximum tolerated dose, pharmacokinetics and potential therapeutic benefits of EPI-506 in CRPC patients. The Company expects to complete this trial before the end of calendar 2017.

Developing EPI-506 as an essential component of a new standard of care for the treatment of pre-CRPC and expand usage earlier in the disease stage

The activated AR is required for the growth and survival of most prostate cancer; therefore, the Company believes the AR NTD is an ideal target for next-generation hormone therapy. If EPI-506 is successful in treating CRPC patients, it is reasonable to expect that EPI-506 may be effective in treating earlier stage patients. Therefore, the Company may



conduct additional clinical studies potentially leading to approval of EPI-506 for use in prostate cancer patients at an earlier disease stage.

Identifying new indication areas with high unmet medical need

Several other diseases and conditions are impacted by activated AR, including certain sub-populations of breast cancer, Kennedy's disease (an orphan neurological condition) and male pattern baldness. While our primary focus will remain the treatment of prostate cancer, we may explore such applications in the future.

Evaluating strategic collaborations to maximize value

We currently retain all commercial rights for our EPI-series drug portfolio. We intend to evaluate potential collaborations that could enhance the value of our prostate cancer program and allow us to leverage the expertise of strategic collaborators. We also intend to explore collaborations in order to develop applications of our product candidate outside prostate cancer.

#### CORPORATE UPDATE AND OVERALL PERFORMANCE

ESSA has entered the clinical development stage and does not currently generate revenue. During the three months ended December 31, 2015, the Company incurred a comprehensive loss of \$4,039,811 (2014 - \$1,444,608). As of December 31, 2015, the Company had cash resources of \$2,609,032 (September 30, 2015 - \$1,579,288) and working capital of \$646,492 (September 30, 2015 - \$4,999,066).

This corporate update highlights significant events and transactions for the three months ended December 31, 2015 and for the subsequent period to the date of this report.

#### **Research and Development Milestones**

Enrollment of First Patient in Phase 1/2 Trial for EPI-506

In November 2015, the Company opened its first clinical trial sites and enrolled the first patient in the Phase 1/2 clinical study of EPI-506. In its Phase 1/2 clinical trial, ESSA intends to demonstrate the safety, tolerability, maximum tolerated-dose, pharmacokinetics, and efficacy of EPI-506 in metastatic CRPC patients who have failed abiraterone or enzalutamide therapy or both.

As part of the clinical study, ESSA will collect molecular biomarker information which may provide useful context in understanding patient outcomes. Androgen receptor splice variant V7 data will be included in such information.

Details relating to the Phase 1/2 clinical trial are now available on the US National Institutes of Health clinical trials website (https://clinicaltrials.gov).

# **Corporate and Finance Highlights**

Private Placement

On January 14, 2016, the Company completed a private placement (the "2016 Financing") of 4,545,452 units of the Company at \$3.30 per unit for aggregate gross proceeds of approximately \$15,000,000.

Each unit consists of one common share of the Company, one seven-year cash and cashless exercise warrant and one-half of one two-year cash exercise warrant (the "2016 Warrants"). Each of the 2016 Warrants has an exercise price of \$3.30.

The financing was led by Clarus Lifesciences, a new investor in the Company, with participation from Deerfield Management Company and other existing shareholders. The Company intends to use the net proceeds from the 2016 Financing for general corporate purposes, including funding research and development, preclinical and clinical expenses, and corporate costs.



Financial advisors provided financial advisory services to the Company in connection with the 2016 Financing and received a commission on closing.

In December 2015, ESSA filed a short form base shelf prospectus with securities regulatory authorities in British Columbia, Alberta and Ontario, and a corresponding shelf registration statement with the United States Securities and Exchange Commission (the "SEC") on Form F-10. The shelf prospectus, subject to Canadian and U.S. securities regulatory requirements, provides for the potential offering from time to time over a 25-month period in Canada and the United States, of up to an aggregate of US\$100 million of ESSA's common shares, warrants to purchase common shares, units comprising common shares and warrants, subscription receipts exercisable for common shares, warrants or units and debt securities.

The shelf prospectus is intended to give ESSA the flexibility to take advantage of financing opportunities when market conditions are favorable. The terms of such future offerings, if any, will be established at the time of such offerings. At the time any of the securities covered by the shelf prospectus are offered for sale, a prospectus supplement containing specific information about the terms of any such offering will be filed with applicable Canadian securities regulatory authorities and the SEC.

On January 26, 2016, ESSA filed a prospectus supplement under its registration statement on Form F-10 with respect to resales in the United States, from time to time, of the common shares issued under the 2016 Financing and the common shares issuable upon the exercise of the 2016 Warrants.

Additional details with respect to the 2016 Financing can be found in the material change report of ESSA dated January 15, 2016.

Senior Leadership Changes

On January 7, 2016, Dr. David Parkinson was appointed as the Company's President and Chief Executive Officer.

David Parkinson has significant experience in the development of novel approaches to cancer therapy. He has served as Vice President, Global Clinical Oncology for Novartis, and as Vice President, Oncology Development at Amgen. During his tenures at Amgen and Novartis, Dr. Parkinson was responsible for clinical development activities leading to a series of successful global drug registrations for important cancer therapeutics, including Gleevec, Femara, Zometa, Kepivance, and Vectibix. In addition, Dr. Parkinson has also served as the Sr. Vice President, Oncology Research and Development at Biogen Idec and as the CEO of the diagnostics company Nodality. Most recently he has been serving as a venture partner at New Enterprise Associates, Inc. (NEA).

Dr. Parkinson replaces Mr. Robert Rieder who announced his departure from the Company and resignation from the Board of Directors.

On January 14, 2016, effective on the closing of the 2016 Financing, Scott Requadt, Managing Director of Clarus Ventures, LLC, was appointed to the board of directors of the Company.

Pursuant to the terms of the subscription agreement between the Company and Clarus Lifesciences III, L.P. ("Clarus"), Clarus is entitled to nominate two directors to the board of directors of the Company, one of which must be an independent director and pre-approved by the Company. The nomination rights will continue for so long as Clarus holds greater than or equal to 1,060,606 Common Shares, subject to adjustment in certain circumstances.

# DISCUSSION OF OPERATIONS

#### **Programs and Potential Products**

Our EPI-Series Drugs

The Company's product candidate, EPI-506, is a selective, oral small molecule pro-drug that blocks the NTD of the AR. The AR is required for the growth and survival of most prostate cancer; therefore, the NTD of the AR is an ideal target for next-generation hormone therapy. Consistent with the inhibition of AR activity by other EPI compounds, experimentation conducted in a test-tube or in a controlled environment outside a living organism ("in vitro" studies)



and experimentation done in or on the living tissue of a whole, living organism ("in vivo" studies) show that EPI-506 selectively blocks AR-dependent proliferation of human prostate cancer cells that express AR and do not inhibit the proliferation of cells that do not express functional AR or do not rely on the AR for growth and survival. By directly inhibiting the NTD of the AR, the Company believes EPI-506 may be able to overcome resistance mechanisms in CRPC.

The Company has initiated a Phase 1/2 clinical trial to determine the safety, tolerability, maximum tolerated dose, pharmacokinetics, and efficacy of EPI-506 in CRPC patients. In Phase 1, the trial will evaluate the safety, tolerability, pharmacokinetics, and maximum-tolerated dose of EPI-506, in multiple-dose escalations. The Phase 2 portion (dose expansion) of the trial will then evaluate activity in three patient cohorts: post-enzalutamide CRPC, post-abiraterone CRPC, and both post-enzalutamide and post-abiraterone CRPC. The Phase 1/2 trial is expected to enroll approximately 150 patients.

The Company licensed the EPI- family of drugs from the UBC and BCCA whose initial lead compound was EPI-001. It is a mixture of four stereoisomers, each of which has the same chemical constitution, but different spatial orientation of its constituent atoms. While all the stereoisomers are active against the AR NTD, the most effective stereoisomer of EPI-001 is EPI-002 and substantial experimentation with EPI-002 has been completed and published. EPI-506 is a pro-drug of EPI-002, meaning that EPI-506 metabolizes to EPI-002 in vivo once it is dosed orally.

# **Pre-clinical Studies**

The Company is focused on developing EPI-506 as our clinical development candidate. The *in vivo* efficacy of EPI compounds has been demonstrated using human prostate cancer xenograft models.

The Company's initial work to support the CRPC indication consisted of pre-clinical studies and bioanalytical development, as well as Good Laboratory Practices ("GLP") and non-GLP toxicology trials in three species. Bioanalytical development for pre-clinical studies has been conducted in Vancouver, Canada.

To formally assess any potential safety issues related to EPI-506, the Company has conducted various dose-ranging non-GLP and IND enabling 28-day GLP toxicity trials in rodents and non-rodents, dose-ranging trials that lead to 28-day GLP toxicology trials. Consistent with the development of other oncology therapies at this early stage, no reproductive toxicology trials are required, given the patient population to be treated. The toxicology trials incorporate toxicokinetic data in order to correlate potential toxic effects with EPI-506 exposure. *In vitro* metabolism data using hepatocytes has been generated. A radiolabeled form of EPI-506 is available and will be used for further metabolism and distribution work *in vivo*.

The Company has used Southwest Research Institute in San Antonio, Texas for cGMP manufacturing of EPI-506 for early clinical trials. Formulation and cGMP production of the final drug product for clinical trials is performed by Catalent Pharma Solutions, St. Petersburg, Florida.

# Planned Clinical Development Program

Phase 1/2 Clinical Trial Design for treating CRPC patients

The Company's IND application to the FDA for EPI-506 to begin a Phase 1/2 clinical trial to determine the safety, tolerability, maximum tolerated dose, pharmacokinetics and potential therapeutic benefits of EPI-506 in CRPC patients was accepted in September 2015 with the first clinical patient enrolled in November 2015. Additionally, we received a "no objection letter" from the Therapeutic Products Directorate of Health Canada ("TPD") in response to the CTA for EPI-506 allowing the clinical trial to be conducted in Canada.

The Phase 1 portion of the trial is expected to enroll approximately 30 patients with CRPC. Following single-dose evaluation, patients are expected to then receive once-daily oral dosing for 28 days to assess safety for dose escalation. Further, patients will continue to receive the trial drug for 12 weeks or longer to assess efficacy. The endpoints of this part of the trial will be to assess safety, tolerability, maximum tolerated dose and pharmacokinetics of EPI-506. Efficacy endpoints include PSA response and radiographic progression criteria. We plan to conduct this Phase 1 portion of the trial at five sites and expect it to be completed by approximately Q3 of calendar 2016 depending on the enrollment rate and number of dose escalation steps.



The Phase 2 portion is initially expected to enroll approximately 120 patients with CRPC. Additional patient cohorts may be added to address relevant questions on patients' tumor response and molecular profile (e.g. AR splice variant status). This trial is currently expected to focus on CRPC patients with progressive metastatic disease and rising PSA who are no longer responding to abiraterone or enzalutamide, or both. The main outcomes to be measured are expected to be:

- PSA response (reduction in blood PSA level of 50% or more);
- PSA progression;
- radiographic progression; and
- objective responses.

The Company expects to collect circulating tumor cells so that the status of AR splice variant and other relevant biological markers related to AR signaling can be determined. The Company expects to conduct this trial in 25 to 30 sites and expect the study completion by December 2017.

#### Phase 3 Clinical Trial

In order to obtain regulatory approval, the Company will be required to carry out at least one Phase 3 trial. At this time, the Company expects that these patients will be a similar population of CRPC patients that were enrolled in the Phase 1/2 trial. However, the results of the Phase 1/2 trial may require modification of the initial patient population based on response and biomarker assessment. In the Phase 3 clinical trials, the key end-point is expected to be overall survival relative to patients receiving the standard-of-care. It is expected the Phase 3 clinical trial will be conducted at many sites around the world.

# QUARTERLY FINANCIAL INFORMATION

The following table summarizes selected unaudited consolidated financial data for each of the last eight quarters, prepared in accordance with IFRS:

		For t	the (	<u> Juarters Endec</u>	1	
	December 31, 2015	September 30, 2015		June 30, 2015		March 31, 2015
Total assets	\$ 4,622,698	\$ 7,539,773	\$	7,744,588	\$	10,979,382
Long-term liabilities	588,408	993,099		2,239,274		880,516
Research and development expense	3,200,937	(791,822)		2,590,652		2,532,553
General and administration	1,226,868	2,177,188		1,065,563		1,320,088
Comprehensive loss	(4,039,811)	(469,155)		(4,858,400)		(4,569,637)
Basic and diluted loss per share	(0.18)	0.02		(0.29)		(0.20)

	For the Quarters Ended						
		December 31, 2014		September 30, 2014		June 30, 2014	March 31, 2014
Total assets	\$	3,983,434	\$	4,201,833	\$	718,047 \$	495,670
Long-term liabilities		296,975		1,640,352		-	=
Research and development expense		644,545		(100,196)		587,503	39,933
General and administration		696,327		571,612		302,680	98,128
Comprehensive loss		(1,444,608)		(562,533)		(922,094)	(160,042)
Basic and diluted loss per share		(0.08)		(0.03)		(0.06)	(0.01)

For the quarters ended March 31, 2014 and June 30, 2014, the Company relied on funds raised in 2012 and tax credit refunds to meet the Company's operating and research and development plans. There were therefore minimal changes in the capitalization of the Company during that time. In the quarter ended September 30, 2014, the Company received its first tranche of the grant from CPRIT of \$2,792,533 which was recorded as a long-term liability for recognition



against qualifying expenditures as those expenditures are made. In the quarter ended September 30, 2015, the Company recorded a receivable of \$3,786,667 for its second tranche of the CPRIT Grant, which was recognized as recoveries of research and development expenditures. The CPRIT Grant is detailed in the accompanying condensed consolidated interim financial statements. The CPRIT Grant agreement was executed by the Chief Executive Officer of CPRIT on July 9, 2014 (the "CPRIT Agreement").

Also in the three months ended September 30, 2014, the Company completed a financing involving the issuance of 1,185,400 Preferred Shares at a price of C\$2.00 per Preferred Share for gross proceeds of \$2,183,270 ("2014 Preferred Shares Financing") which supplemented the Company's financial resources. In the three months ended December 31, 2014, the Company completed an offering of 679,640 special warrants at C\$2.00 per special warrant for gross proceeds of \$1,208,944 ("2014 Special Warrant Financing"). On January 16, 2015, the Company issued 4,363,634 special warrants at a price of \$2.75 per special warrant for gross proceeds of \$11,999,994 ("2015 Special Warrant Financing"). Accordingly, with these additional resources, the Company has accelerated its work relating to the IND filing resulting in a significant increase in comprehensive loss over prior periods. The IND application was filed on March 31, 2015 with additional chemistry and pharmaceutical data work provided to the FDA in the following quarters. The IND was ultimately approved in September 2015.

# Three months ended December 31, 2015 and 2014

The Company incurred a comprehensive loss of \$4,039,811 for the three months ended December 31, 2015 compared to a comprehensive loss of \$1,444,608 for the three months ended December 31, 2014. Significant changes are as follows:

#### Research and Development

- The overall Research and Development ("**R&D**") expense for the three months ended December 31, 2015 was \$3,200,937 compared to \$644,545 for the three months ended December 31, 2014. The gross expense for 2015 was \$3,200,937 (2014 \$1,948,094) before recognition of qualifying Cancer Prevention and Research Institute of Texas ("**CPRIT**") Product Development and Relocation Grant (the "**CPRIT Grant**") funds of \$nil (2014 \$1,303,549). This reflects a significantly higher investment in research and development activities, inclusive of preclinical work, from the amounts expended in the comparative periods.
- In the fourth quarter of fiscal 2014, the Company established office space and began to hire staff in Houston, Texas in order to undertake the preclinical work needed for the IND submission as well as developing the clinical protocol for the Phase 1/2 study that will be administered from ESSA's Houston office. Overall, R&D activity is higher than in the comparative period as financing secured in late fiscal 2014 and fiscal 2015 permitted a more robust research program compared to the prior period when the Company was focusing on securing financing.
- Pharmacology costs of \$125,436 (2014 \$611,870) have decreased compared to the comparative period due to the completion of testing and experimentation on the Company's EPI-series drugs. The investment for the comparative period was significant as the Company worked with its research facility partners to complete the documentation and information to supplement its IND application as filed at the end of March 2015.
- Manufacturing costs of \$948,146 (2014 \$404,168) have increased compared to the comparative period due to the ongoing production of clinical trial material to support the Company's Phase 1/2 clinical study. In the comparative period, manufacturing costs were related to less costly manufacturing process development activities, rather than large scale clinical batch production.
- Clinical costs of \$615,848 (2014 \$Nil) related to work performed by the clinical research organization in preparation for the Phase 1/2 clinical trial which commenced in November 2015.
- Consulting fees have increased to \$423,171 (2014 \$149,637) as the Company has engaged qualified
  professionals to conduct specific R&D services for the Company in relation to the IND filing, in addition to
  regular payments made to the Company's Chief Scientific Officer and Chief Technical Officer over the three
  periods.



- Legal patents and license fees have increased to \$261,926 (2014 \$123,080) as the Company has submitted a number of patent applications for which the Company owns the rights. The Company has adopted a tiered patent strategy to protect its intellectual property as the pharmaceutical industry places significant importance to patents for the protection of new technologies, products and processes. The Company anticipates that there will be ongoing investment into patent applications.
- Salaries and benefits relate to establishment of payroll, including the Company's Chief Medical Officer, Executive VP of Research and 14 preclinical and clinical staff in Texas. The Company has invested significantly over the past year to develop a team to efficiently advance the IND application and preparation for Phase 1/2 clinical trials.

Research and development expenses include the following major expenses by nature for the three months ended December 31, 2015 and 2014:

		2015		2014
		61.5.040	Φ.	
Clinical	\$	615,848	\$	-
Consulting		423,171		149,637
Legal patents and license fees		261,926		123,080
Manufacturing		948,146		404,168
Other		82,820		313
Pharmacology		125,436		611,870
Salaries and benefits		534,307		284,601
Share-based payments (Note 10)		119,962		264,215
Travel		89,321		110,210
CPRIT grant claimed on eligible				
expenses (Note 17)	-	<u>-</u>		(1,303,549)
Total	\$	3,200,937	\$	644,545

Share-based payments expense of \$119,962 (2014 - \$264,215) relates to the value assigned to stock options granted to key management and consultants of the Company conducting research and development activities. The expense is recognized in relation to the grant and vesting of these equity instruments as measured by the Black-Scholes pricing model.

#### General and administrative

General and administration expenses for the three months ended December 31, 2015 increased to \$1,226,868 from \$696,327 in the comparative period. Significant components of the expense in the current period included:

- Consulting and subcontractor fees of \$13,381 (2014 \$66,387). In the current year, the costs related to
  ongoing administrative support and intellectual property consulting, and one-time professional recruiting
  services. In the prior periods, costs were related to the CEO and CFO who have since been converted to full
  time employees included in salaries and benefits.
- Director fees of \$64,000 (2014 \$Nil) commencing with the Company becoming publicly-listed on the TSX Venture Exchange ("TSX-V") in January 2015.
- Investor relations expense of \$99,354 (2014 \$11,866). Concurrently with the Company's listing on the TSX-V in January 2015, the Company engaged several investor relations consultants and incurred costs for shareholder communications and news releases.
- Professional fees for legal and accounting services of \$192,374 (2014 \$316,641) were incurred in conjunction with the corporate activities in fiscal 2016. These services have been engaged to support the Company's financing activities. In the comparative period, the Company engaged these services for working towards listing on the TSX-V (occurred in January 2015), the NASDAQ (occurred in July 2015) and



graduation to the TSX (occurred in July 2015). The Company has worked with its professional service providers to develop corporate structures and compliance standards to meet new and developing reporting requirements as a public company. Consequently, regulatory fees and transfer agent costs have increased for initial listing fees and associated transaction costs to \$39,049 (2014 - \$6,801).

- Rent expense of \$134,603 (2014 \$12,595) relating primarily to the establishment of the Houston office at the end of fiscal 2014.
- Salaries and benefits expense of \$291,909 (2014 \$164,529) relates primarily to the establishment of the CEO and CFO as full time employees of the organization.
- Other expense categories have increased and been established as overall corporate activity has increased.
   These expenses predominantly relate to costs toward becoming a reporting issuer and publicly listed company.

General and administrative expenses include the following major expenses by nature for the three months ended December 31, 2015 and 2014:

		2015	2014
Amortization	\$	16,441	\$ 7,701
Consulting and subcontractor fees		13,381	66,387
Director fees		64,000	-
Investor relations		99,354	11,866
Office, insurance, IT and communications		224,716	35,380
Professional fees		192,374	316,641
Regulatory fees and transfer agent		39,049	6,801
Rent		134,603	12,595
Salaries and benefits		291,909	164,529
Share-based payments (Note 10)		103,873	110,221
Travel and entertainment		47,168	4,013
CPRIT grant claimed on eligible expenses (Note 17)	_		 (39,807)
Total	\$	1,226,868	\$ 696,328

Share-based payments expense of \$103,873 (2014 - \$110,221) relates to the value assigned to stock options granted to key management and consultants of the Company. The expense is recognized in relation to the grant and vest of these equity instruments as measured by the Black-Scholes pricing model.

# Derivative liability

The 2015 Special Warrant Financing has increased the Company's net financial assets denominated in U.S. dollars and exposure to fluctuations in the U.S./Canadian exchange rate. In conjunction with the 2015 Special Warrant Financing, the Company issued 257,018 broker warrants exercisable at a price of \$2.75 per Common Share. As these broker warrants are denominated in U.S. dollars and are exercisable into Common Shares of the Company which has a functional currency of Canadian dollars, the instrument contains an embedded derivative liability. These warrants are measured at fair value with changes recognized in the statement of net loss and comprehensive loss at each reporting date. During the three months ended December 31, 2015, the Company recorded a gain of \$382,649 (2014 - \$Nil) with respect to the derivative liability.



#### **USE OF PROCEEDS**

During the year ended September 30, 2015, the Company received total net proceeds of \$12,057,008 from the following financings:

- In October 2014, the Company received net proceeds of \$1,083,578 in relation to the 2014 Special Warrant Financing.
- In January 2015, the Company received net proceeds of \$10,973,430 in relation to the 2015 Special Warrant Financing.

The following table sets out a comparison of how the Company used the proceeds following the closing dates, an explanation of the variances and the impact of the variance on the ability of the Company to achieve its business objectives and milestones.

Intended Use of Proceeds	Actual Use of Proceeds
To continue the development of EPI-506 Phase 1/2 clinical program through the end of calendar year 2015.	The proceeds have been used as intended to further the development of EPI-506 Phase 1/2 clinical program while meeting administrative requirements.
	During the three months ended December 31, 2015, the Company incurred \$3,200,937 in research and development costs, net of recoveries in relation to the development of the EPI-506 Phase 1/2 clinical program. An additional \$1,226,868 has been incurred for general and administrative costs in support of the Company's research and development activities.
	During the year ended September 30, 2015, the Company incurred \$4,975,927 in research and development costs, net of recoveries in relation to the development of the EPI-506 Phase 1/2 clinical program. An additional \$5,259,167 has been incurred for general and administrative costs in support of the Company's research and development activities.
	As at December 31, 2015, the Company has fully expended the funds raised in these financings towards the completion of the Phase 1/2 clinical program.

# LIQUIDITY AND CAPITAL RESOURCES

Operational activities during the three months ended December 31, 2015 were financed mainly by proceeds from equity financings completed in July 2014, October 2014 and January 2015, and the CPRIT Grant. At December 31, 2015, the Company had available cash reserves of \$2,609,032 and \$41,306 in accounts receivable related primarily to GST input tax credits, to settle current liabilities of \$3,365,816. This compares to cash reserves of \$1,579,288 at September 30, 2015 and \$3,849,605 in accounts receivable related primarily to the second CPRIT advance refund of \$3,786,667, received in the period ended December 31, 2015, to settle current liabilities of \$2,091,162.

Cash used in operating activities for the three months ended December 31, 2015 was \$2,601,340 (2014 - \$2,066,940). Working capital items generated cash of \$1,498,526 (2014 - \$125,665).

Cash used in investing activities for the three months ended December 31, 2015 was \$1,976 (2014 - \$55,536) as the Company invested in equipment in the ongoing establishment of its Houston office.



Cash generated by financing activities for the three months ended December 31, 2015 was \$3,768,052 (2014 - \$2,083,578), including \$3,786,667 received from the CPRIT grant and \$1,194 proceeds received on exercise of warrants, offset by \$19,809 cash used in deferred financing costs in relation to the 2016 Financing. In the comparative period, the Company received gross proceeds of \$1,208,944 from the 2014 Special Warrant Financing, as previously described above, offset by \$125,365 in share issuance costs. The Company also received \$1,000,000 as subscriptions received in advance on the 2015 Special Warrant Financing.

Subsequent to the period ended December 31, 2015, the Company completed the 2016 Financing for gross proceeds of approximately \$15,000,000. The Company believes that this funding will provide adequate resources to execute its planned expenditures beyond the fiscal 2016 year.

Future cash requirements may vary materially from those expected due to a number of factors, including the costs associated with pre-clinical studies, and the ensuing costs associated with Phase 1/2 clinical trials of up to 150 patients in 2015-2016 and to take advantage of strategic opportunities. As a result, it will be necessary to raise additional funds in the future. These funds may come from sources such as entering into strategic collaboration arrangements, the issuance of shares from treasury, or alternative sources of financing. However, there can be no assurance that we will successfully raise funds to continue the development and commercialization of EPI-506 and our operational activities.

#### CONTRACTUAL OBLIGATIONS

As of December 31, 2015, and in the normal course of business, we have the following obligations to make future payments, representing contracts and other commitments that are known and committed.

Contractual obligations	2016	2017	2018	2019	2020
Minimum annual royalty per License Agreement (CAD) (1) Lease on Vancouver office space	\$ 65,000	\$ 85,000	\$ 85,000	\$ 85,000	\$ 85,000
(CAD)	 36,383	 48,510	 48,510	 48,510	 48,510
Total (in CAD)	\$ 101,383	\$ 133,510	\$ 133,510	\$ 133,510	\$ 133,510
Lease on US office spaces (USD)	\$ 181,244	\$ 245,690	\$ 250,372	\$ 255,053	\$ 57,789

# Notes:

# OFF-BALANCE SHEET ARRANGEMENTS & PROPOSED TRANSACTIONS

We have no material undisclosed off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our results of operations, financial condition, revenues or expenses, liquidity, capital expenditures or capital resources that are material to investors.

We have no material proposed transactions that have, or are reasonably likely to have, a current or future effect on our results of operations, financial condition, revenues or expenses, liquidity, capital expenditures or capital resources that are material to investors.



ESSA has the worldwide, exclusive right to develop products based on Licensed IP, as defined in, and pursuant to, the License Agreement dated December 22, 2010 among ESSA, UBC and BCCA, as amended. The Company must pay a minimum annual royalty of \$65,000 in the 2015 and 2016 calendar years, increasing to \$85,000 in 2017 and for each year thereafter.

#### RELATED PARTY TRANSACTIONS

Compensation accrued and paid to key management personnel for the three months ended December 31, 2015 and 2014 are as follows:

8.500				
75,957 48,680 53,750 35,000 92,841 61,894 21,000	\$	43,759 19,280 14,713 37,435 12,640	\$	52,259 95,237 63,393 91,185 47,640 92,841 61,894 22,865 20,200
17,250	<u> </u>	15,863	ф.	33,113
	75,957 48,680 53,750 35,000 92,841 61,894 21,000 17,250	48,680 53,750 35,000 92,841 61,894 21,000 17,250 17,250	75,957 19,280 48,680 14,713 53,750 37,435 35,000 12,640 92,841 - 61,894 - 21,000 1,865 17,250 2,950 17,250 15,863	75,957 19,280 48,680 14,713 53,750 37,435 35,000 12,640 92,841 - 61,894 - 21,000 1,865 17,250 2,950 17,250 15,863

Share-based payments to related parties represents the fair value of options granted and vested in the period to key management personnel.

For the three months ended December 31, 2014		Salaries, sulting fees, director fees		Share-based payments (a)		Total compensation
Robert Rieder, Former Chief Executive Officer	\$	107,202	\$	42,725	\$	149,927
David Wood, Chief Financial Officer	Ψ	52,830	Ψ	27,187	Ψ	80,017
Dr. Frank Perabo, Chief Medical Officer		53,750		132,101		185,851
Paul Cossum, Executive VP of R&D		35,000		104,273		139,273
Dr. Marianne Sadar, Chief Scientific Officer		26,415		2,254		28,669
Dr. Raymond Andersen, Chief Technology Officer		26,415		2,254		28,669
Richard Glickman, Director and Chairman of the Board		7,925		3,919		11,844
Gary Sollis, Director		5,283		6,253		11,536
Total compensation	\$	314,820	\$	320,966	\$	635,786

Included in accounts payable and accrued liabilities at December 31, 2015 is \$264,138 (September 30, 2015 – \$82,414; September 30, 2014 - \$21,709) due to related parties with respect to the transactions detailed above and expense reimbursements. Amounts due to related parties are non-interest bearing, with no fixed terms of repayment.

Dr. Parkinson, CEO, is entitled to a payment of six months of base salary upon termination without cause and a payment of one year of base salary upon termination without cause after 12 months of employment. This amount increases to 18 months if the termination without cause occurs after a change of control event or within 60 days prior to a change of control event where such event was under consideration at the time of termination. Mr. Wood, CFO, is entitled to a payment of one year of base salary upon termination without cause, whether or not the termination was caused by a change of control event. Mr. Perabo, CMO, is entitled to a payment of six months of base salary upon termination without cause, and a payment of one year of base salary upon termination caused by a change of control event. Mr. Cossum, Executive Vice-President of Research and Development, is entitled to a payment of six months of base salary upon termination without cause, and a payment of one year of base salary upon termination caused by a



change of control event. Stock options held by the CEO, CFO, CMO and Executive Vice-President of Research and Development vest immediately upon a change of control.

# CHANGES IN OR ADOPTION OF ACCOUNTING POLICIES

The accounting policies adopted in the preparation of the condensed consolidated interim financial statements are detailed in Notes 2 and 3 of the Company's annual consolidated financial statements for the year ended September 30, 2015 with the exception of the policy with respect to presentation currency:

# **Change in Presentation Currency**

The Company has retroactively changed its presentation currency to the United States dollar ("\$" or "US\$") from the Canadian dollar ("C\$").

The functional currency of an entity is the currency of the primary economic environment in which the entity operates. From inception to December 31, 2015, the functional currency of the Company has been the Canadian dollar and its subsidiary's the United States dollar. The functional currency determinations were conducted through an analysis of the consideration factors identified in IAS 21, *The Effects of Changes in Foreign Exchange Rates*. The 2016 Financing completed subsequent to period end and changes to the Company's operations have resulted in a change to the currency in which the Company's management conducts its operating, capital and financing decisions. Consequently, the functional currency of the Company will be the US\$ effective January 1, 2016.

In anticipation of the change in functional currency, the Company has adopted the US\$ as the presentation currency for the consolidated entity. For comparative reporting purposes, historical financial statements were translated into the US\$ reporting currency whereby assets and liabilities were translated at the closing rate in effect at the end of the comparative periods; revenues, expenses and cash flows were translated at the average rate in effect for the comparative periods and equity transactions were translated at historic rates. The historic translation had an impact of \$73,503 as an unrealized foreign exchange as at October 1, 2014.

These financial statements are presented in United States dollars. All financial information is expressed in United States dollars unless otherwise stated.

#### New standards not yet adopted

IFRS 9 Financial Instruments (Revised)

IFRS 9 was issued by the IASB in October 2010. It incorporates revised requirements for the classification and measurement of financial liabilities and carrying over the existing derecognition requirements from IAS 39 Financial Instruments: recognition and measurement. The revised financial liability provisions maintain the existing amortized cost measurement basis for most liabilities. New requirements apply where an entity chooses to measure a liability at fair value through profit or loss – in these cases, the portion of the change in fair value related to changes in the entity's own credit risk is presented in other comprehensive income rather than within profit or loss. IFRS 9 is effective for annual periods beginning on or after January 1, 2018. The impact of IFRS 9 on the Company's consolidated financial instruments has not yet been determined.

# CRITICAL ACCOUNTING ESTIMATES

The Company makes estimates and assumptions about the future that affect the reported amounts of assets and liabilities. Estimates and judgments are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions.

The effect of a change in an accounting estimate is recognized prospectively by including it in comprehensive income in the period of the change, if the change affects that period only, or in the period of the change and future periods, if the change affects both. Significant assumptions about the future and other sources of estimation uncertainty that management has made at the statement of financial position date, that could result in a material adjustment to the



carrying amounts of assets and liabilities, in the event that actual results differ from assumptions that have been made, relate to the following key estimates:

#### Intangible Assets – impairment

The application of the Company's accounting policy for intangible assets expenditures requires judgment in determining whether it is likely that future economic benefits will flow to the Company, which may be based on assumptions about future events or circumstances. Estimates and assumptions may change if new information becomes available. If, after expenditures are capitalized, information becomes available suggesting that the recovery of expenditures is unlikely, the amount capitalized is written off in profit or loss in the period the new information becomes available.

# Intangible Assets – useful lives

Following initial recognition, the Company carries the value of intangible assets at cost less accumulated amortization and any accumulated impairment losses. Amortization is recorded on a straight-line basis based upon management's estimate of the useful life and residual value. The estimates are reviewed at least annually and are updated if expectations change as a result of technical obsolescence or legal and other limits to use. A change in the useful life or residual value will impact the reported carrying value of the intangible assets resulting in a change in related amortization expense.

# Product development and relocation grant

Pursuant to the terms of the Company's CPRIT Grant, the Company must meet certain terms and conditions to qualify for the grant funding. The Company has assessed its performance relative to these terms as detailed in the accompanying unaudited condensed consolidated interim financial statements (Note 15) and has judged that there is reasonable assurance the Company will meet the terms of the grant and qualify for the funding. The Company has therefore taken into income a portion of the grant that represents expenses the Company has incurred to date under the grant parameters. The expenses are subject to assessment by CPRIT for compliance with the grant regulations which may result in certain expenses being denied and incurred in a future period.

#### Share-based payments and compensation

The Company has applied estimates with respect to the valuation of shares issued for non-cash consideration. Shares are valued at the fair value of the equity instruments granted at the date the Company receives the goods or services.

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the fair value of the underlying common shares, the expected life of the share option, volatility and dividend yield and making assumptions about them. Prior to listing on the TSX-V, the fair value of the underlying common shares was assessed as the most recent issuance price per common share for cash proceeds. Following listing on the TSX-V, the Company makes reference to prices quoted on the TSX-V (TSX since ESSA's listing was graduated to the TSX). The assumptions and models used for estimating fair value for share-based payment transactions are discussed in Note 10 of the accompanying unaudited condensed consolidated interim financial statements.

#### Derivative financial instruments

Certain broker's warrants are treated as derivative financial liabilities. The estimated fair value, based on the Black-Scholes model, is adjusted on a quarterly basis with gains or losses recognized in the statement of net loss and comprehensive loss. The Black-Scholes model is based on significant assumptions such as volatility, dividend yield and expected term as detailed in Note 8 of the accompanying unaudited condensed consolidated interim financial statements.



#### FINANCIAL INSTRUMENTS AND RISKS

The Company's financial instruments consist of cash, receivables, accounts payable and accrued liabilities and derivative liability. Cash is measured based on level 1 inputs of the fair value hierarchy. The fair value of receivables and accounts payable and accrued liabilities approximates their carrying values due to their short term to maturity. The derivative liability is measured using level 3 inputs.

Fair value estimates of financial instruments are made at a specific point in time, based on relevant information about financial markets and specific financial instruments. As these estimates are subjective in nature, involving uncertainties and matters of judgement, they cannot be determined with precision. Changes in assumptions can significantly affect estimated fair values.

#### Financial risk factors

The Company's risk exposures and the impact on the Company's financial instruments are summarized below:

#### Credit risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and receivables. The Company's receivables are primarily due from refundable GST/HST and investment tax credits. The Company limits its exposure to credit loss by placing its cash with major financial institutions. Credit risk with respect to investment tax credits and GST/HST is minimal as the amounts are due from government agencies.

# 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 December 31, 2015, the Company had current assets of \$4,226,700 to settle current liabilities of \$3,365,816. All of the Company's current financial liabilities have contractual maturities of 30 days or due on demand and are subject to normal trade terms. The Company does not generate revenue and will be reliant on equity financing and proceeds from the CPRIT Grant to fund operations. Equity financing is dependent on market conditions and may not be available on favorable terms. The CPRIT Grant is dependent on the Company completing all the milestones (see accompanying unaudited condensed consolidated interim financial statements for details with respect to the CPRIT Grant terms).

#### Market risk

Market risk is the risk of loss that may arise from changes in market factors such as interest rates, and foreign exchange

# (a) Interest rate risk

The Company has cash balances and no interest-bearing debt and therefore is not exposed to risk in the event of interest rate fluctuations.

# (b) Foreign currency risk

Historically, the Company has been exposed to foreign currency risk on fluctuations related to accounts payable and accrued liabilities that are denominated in United States dollars as the Company was financed and functioning in Canadian dollars. Over time, the Company has become increasingly exposed to the United States dollar due to the CPRIT Grant (Note 15 of the accompanying consolidated financial statements) and movement of operations to Houston pursuant to the terms of the CPRIT Grant. As at December 31, 2015, the Company's current assets and liabilities were predominately denominated in US dollars due to the receipt of the CPRIT Grant funds in the period and expenditures in the United States. A 10% change in the foreign exchange rate between the Canadian and U.S. dollar would result in a fluctuation of \$82,088 in the net loss realized for the period.



The Company adopted the US dollar as its functional currency effective January 1, 2016. The financing completed in US dollars in January 2016 aligned the Company's financing and expenditures so that the Company's foreign currency risk exposure now relate to net monetary assets denominated in Canadian dollars. The Company does not currently engage in hedging activities.

# (c) Price risk

The Company is exposed to price risk with respect to equity prices. The Company closely monitors individual equity movements, and the stock market to determine the appropriate course of action to be taken by the Company.

#### ADDITIONAL INFORMATION

Additional information can be found on Sedar at <a href="www.sedar.com">www.sedar.com</a>, the website of the SEC at <a href="www.sec.gov">www.sec.gov</a> and the Company's website at <a href="www.essapharma.com">www.essapharma.com</a>.

#### **OUTSTANDING SHARE CAPITAL**

Equity instruments outstanding as of the date of this MD&A:	
Common shares	27,409,223
Stock options	3,833,519
Warrants	281,363

#### RISK FACTORS

Prior to making an investment decision investors should consider the investment, operational and intellectual property risks set out in the Company's Annual Report on Form 20-F located on SEDAR at <a href="www.sedar.com">www.sedar.com</a> and the SEC's Electronic Document Gathering and Retrieval System ("EDGAR") website at <a href="www.sec.gov/edgar.">www.sec.gov/edgar.</a>, which are in addition to the usual risks associated with an investment in a business at an early stage of development. The directors of the Company consider the risks set out in the Form 20-F to be the most significant to potential investors in the Company, but are not all of the risks associated with an investment in securities of the Company. If any of these risks materialize into actual events or circumstances or other possible additional risks and uncertainties of which the Directors are currently unaware, or which they consider not to be material in relation to the Company's business, actually occur, the Company's assets, liabilities, financial condition, results of operations (including future results of operations), business and business prospects, are likely to be materially and adversely affected. In such circumstances, the price of the Company's securities could decline and investors may lose all or part of their investment. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "Forward-Looking and Other Statements."

# INTERNAL CONTROLS OVER FINANCIAL REPORTING

#### Disclosure Controls and Procedures ("DC&P")

The Company has established disclosure controls and procedures to ensure that information disclosed in this MD&A and the related consolidated financial statements was properly recorded, processed, summarized and reported to the Company's Board and Audit Committee. The Company's certifying officers conducted or caused to be conducted under their supervision an evaluation of the disclosure controls and procedures as required under Canadian Securities Administration regulations, as at December 31, 2015. Based on the evaluation, the Company's certifying officers concluded that the disclosure controls and procedures were effective to provide a reasonable level of assurance that information required to be disclosed by the Company in its annual filings and other reports that it files or submits under Canadian securities legislation is recorded, processed, summarized and reported within the time period specified and that such information is accumulated and communicated to the Company's management, including the certifying officers, as appropriate to allow for timely decisions regarding required disclosure.



It should be noted that while the Company's certifying officers believe that the Company's disclosure controls and procedures provide a reasonable level of assurance and that they are effective, they do not expect that the disclosure controls and procedures 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.

#### **Internal Control over Financial Reporting ("ICFR")**

The Company's certifying officers acknowledge that they are responsible for designing internal controls over financial reporting, or causing them to be designed under their supervision in order to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS.

The Company ceased to be a venture issuer, as defined by National Instrument ("NI") 51-102 – Continuous Disclosure Obligations on July 9, 2015 as a result of completing its listing on the NASDAQ. The Company's Audit Committee is comprised of Franklin Berger (chair), Richard Glickman, and Gary Sollis, all of whom are "financially literate" as defined in NI 52-110 – Audit Committees ("NI 52-110") and the rules of NASDAQ. Each member of the Audit Committee is considered independent pursuant to NI 52-110, Rule 10A-3 under the Exchange Act and the rules of NASDAQ. Our Board has determined that Dr. Glickman is an "audit committee financial expert" as defined in Item 16A of Form 20-F.

Management has adopted the internal control framework of the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") *Internal Control – Integrated Framework* (2013).

The Company did not have any significant changes to its ICFR systems in the period from September 1, 2015 to December 31, 2015.

#### **Limitations of Controls and Procedures**

The Company's management, including the Chief Executive Officer and Chief Financial Officer, believe that any disclosure controls and procedures or internal controls over financial reporting, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, they cannot provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been prevented or detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by unauthorized override of the control. The design of any systems of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Accordingly, because of the inherent limitations in a cost effective control system, misstatements due to error or fraud may occur and not be detected.

# FORWARD-LOOKING AND OTHER STATEMENTS

This MD&A, including the documents incorporated by reference herein, contains forward-looking statements or forward-looking information within the meaning of the U.S. Private Securities Litigation Reform Act and applicable Canadian securities laws. All statements in this MD&A, other than statements of historical facts, are forward-looking statements. These statements appear in a number of different places in this MD&A and can be identified by words such as "anticipates", "estimates", "projects", "expects", "intends", "believes", "plans", "will", "could", "may", or their negatives or other comparable words. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements. Examples of such forward looking statements include, but are not limited to:

- the initiation, timing, cost, progress and success of ESSA's research and development programs, pre-clinical studies and clinical trials;
- the Company's ability to advance its product candidate into, and successfully complete, clinical trials;
- the Company's ability to achieve profitability;



- the Company's ability to obtain funding for operations, including research funding;
- the Company's ability to recruit sufficient numbers of patients for future clinical trials;
- the Company's ability to establish and maintain relationships with collaborators with acceptable development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts;
- the implementation of the Company's business model and strategic plans;
- the Company's ability to develop and commercialize product candidates;
- the Company's commercialization, marketing and manufacturing capabilities and strategy;
- the Company's ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others;
- the Company's expectations regarding federal, state, provincial and foreign regulatory requirements;
- whether the Company will receive, and the timing and costs of obtaining, regulatory approvals in the United States, Canada, the European Union and other jurisdictions;
- the therapeutic benefits, effectiveness and safety of the Company's product candidate;
- the accuracy of the Company's estimates of the size and characteristics of the markets that may be addressed by the Company's product candidate;
- the rate and degree of market acceptance and clinical utility of the Company's product candidate, if any;
- the timing of, and the Company's ability and the Company's collaborators' ability, if any, to obtain and maintain regulatory approvals for the Company's product candidate;
- the Company's expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- the Company's ability to engage and retain the employees required to grow its business;
- the compensation that is expected to be paid to the Company's employees;
- the Company's future financial performance and projected expenditures;
- developments relating to the Company's competitors and its industry, including the success of competing therapies that are or may become available; and
- estimates of the Company's expenses, future revenue, capital requirements and its needs for additional financing.

Such statements reflect the Company's current views with respect to future events, are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements, including those described under "Risk Factors". In making the forward looking statements included in this MD&A, the Company has made various material assumptions, including but not limited to:

- our ability to obtain positive results of clinical trials;
- our ability to obtain required regulatory approvals:
- our ability to successfully out-license or sell future products, if any, and in-license and develop new products;
- favourable general business and economic conditions;
- the availability of financing on reasonable terms;
- our ability to attract and retain skilled staff;
- market competition;
- the products and technology offered by the Company's competitors; and
- our ability to protect patents and proprietary rights.

If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual results may vary significantly from those expressed or implied by forward-looking statements. The forward-looking statements represent our views as of the date of this document. While we may elect to update these forward-looking statements in the future, we have no current intention to do so except as to the extent required by applicable law.

