

# FORM 51-102F1 MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE AND NINE MONTHS ENDED JUNE 30, 2017 AND 2016

ESSA Pharma Inc. 900 West Broadway – Suite 720 Vancouver, BC V5Z 1K5 Canada ESSA Pharmaceuticals Corp. 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 AND NINE MONTHS ENDED JUNE 30, 2017 AND 2016

This management's discussion and analysis ("**MD&A**") of ESSA Pharma Inc. (the "**Company**" or "**ESSA**") for the three and nine months ended June 30, 2017 and 2016 is dated as of August 11, 2017.

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 and nine months ended June 30, 2017 and 2016, the audited consolidated financial statements for the years ended September 30, 2016 and 2015, and the related notes thereto. The condensed consolidated interim 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 ("USD" or "\$" or "US\$"), unless otherwise indicated. Canadian dollars are presented as "C\$" or "CAD", where indicated.

This MD&A contains 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 "Cautionary Note Regarding Forward-Looking Statements", located at the end of this document. As a result of many factors, the Company's 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 Capital Market ("**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. The Company believes its 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. The Company's Canadian Clinical Trial Application ("**CTA**") submission to Health Canada was subsequently also accepted and the clinical trial continues to enroll patients in the United States and Canada. Through this Phase 1/2 clinical trial, the Company is exploring the safety, tolerability, maximum tolerated dose and pharmacokinetics of EPI-506, in addition to tumor response rates in asymptomatic or minimally symptomatic patients with metastatic CRPC 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 including radiographic responses.

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 have 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 either interfering with the production of androgen or 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, the Company believes 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. The Company intends to initially focus on patients who have failed abiraterone or enzalutamide therapies for the following reasons:

- CRPC treatment remains the prostate cancer market segment with a significant unmet therapeutic need and is therefore a potentially large market;
- the Company believes that the unique mechanism of action of its product candidate is well suited to treat patients who have failed androgen receptor ligand-binding domain focused therapies; and
- the Company expects the large number of patients with unmet therapeutic need in this area will facilitate timely enrollment in its 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. In pre-clinical studies, EPI-001 has been shown to shrink benign prostate tissue in mice, and both EPI-506 and EPI-002 have been demonstrated to inhibit prostate tumors in mice.

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. The Company is not currently aware of any success by other drug development companies in finding drugs that bind to this drug target. The nature of the highly specific binding of the EPI compounds to the NTD, and the biological consequences of that binding, have been defined in recent scientific studies.

The Company is currently conducting a Phase 1/2 clinical trial with the Phase 1 dose-escalation group, expected to comprise approximately 30 patients, being conducted at five sites in the United States and Canada. 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 as well as the presence of mutations in the DNA coding the androgen receptor. 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 clinical trial is successful, the Company expects FDA approval would be sought to commence a Phase 3 trial in a similar patient population.

In addition, the Company has recently initiated the development of a next generation series of EPI compounds. These compounds are the result of chemical modifications to the basic EPI structure designed to improve upon the characteristics of the first generation EPI-506. It is hoped the improved characteristics from further studies would include significantly enhanced potency, improved pharmaceutical characteristics including formulation, stability, ease of manufacture and potentially improved bioavailability.

The British Columbia Cancer Agency ("**BCCA**") and the University of British Columbia ("**UBC**") are joint owners of the intellectual property that constitutes the Company's primary asset(s). The Company has entered into a joint agreement with the BCCA and UBC which provides them with exclusive access to the issued patents and the patent applications to its EPI-series compounds, including both EPI-506 and next generation compounds.

## 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 prostate cancer, either as a single agent or in combination with other agents. The Company intends to accomplish those objectives while maximizing shareholder value. Specific components of the Company's strategy include:



### Advancing EPI-506 through clinical development and regulatory approval in CRPC patients

The Company is conducting 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. It is currently estimated that the Phase 1 clinical trial will proceed to completion as planned in the second half of calendar 2017. Once the Phase 1 clinical trial is complete, the Company plans to review the data, including safety, tolerability, evidence for efficacy and pharmacological and biomarker data. This information will inform the final size, design and timing of a Phase 2 clinical trial. The previous guidance for Phase 1 completion in the first half of calendar 2017 has been updated to reflect the longer than expected period to determine a Phase 2 dose, due to lower than predicted bioavailiability and the requirement for considerably higher doses than originally planned. Aggressive dose escalation, enabled by the fact that EPI-506 has been generally well-tolerated by patients, has enabled achievement of drug exposures in patients (as measured by the maximal concentration achieved after a dose ("**Cmax**") and the area under the curve of drug exposure ("**AUC**")). Preliminary data from the Phase 1 portion of the ongoing Phase 1/2 clinical trial, up to the 2,400 mg cohort, was summarized in a poster presentation at the June 2017 meeting of the American Society of Clinical Oncology ("**ASCO**"). Additional cohorts of patients are being enrolled in an effort achieve maximum exposure with acceptable tolerability.

# Developing EPI-506 as an essential component of a new standard of care for the treatment of pre-CRPC and expanding 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. Such studies would likely include EPI-506 in combination with anti-androgens; the Company is currently generating *in vitro* and *in vivo* data in collaboration with academic investigators in this regards.

#### 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 the Company's primary focus will remain the treatment of prostate cancer, the Company may explore such applications in the future.

#### Next Generation N-Terminal Domain Inhibitor Research Program

The Company is also investing effort in the identification of a next-generation androgen receptor N-terminal domain inhibitor. The purpose of the next-generation program is to identify drug candidates with improved potency and pharmacological properties compared to ESSA's first-generation compounds. Several candidate molecules have been screened which display 10-20 times higher potency than EPI-002 as measured in preclinical models of androgen receptor inhibition. ESSA intends to conduct additional preclinical studies to identify a possible lead candidate for further IND-enabling studies. If preclinical studies proceed as planned, the Company anticipates the nomination of a next-generation drug candidate could occur in calendar 2018.

#### Evaluating strategic collaborations to maximize value

The Company currently retains all commercial rights for its EPI-series drug portfolio. The Company intends to evaluate potential collaborations that could enhance the value of its prostate cancer program and allow it to leverage the expertise of strategic collaborators. The Company also intends to explore collaborations in order to develop applications of its 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 nine months ended June 30, 2017, the Company recorded a comprehensive loss of \$2,553,713 (2016 - \$9,240,783). As of June 30,

2017, the Company had cash resources of \$7,329,497 (September 30, 2016 - \$8,985,095) and working capital of \$4,578,909 (September 30, 2016 - \$6,389,257).

This corporate update highlights significant events and transactions for the nine months ended June 30, 2017 and for the subsequent period to the date of this report.

## **Research and Development Milestones**

### Progress in the Conduct of the Phase 1/2 Clinical 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. The goal of the Phase 1/2 clinical trial was 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. A summary of the status of the clinical trial was presented in a poster session at the June 2017 ASCO Annual Meeting. Clinical data was available for patients who had been treated with doses as high as 2,400 mg daily. The drug was generally well-tolerated, with the major side effects of a gastrointestinal nature. The 2,400 mg dose level was associated with AUCs at the lower end of the target efficacy zone as calculated from the preclinical animal models. Minor PSA declines of short duration were observed. The clinical trial continues to enroll patients in both the United States and Canada, towards its goal of greater exposure with acceptable tolerability. Patients have most recently been enrolled in two parallel cohorts, each receiving 3,600 mg per day administered as a single dose or split into two doses over the day.

As part of the clinical study, ESSA has been collecting 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 available on the US National Institutes of Health clinical trials website (see <u>https://clinicaltrials.gov</u>).

## **Corporate and Finance Highlights**

#### Debt Financing

On November 18, 2016, Silicon Valley Bank ("**SVB**") entered into a \$10,000,000 capital term loan facility agreement ("**SVB Term Loan**") with the Company. The Company has initially drawn down \$8,000,000 from the SVB Term Loan. There was a conditional option to receive an additional \$2,000,000 by April 28, 2017, subsequently amended to July 31, 2017, upon positive data for the Company's ongoing Phase 1 clinical trial of EPI-506 and receipt of the third and final tranche of the Cancer Prevention Research Institute of Texas ("**CPRIT**") grant of \$5,422,000 (the "**CPRIT Grant**"), which, as further described below, has been partially received. The Company is in communication with SVB to further extend the date beyond July 31, 2017 by which the additional \$2,000,000 can be drawn.

The SVB Term Loan bears an interest rate of Wall Street Journal Prime Rate ("**WSJ Prime Rate**") plus 3% per annum and will mature on September 1, 2020. The SVB Term Loan requires a final payment of 8.6% of the amount advanced ("**Final Payment**"), due upon the earlier of the maturity or termination of the SVB Term Loan. The Company is required to make interest only payments until December 31, 2017. The interest only payment period would be extended by six months if the second tranche of \$2,000,000 was drawn by the Company. The SVB Term Loan contains a voluntary prepayment option whereby the principal amount can be prepaid in whole, or in part, for a fixed fee if a prepayment is made on or before the second anniversary of the SVB Term Loan.

The SVB Term Loan is secured by a perfected first priority lien on all of the Company's assets, with a negative pledge on the Company's intellectual property. The SVB Term Loan is subject to standard events of default, including default in the event of a material adverse change. There are no financial covenants under the SVB Term Loan.

Upon funding of the respective tranches of the SVB Term Loan, the Company is required to grant to SVB common share purchase warrants. In connection with the initial \$8,000,000 draw, the Company granted an aggregate of 149,532 warrants, exercisable at a price of \$2.14 per share for a period of seven years until November 18, 2023.



## **CPRIT** Funding

During the nine months ended June 30, 2017, the Company received \$5,192,799 as part of the third and final tranche of the CPRIT Grant, totalling \$5,422,000. A final amount of \$229,201 remains outstanding, to be received by the Company upon final compliance reporting at the end of the grant period, which is designated as December 31, 2017.

#### Financing

Subsequent to June 30, 2017, on July 12, 2017, the Company announced a proposed overnight marketed public offering in Canada and a concurrent private placement in the United States. The Company received sufficient investor interest to advance the proposed transaction but did not obtain conditional approval by financial regulators due to levels of insider and institutional participation. While alternative transaction structures have been identified that may be pursued, additional data is currently being received from the higher-dose cohorts in the Phase 1 clinical trial of EPI-506. As a result, the Company intends to delay an offering until after such data can be announced.

### NASDAQ Deficiency

Subsequent to June 30, 2017, on July 21, 2017, the Company received notifications from the NASDAQ that it was not in compliance with two requirements for continued listing, being the maintenance of a minimum bid price of US\$1 and a minimum market value of US\$35,000,000, noncompliance constituting continued deficiency for a period of 30 consecutive business days.

The Company has been provided a grace period for 180 calendar days to regain compliance with these requirements.

### **DISCUSSION OF OPERATIONS**

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

#### **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 does 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 is currently conducting 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, expected to comprise approximately 30 patients, the clinical trial will evaluate the safety, tolerability, pharmacokinetics, and maximum-tolerated dose of EPI-506, in multiple-dose escalations. If the Phase 1 portion is successful, the Phase 2 portion (dose expansion) of the clinical trial will evaluate activity in three patient cohorts: post-enzalutamide CRPC, post-abiraterone CRPC, and both post-enzalutamide and post-abiraterone CRPC.

The Company licensed the EPI-family of drugs from UBC and the 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 that had been identified at the initiation of the program 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 its 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, as well as 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 used Southwest Research Institute in San Antonio, Texas for manufacturing initial clinical supply batches of EPI-506 under Current Good Manufacturing Practices ("**CGMP**"). Manufacturing for the ongoing Phase 1 clinical trial is being conducted by Sigma Aldrich Fine Chemicals, Madison, Wisconsin. Formulation and CGMP production of the final drug product for clinical trials is performed by Catalent Pharma Solutions, St. Petersburg, Florida.

In addition to EPI-506, the Company is working on the advancement of next generation compounds. A series of compounds have been identified which, while retaining the common mechanism of action to interfere with androgen receptor-mediated signaling, include improved pharmaceutical properties such as much enhanced potency, reduced susceptibility to metabolism and improved drug-like properties. Several of these compounds are currently being characterized in more detail with a goal of selecting a next generation development compound. The Company also continues to conduct preclinical combination studies.

#### **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, the Company received a "no objection letter" from the Therapeutic Products Directorate of Health Canada in response to the CTA for EPI-506 allowing the clinical trial to be conducted in Canada.

The Phase 1 portion of the clinical trial is expected to enroll approximately 30 patients with CRPC. Following singledose evaluation, patients receive once-daily oral dosing for 28 days to assess safety for dose escalation. Further, patients continue to receive the trial drug for 12 weeks or longer to assess efficacy. The endpoints of this part of the trial are to assess safety, tolerability, maximum tolerated dose and pharmacokinetics of EPI-506. Efficacy endpoints include PSA response and radiographic progression criteria. This Phase 1 portion of the clinical trial is being conducted at five sites in the United States and Canada. The Company hopes to establish a dose for the Phase 2 clinical trial in the second half of calendar 2017, depending on the enrollment rate and number of dose escalation steps, and clinical results. Depending on the results of the Phase 1 portion of the clinical trial, additional patient cohorts may be added to address relevant questions on patients' tumor response and molecular profile (e.g. AR splice variant status).

If the Phase 1 dose-escalation portion of the clinical trial is successful, the Phase 2 portion of the clinical trial is expected to focus on CRPC patients with progressive metastatic disease 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. If Phase 1 proceeds to completion in the second half of calendar 2017 as planned, depending on the enrollment rate, dose-escalation steps, and clinical result, the Company hopes to conduct the expanded Phase 2 portion of the clinical trial in the United States and Canada and hopes to complete the trial in the first half of calendar 2019.

On June 5, 2017, the Company announced that early data from the Phase 1 portion of the ongoing Phase 1/2 clinical trial of its product candidate, EPI-506, was featured in a presentation during the 2017 ASCO Annual Meeting held in Chicago. A principal investigator of the clinical trial presented a poster describing the current status of the trial entitled, "Efficacy, safety, tolerability and pharmacokinetics of EPI-506 (ralaniten acetate), a novel androgen receptor NTD inhibitor, in men with metastatic castration-resistant prostate cancer progressing after enzalutamide and/or abiraterone."

The preliminary data presented was from the Phase 1 portion of the ongoing Phase 1/2 clinical trial of EPI-506, up to the 2,400 mg cohort. The open-label, single-arm, dose-escalation study is currently evaluating the safety, pharmacokinetics, maximum tolerated dose and anti-tumor activity of EPI-506 in men with end-stage metastatic CRPC who have progressed after prior enzalutamide and/or abiraterone treatment, and may have received one prior line of chemotherapy. Twenty-one patients were available for analysis as of the May 12, 2017 ASCO data cut-off and each patient had received four or more prior therapies for prostate cancer at the time of study entry.

Drug exposures were considered below the target range in most patients, with only the last two dose cohorts achieving drug plasma that approached target concentrations. At the time the poster was prepared at May 12, 2017, four patients remain on study for an extended treatment duration, while seventeen patients discontinued treatment, primarily due to study progression and, it is believed, being dosed with low levels of drug in early cohorts.

The data indicated that EPI-506 was well-tolerated and demonstrated an acceptable safety profile in doses up to 2,400 mg. No treatment-related serious adverse events were reported. The most common adverse events ("**AE**") were diarrhea (8/21) and nausea (6/21), either Grade 1 or 2. Anemia was the only AE greater than or equal to Grade 3 observed in more than one patient (3/21) but was considered by investigators to be unrelated to EPI-506. Other AEs greater than or equal to Grade 3 considered potentially related to EPI-506 included a single case of elevated aspartate aminotransferase ("**AST**") reported as possibly related, and a single case of elevated amylase deemed probably related.

The previous guidance for Phase 1 completion in the first half of calendar 2017 and Phase 2 completion in the second half of calendar 2018 has been updated to reflect the longer period than expected to determine a Phase 2 dose. Additional cohorts of patients have been enrolled in an effort to reach drug exposures associated with efficacy in preclinical animal models. At the date of this MD&A, patients are currently being enrolled or treated in two parallel cohorts, one receiving two doses per day and the other cohort receiving one dose per day.

## Phase 3 Clinical Trial

In order to obtain regulatory approval, the Company expects that it will be required to carry out at least one Phase 3 clinical trial. At this time, the Company expects that the patients involved in the Phase 3 clinical trial will be similar to the population of CRPC patients that were enrolled in the Phase 1/2 clinical trial. However, the results of the Phase 1/2 clinical trial may suggest 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.

# SELECTED QUARTERLY FINANCIAL INFORMATION

ESSA was incorporated on January 6, 2009 and did not engage in any material financial or commercial activity until commencing operations in 2010. The Company has not earned revenues or declared dividends as of June 30, 2017. Effective January 1, 2016, the Company changed its functional currency from the Canadian dollar to the United States dollar and, in anticipation thereof, adopted the United States dollar as the presentation currency as at October 1, 2015. See "Changes in or Adoption of Accounting Policies – Change in Functional and Presentation Currency".

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

	For the Quarters Ended								
		June 30, 2017		March 31, 2017	Ι	December 31, 2016		September 30, 2016	
Total assets	\$	8,405,965	\$	13,738,990	\$	15,980,790	\$	10,402,562	
Long-term liabilities		7,105,830		15,931,442		13,029,510		7,309,467	
Research and development expense		2,920,181		2,548,761		(908,493)		3,951,799	
General and administration		1,302,314		1,363,493		1,369,819		1,236,873	
Comprehensive income (loss)	\$	3,592,404	\$	(7,610,579)	\$	1,464,462	\$	(4,236,768)	
Basic income (loss) per share		0.12		(0.26)		0.05		(0.15)	
Diluted income (loss) per share		0.12		(0.26)		0.05		(0.15)	

	For the Quarters Ended								
		June 30, 2016		March 31, 2016		December 31, 2015		September 30, 2015	
Total assets	\$	13,666,625	\$	17,470,959	\$	4,622,698	\$	7,539,773	
Long-term liabilities		8,350,043		9,217,777		588,408		993,099	
Research and development expense		3,362,948		2,544,517		3,200,937		(791,822)	
General and administration		1,305,780		1,874,597		1,226,868		2,177,188	
Comprehensive loss	\$	(3,865,757)	\$	(1,335,215)	\$	(4,039,811)	\$	(469,155)	
Basic income (loss) per share		(0.13)		(0.04)		(0.18)		0.02	
Diluted income (loss) per share		(0.13)		(0.04)		(0.18)		0.02	

The Company's quarterly results can vary depending on several factors, including the timing of CPRIT grant funding, fluctuations in the Company's derivative liabilities, and whether the Company has granted any stock options, none of which are predictable. CPRIT grant funding is taken proportionately into income against Research and Development expenses incurred to date, which in some cases may have been incurred in previous quarters. Fluctuations on derivative liabilities are discussed further in the *Derivative Liabilities* section below. The granting of stock options results in share-based payment charges, reflecting the vesting of such stock options. General operating costs other than the specific items noted above tend to be quite similar from period to period.

## Nine months ended June 30, 2017 and 2016

The Company recorded a comprehensive loss of \$2,553,713 for the nine months ended June 30, 2017 compared to a comprehensive loss of \$9,240,783 for the nine months ended June 30, 2016. During the current period, the Company recognized Research and Development expense of \$4,560,449 (2016 - \$9,108,402), net of the CPRIT grant funds recorded as recoveries of \$5,192,799 (2016 - \$nil). In addition, the Company recognized a gain of \$6,706,226 (2016 - \$5,533,529) with respect to the fair value of the Company's derivative liabilities, carried at fair value under the Black Scholes valuation methodology, resulting from the warrants ("**2016 Warrants**") issued in connection with a

private placement offering of units of the Company on January 14, 2016, for aggregate gross proceeds of approximately \$15,000,000 ("**January 2016 Financing**").

Other significant changes in comprehensive income (loss) are as follows:

#### Research and Development

- The overall net Research and Development ("**R&D**") expense for the nine months ended June 30, 2017 was \$4,560,449 compared to \$9,108,402 for the nine months ended June 30, 2016. The gross expense for the nine months ended June 30, 2017 was \$9,753,248 (2016 \$9,108,402) before recognition of qualifying CPRIT funds of \$5,192,799 (2016 \$nil). The increase in the gross expense from prior period reflects expanded clinical activity, including dosing of multiple cohorts and additional clinical sites, compared to earlier stages of enrolment in the clinical trial in the prior period.
- Manufacturing costs for the nine months ended June 30, 2017 of \$3,439,781 (2016 \$2,169,116) have increased compared to the comparative period in 2016, reflecting the increased drug supply required for the higher dosages, increased number of patients enrolled in later cohorts of the clinical trial, and additional formulation work, compared to earlier stages of enrolment in the clinical trial in the prior period.
- Clinical costs for the nine months ended June 30, 2017 of \$2,330,977 (2016 \$2,169,736) have increased compared to the comparative period in 2016 due to increased work performed by the clinical research organization while administering the Phase 1/2 clinical trial, which commenced in November 2015.
- Consulting fees have decreased to \$688,979 for the nine months ended June 30, 2017 (2016 \$883,951) compared to the comparative period in 2016. In the prior period, the Company recorded milestone bonuses payable to the Chief Scientific Officer ("**CSO**") and Chief Technical Officer ("**CTO**") on various publications and patent filings.
- Legal patents and license fees have decreased to \$587,255 for the nine months ended June 30, 2017 (2016 \$750,803) compared to the comparative period in 2016 due to the timing of filings in various jurisdictions. 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 on patents for the protection of new technologies, products and processes. The Company anticipates that there will be ongoing investment into patent applications.

	Three months ended			Three months ended	Nine months ended			Nine months ended		
	J	June 30, 2017		June 30, 2016 Jur		June 30, 2017		June 30, 2016		
Clinical	\$	503,316	\$	790,451	\$	2,330,977	\$	2,169,736		
Consulting		222,065		295,780		688,979		883,951		
Legal patents and license fees		246,860		306,170		587,255		750,803		
Manufacturing		1,028,318		685,118		3,439,781		2,169,116		
Other		23,198		98,164		194,099		276,928		
Pharmacology		80,588		456,921		318,062		710,882		
Program administration		94,965		99,419		282,304		192,883		
Royalties		-		-		48,863		46,228		
Salaries and benefits		656,241		522,750		1,631,849		1,517,057		
Share-based payments (Note 10*)		24,284		49,949		108,587		235,143		
Travel		40,346		58,226		122,492		155,675		
CPRIT grant claimed on eligible										
expenses (Note 16*)		_				(5,192,799)				
Total	\$	2,920,181	\$	3,362,948	\$	4,560,449	\$	9,108,402		

R&D expenses include the following major expenses, by nature, for the three and nine months ended June 30, 2017 and 2016:

\* See the Notes set out in the accompanying condensed consolidated interim financial statements for the three and nine months ended June 30, 2017.

Share-based payments expense of \$108,587 for the nine months ended June 30, 2017 (2016 - \$235,143) 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 administrative expenses for the nine months ended June 30, 2017 decreased to \$4,035,626 from \$4,407,245 in the comparative period in 2016. Significant components of the expense in the current period included:

- Director fees for the nine months ended June 30, 2017 of \$140,750 (2016 \$183,008); the Board of directors and various committees held fewer formal meetings during the current period, compared to the prior period, although regular, non-remunerated meetings have been held.
- Investor relations expense for the nine months ended June 30, 2017 of \$167,390 (2016 \$240,749); the Company has rationalized the number of investor relations consultants used, and targeted its spend on shareholder communications and news releases.
- Professional fees for legal and accounting services for the nine months ended June 30, 2017 of \$484,626 (2016 \$552,188) were incurred in conjunction with the corporate activities in fiscal 2017 to date; in the current period, the Company engaged in a United States R&D tax credit study, in comparison with the prior period, during which the Company incurred more costs in relation to regulatory filings. Consequently, regulatory fees and transfer agent costs have also decreased to \$46,718 (2016 \$128,258) due to decreased regulatory activity.
- Salaries and benefits expense for the nine months ended June 30, 2017 has increased to \$1,533,969 (2016 \$1,456,505) due to corporate staffing changes, such as the change in Chief Executive Officer (appointed January 2016), the addition of a Chief Operating Officer (appointed in August 2016), as disclosed under the heading "Related Party Transactions", and with respect to general administrative support staff. In the prior period, the Company incurred various termination costs in relation to the resignation of the former Chief Executive Officer.

	Three months			Three months		Nine months		Nine months
	ended		ended		ended		ended	
	J	une 30, 2017		June 30, 2016		June 30, 2017		June 30, 2016
Amortization	\$	11,536	\$	16,580	\$	34,609	\$	49,601
Consulting and subcontractor fees		22,634		26,668		65,503		59,689
Director fees		45,750		47,250		140,750		183,008
Insurance		104,819		103,570		312,880		331,837
Investor relations		47,924		61,498		167,390		240,749
Office, IT and communications		39,680		60,049		161,035		232,593
Professional fees		98,033		132,189		484,626		552,188
Regulatory fees and transfer agent		823		10,378		46,718		128,258
Rent		99,844		216,611		331,662		495,437
Salaries and benefits		676,848		394,957		1,533,969		1,456,505
Share-based payments (Note 10*)		101,341		189,393		592,090		547,721
Travel and entertainment		53,082		46,637		164,394		129,659
Total	\$	1,302,314	\$	1,305,780	\$	4,035,626	\$	4,407,245

General and administrative expenses include the following major expenses, by nature, for the three and nine months ended June 30, 2017 and 2016:

\* See the Notes set out in the accompanying condensed consolidated interim financial statements for the three and nine months ended June 30, 2017.

Share-based payments expense of \$592,090 for the nine months ended June 30, 2017 (2016 - \$547,721) relates to the value assigned to stock options granted to key management and non-R&D consultants of the Company. The expense is recognized in relation to the grant and vesting of these equity instruments as measured by the Black-Scholes pricing model.

## Derivative liabilities

At September 30, 2015, the Company recorded a derivative liability of \$993,099 on 257,018 United States dollardenominated broker warrants issued in connection with the offering by the Company of special warrants on January 16, 2015 for aggregate gross proceeds of approximately \$12,000,000 ("**2015 Special Warrant Financing**"). The Company recorded a gain of \$382,649 with respect to this derivative liability during the three months ended December 31, 2015. On January 1, 2016, as part of the Company's functional currency change from the Canadian dollar to the United States dollar, the Company de-recognized this derivative liability.

Concurrently on January 1, 2016, the Company recognized a derivative liability of \$82,743 on 25,000 Canadian dollardenominated broker warrants issued in connection with the offering by the Company of convertible debentures in July of 2014 for aggregate gross proceeds of approximately \$900,000. As these broker warrants are denominated in Canadian dollars and are exercisable into common shares of the Company which has a functional currency of United States dollars, the instrument now contains an embedded derivative liability. During the nine months ended June 30, 2017, the Company recorded the resulting change in fair value of \$40,815 (2016 - \$28,602) with respect to this derivative liability in the statement of loss and comprehensive loss.

The 2016 Warrants have increased the Company's exposure to fluctuations in the market price of the Company's common stock. Under a cashless exercise, the 2016 Warrants are exercisable for a variable number of common shares, resulting in an embedded derivative, for which the Company has recognized a derivative liability. These warrants are measured at fair value with changes recognized in the statement of loss and comprehensive loss at each reporting date. During the nine months ended June 30, 2017, the Company recorded the resulting change in fair value of \$6,665,411 (2016 - \$4,254,544) in the statement of loss and comprehensive loss.

Derivative warrant liabilities are discussed under the heading "*Critical Accounting Estimates*" and Note 8 of the accompanying condensed consolidated interim financial statements for the nine months ended June 30, 2017.

## Three months ended June 30, 2017 and 2016

The Company earned a comprehensive income of \$3,592,404 for the three months ended June 30, 2017 compared to a comprehensive loss of \$3,865,757 for the three months ended June 30, 2016.

The detailed changes for the research and development and general and administrative expenses for the three months ended June 30, 2017 and 2016 are included in the tables above. The Company has continued and expanded its clinical studies and has therefore increased investment in research and development costs, including manufacturing costs of \$1,028,328 (2016 - \$685,118).

General and administrative expenses of \$1,302,314 (2016 - \$1,305,780) have decreased over the prior period due primarily to similar decreases in the nine month periods ended June 30, 2017 and 2016.

In addition, the Company recognized a gain of \$\$,192,368 (2016 – \$867,734) with respect to the fair value of the Company's derivative liabilities, carried at fair value under the Black Scholes valuation methodology, resulting from the 2016 Warrants issued in connection with the January 2016 Financing.

## **USE OF PROCEEDS**

During the nine-month period ended June 30, 2017, the Company received total net proceeds of \$7,779,102 from the SVB debt financing.



During the year ended September 30, 2016, the Company received total net proceeds of \$18,919,803 from the following financings:

- in January 2016, the Company received net proceeds of \$13,982,604 in relation to the January 2016 Financing; and
- in March 2016, the Company received net proceeds of \$4,937,201 in relation to the private placement offering of common shares of the Company on March 21, 2016 ("**March 2016 Financing**").

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 offering by the Company of special warrants; and
- 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 intended to use the proceeds from the above financings, based on its disclosure, against how the Company actually used the proceeds following the respective 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	The proceeds have been used as intended to further the development of the EPI-506 Phase 1/2 clinical trial program while meeting administrative requirements.
1/2 clinical program through Phase 1.	During the nine months ended June 30, 2017, the Company incurred \$9,753,248 in gross R&D costs in relation to the development of the EPI-506 Phase 1/2 clinical trial program. An additional \$4,035,626 has been incurred for general and administrative costs in support of the Company's research and development activities.
	During the year ended September 30, 2016, the Company incurred \$13,060,201 in R&D costs, net of recoveries, in relation to the development of the EPI-506 Phase 1/2 clinical trial program. An additional \$5,644,118 has been incurred for general and administrative costs in support of the Company's research and development activities.
	As at June 30, 2017, the Company has not yet fully expended the funds raised in these financings towards the completion of the Phase 1/2 clinical trial program.

# LIQUIDITY AND CAPITAL RESOURCES

Operational activities during the nine months ended June 30, 2017 were financed mainly by proceeds from equity financings completed in July 2014, October 2014, January 2015, January 2016, and March 2016, the SVB Term Loan, and the CPRIT Grant. At June 30, 2017, the Company had available cash reserves of \$7,329,497 (September 30, 2016 - \$8,985,095) and \$13,861 (September 30, 2016 - \$15,882) in accounts receivable related primarily GST input tax credits, to settle current liabilities of \$3,478,312 (September 30, 2016 - 3,629,952).

Cash used in operating activities for the nine months ended June 30, 2017 was \$14,337,606 (2016 - \$11,907,503). Working capital items used cash of \$1,172,757 (2016 - \$897,755 cash provided).

Cash used in investing activities for the nine months ended June 30, 2017 decreased to \$nil (2016 - \$9,983) as the Company invested in equipment in the ongoing establishment of its Houston office in the prior period. Cash generated by financing activities for the nine months ended June 30, 2017 was \$12,685,340 (2016 - \$22,744,099),

including \$5,192,799 received from the CPRIT Grant, \$8,000,000 gross proceeds received from the SVB debt financing, and \$2,939 received from the exercise of stock options, offset by \$220,898 cash used in related transaction costs and \$289,500 in interest paid. In the nine months ended June 30, 2016, the Company received the second tranche of CPRIT financing of \$3,876,667, received gross proceeds from two private placement financings of \$19,999,992, received proceeds on options exercised of \$36,465, received proceeds on warrants exercised of \$1,194, and incurred \$1,080,219 cash in share issuance costs.

As described above, the Company completed the January 2016 Financing and March 2016 Financing during the year ended September 30, 2016, for aggregate gross proceeds of approximately \$20,000,000. In November 2016, the Company also received \$8,000,000 as the initial draw down on the SVB Term Loan, with a conditional option for an additional \$2,000,000 by April 28, 2017, subsequently amended to July 31, 2017. In January 2017 and March 2017, the Company received \$3,992,799 and \$1,200,000, respectively, as portions of the third and final tranche of CPRIT funding of \$5,422,000. The Company will need to raise funds from additional sources in order to execute its planned expenditures through the fiscal 2017 year.

The Company does not currently generate revenue. Future cash requirements may vary materially from those expected due to a number of factors, including the costs associated with Phase 1/2 clinical trials in 2017-2018 and to take advantage of strategic opportunities. Longer dose escalation and additional cohorts of patients in Phase 1 of the clinical trial needed to determine a Phase 2 dose could require drug manufacturing costs to be incurred earlier than contemplated, and could prolong operating expenditures required to complete Phase 1. As a result, it will be necessary for the Company 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 the Company will successfully raise funds to continue the development and commercialization of EPI-506 and its operational activities (see "*Risk Factors*").

#### CONTRACTUAL OBLIGATIONS

Contractual obligations		2017		2018		2019		2020		2021		After 5 years
Minimum annual royalty per License Agreement (CAD) <sup>(1)</sup>	\$	-	\$	85,000	\$	85,000	\$	85,000	\$	85,000	\$	850,000
Lease on Vancouver office space (CAD)		10,238		40,953		40,953		40,953		40,953		
Total (in CAD) Total (in USD) <sup>(2)</sup>	\$ \$	10,238 7,890	\$ \$	125,953 97,059	\$ \$	125,953 97,059	\$ \$	125,953 97,059	\$ \$		\$ \$	850,000 686,563
SVB loan payments (USD) Lease on US office spaces (USD)	\$ <u>\$</u>	144,222 42,134	\$ <u>\$</u>	2,558,103 <u>170,485</u>	\$ 3 <u>\$</u>	3,217,471 175,166	\$ : <u>\$</u>	3,905,471 <u>44,474</u>	\$ <u>\$</u>	-	\$ <u>\$</u>	-
Total (USD)	\$	194,246	\$	2,825,647	\$ 3	3,489,696	\$ -	4,047,004	\$	97,059	\$	686,563

As of June 30, 2017, and in the normal course of business, the Company has the following obligations to make future payments, representing contracts and other commitments that are known and committed.

Notes:

- (1) 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 "License Agreement"). A copy of the License Agreement is available as Exhibit 4.2 to Amendment No. 1 to the Company's Form 20-F registration statement filed on June 11, 2015 (File No. 001-37410) on the SEC's Electronic Data Gathering and Retrieval System, or "EDGAR", at www.sec.gov. The Company must pay a minimum annual royalty of C\$85,000 for the 2017 calendar year and for each year thereafter. Additional milestone payments of C\$50,000 and C\$900,000, which have been excluded from the above table, are due upon the enrolment of the first patient in Phase 2 and Phase 3 of the clinical trial, respectively, which are expected to occur in 2017 and 2018, respectively.
- <sup>(2)</sup> Translated at the indicative exchange rate of the Bank of Canada of 0.7706 as at June 30, 2017.

## **OFF-BALANCE SHEET ARRANGEMENTS & PROPOSED TRANSACTIONS**

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

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

## **RELATED PARTY TRANSACTIONS**

Compensation accrued and paid to key management personnel for the nine months ended June 30, 2017 and 2016 are as follows:

	2017	2016
Salaries, consulting fees, and director fees Share-based payments <sup>(1)</sup>	\$ 1,623,895 634,149	\$ 1,706,782 648,711
Total compensation	\$ 2,258,044	\$ 2,355,493

Note:

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

Key management personnel include: Dr. David R. Parkinson, Chief Executive Officer ("**CEO**"); Robert Rieder, former CEO; David Wood, Chief Financial Officer ("**CFO**"); Peter Virsik, Executive Vice-President and Chief Operating Officer ("**COO**"); Dr. Frank Perabo, Chief Medical Officer ("**CMO**"); Paul Cossum, former Executive Vice-President of Research and Development ("**EVP R&D**"); Dr. Marianne Sadar, Chief Scientific Officer; Dr. Raymond Andersen, Chief Technology Officer; Richard Glickman, Director and Chairman of the Board; Gary Sollis, Director; Franklin Berger, Director; and Scott Requadt, Director.

During the nine months ended June 30, 2017, the Company granted nil (2016 - 600,000) options to key management personnel. The vesting of options granted to key management personnel in prior periods was recorded as share-based payments expense in the statement of income and comprehensive income at a value of \$634,149 (2016 - \$648,711).

The balance of the share-based payments expense included in related party compensation in the nine months ended June 30, 2017 relates to the vesting of stock options granted in prior periods.

Included in accounts payable and accrued liabilities at June 30, 2017 is \$131,519 (September 30, 2016 – \$276,399) due to related parties with respect to key management personnel compensation 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 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. Dr. 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. Virsik, COO, is entitled to a payment of six months of base salary upon termination without cause, increasing to one year following one year of employment. This amount increases to 18 months of salary if termination without cause occurs within 18 months after a change of control event. Stock options held by the CEO, CFO, CMO, EVP R&D, and COO 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 for the three and nine months ended June 30, 2017 are detailed in Notes 2 and 3 of the Company's annual consolidated financial statements for the years ended September 30, 2016 and 2015:

## **Change in Functional and Presentation Currency**

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 January 2016 Financing 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 became the United States dollar effective January 1, 2016.

The Company adopted the United States dollar as the presentation currency for the consolidated entity as at October 1, 2015. For comparative reporting purposes, historical financial statements were translated into the United States dollar 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.

All financial information presented in this MD&A 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 carries 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 condensed consolidated interim financial instruments and financial statements has not yet been determined.

## IFRS 15 Revenue from Contracts with Customers

IFRS 15 is a new standard to establish principles for reporting the nature, amount, timing, and uncertainty of revenue and cash flows arising from an entity's contracts with customers. It provides a single model in order to depict the transfer of promised goods or services to customers. IFRS 15 supersedes IAS 11, Construction Contracts, IAS 18, Revenue, IFRIC 13, Customer Loyalty Programs, IFRIC 15, Agreements for the Construction of Real Estate, IFRIC 18, Transfers of Assets from Customers, and SIC-31, Revenue – Barter Transactions involving Advertising Service. IFRS 15 is effective for annual periods beginning on or after January 1, 2018. The impact of IFRS 15 on the Company's financial instruments and financial statements has not yet been determined.

## IFRS 16 Leases

IFRS 16 is a new standard that sets out the principles for recognition, measurement, presentation, and disclosure of leases including guidance for both parties to a contract, the lessee and the lessor. The new standard eliminates the classification of leases as either operating or finance leases as is required by IAS 17 and instead introduces a single lessee accounting model. IFRS 16 is effective for annual periods beginning on or after January 1, 2019. The impact of IFRS 16 on the Company's leases and financial statements 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 for the three and nine months ended June 30, 2017 (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. The Company makes reference to prices quoted on the TSX and NASDAQ. 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 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, expected term and liquidity discounts as detailed in Note 8 of the accompanying condensed consolidated interim financial statements. On January 1, 2016, as part of the Company's functional currency change from the Canadian dollar to the United States dollar, the Company de-recognized a derivative liability on United States dollar-denominated warrants and recognized a new liability on Canadian dollar-denominated warrants; see discussion under the heading "Selected Annual Financial Information - Derivative Liabilities."

## 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. During the period ended June 30, 2017, the Company recognized a gain on derivative liability of 6,706,226 (2016 – 5,533,529) through profit or loss.

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 to refundable GST 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 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 June 30, 2017, the Company had working capital of \$4,579,624. During the year ended September 30, 2016, the Company completed financings totaling approximately \$20,000,000 as described above. During the nine month period ended June 30, 2017, the Company entered into the SVB Term Loan for \$10,000,000, pursuant to which the Company has initially drawn down \$8,000,000. In January 2017 and March 2017, the Company received \$3,992,799 and \$1,200,000, respectively, as portions of the third and final tranche of CPRIT funding of \$5,422,000. All of the Company's current financial liabilities have contractual maturities of 30 days or are due on demand and are subject to normal trade terms. The Company does not generate revenue and will be reliant on equity or debt financing and proceeds from the CPRIT Grant to fund operations and repay debt obligations. Equity and debt financings are dependent on market conditions and may not be available on favorable terms. The CPRIT Grant is dependent on the Company completing all the contractual obligations thereunder (see accompanying 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 rates.

(a) Interest rate risk

As at June 30, 2017, the Company has cash balances which are interest bearing. Interest income is not significant to the Company's projected operational budget and related interest rate fluctuations are not significant to the Company's risk assessment.

The Company's SVB Term Loan is interest-bearing debt at a variable rate. A 10% change in the WSJ Prime Rate would result in an increase of \$32,640 or decrease of \$3,037 in the net loss realized for the period.

(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 financings completed in United States dollars, the United States dollar-denominated CPRIT Grant (see Note 16 of the accompanying condensed consolidated interim financial statements) and movement of operations to Houston pursuant to the terms of the CPRIT Grant. Accordingly, the Company adopted the United States dollar as its functional currency from the Canadian dollar as of January 1, 2016, so that the Company's foreign currency risk exposure now relates to net monetary assets denominated in Canadian dollars. A 10% change in the foreign exchange rate between the Canadian and United States dollar would result in a fluctuation of \$45,953 in the net loss realized for the period. 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 regarding the Company can be found on SEDAR at www.sedar.com, the website of the SEC at www.sec.gov and the Company's website at www.essapharma.com. The Company's Annual Report on Form 20-F for the fiscal year ended September 30, 2016 also provides additional information on the Company, and can be accessed through SEDAR at www.sedar.com, or the website of the SEC at www.sec.gov.

## **OUTSTANDING SHARE CAPITAL**

The following table sets out the equity instruments of the Company outstanding as of the date of this MD&A:

Equity instruments:	
Common shares	29,101,889
Stock options	3,871,519
Warrants	6,992,710

### **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 posted on SEDAR at www.sedar.com and the SEC's EDGAR website at www.sec.gov, 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, and the following additional risk factor, 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.

# ESSA may not be able to generate sufficient cash to service its indebtedness, which currently consists of its capital term loan facility with Silicon Valley Bank.

On November 18, 2016, the Company entered into a capital term loan facility agreement with SVB, providing for the SVB Term Loan in the total amount of \$10,000,000. The Company has initially drawn down \$8,000,000 of the SVB Term Loan, and has a conditional option to draw down an additional \$2,000,000 by July 31, 2017 upon (i) positive data for its ongoing Phase 1 clinical trial of EPI-506 and (ii) receipt of the third and final tranche of the CPRIT Grant of \$5,422,000. The SVB Term Loan bears an interest rate of WSJ Prime Rate plus 3% per annum and will mature on September 1, 2020. The SVB Term Loan requires a final payment of 8.6% of the amount advanced, due upon the earlier of the maturity or termination of the SVB Term Loan. The Company is required to make interest only payments until December 31, 2017. The interest only payment period would have been extended by six months if the second tranche of \$2,000,000 was drawn. The SVB Term Loan is secured by perfected first priority lien on all of the Company's assets, with a negative pledge on intellectual property. The SVB Term Loan does not contain any financial covenants. As at the date of this MD&A, the Company is in communication with SVB to extend the deadline to draw the additional \$2,000,000 beyond July 31, 2017.

ESSA's ability to make scheduled payments or to refinance its debt obligations depends on numerous factors including, but not limited to, the amount of its cash reserves, capital requirements and its ability to raise additional capital. ESSA may be unable to maintain a level of cash reserves or cash flows sufficient to permit it to pay the principal, premium, if any, and interest on its existing or future indebtedness. If the Company's cash flows and capital resources are insufficient to fund its debt obligations, the Company may be required to seek additional capital, restructure or refinance its indebtedness, or delay or abandon its business expansion, R&D projects or other capital expenditures, which could have a material adverse effect on ESSA's business, financial condition, prospects or results of operations. There is no assurance that ESSA would be able to take any of such actions, or that such actions would permit the Company to meet its scheduled debt service obligations. In addition, since the Company is in the clinical development stage, and does not currently generate revenue, it expects to finance future cash needs through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangement. However, additional capital may not be available on reasonable terms, if at all. Even if the Company is able to commercialize a product candidate, there can be no assurance that the Company will generate sufficient revenues or cash flow to service its debt obligations.

Further, in the event of the Company's breach of the agreement with SVB providing for the SVB Term Loan, the Company may not be allowed to draw additional amounts under the agreement, may be required to repay any outstanding amounts earlier than anticipated and the lenders may foreclose on their security interest in the Company's assets.



SVB may also declare the Company to be in breach of the SVB Term Loan agreement in the event of a "Material Adverse Change", which has been defined to include a material impairment in the Company's assets acting as collateral under the SVB Term Loan, a material adverse change in the business, operations, or condition (financial or otherwise) of the Company, or a material impairment of the prospect of repayment of any portion of its debt obligations. There can be no guarantee that the Company will not experience a "Material Adverse Change".

If any of these risks materialize into actual events or circumstances or other possible additional risks and uncertainties of which the directors of the Company 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. The Company's 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 "*Cautionary Note Regarding Forward-Looking Statements.*"

# DISCLOSURE CONTROLS AND PROCEDURES AND 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 condensed consolidated interim 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 laws, as at September 30, 2016. 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, interim 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. As at September 30, 2016, the Company's certifying officers conducted or caused to be conducted under their supervision an evaluation of the design and operating effectiveness of the Company's internal control over financial reporting, as required under Canadian securities laws. Based on such evaluation, the Company's certifying officers concluded that the Company's internal control over financial reporting was effective.

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. The Company's Board has determined that Mr. Berger 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 Internal Control – Integrated Framework (2013).



The Company did not have any significant changes to its ICFR systems in the period from October 1, 2016 to June 30, 2017 that materially affected, or are reasonably likely to materially affect the Company's ICFR.

## **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.

# CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This MD&A contains forward-looking statements or forward-looking information within the meaning of the United States 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", "hopes" or their negatives or other comparable words. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements to be statements. Examples of such forward looking statements include, but are not limited to statements related to:

- the initiation, timing, cost, location, progress and success of, strategy and plans with respect to, ESSA's research and development programs (including research programs with regards to next-generation drug candidates and compounds), pre-clinical studies and clinical trials;
- the Company's ability to advance its product candidate through, and successfully complete, clinical trials;
- the Company's ability to achieve profitability;
- the Company's ability to obtain funding for operations, including research funding, and the timing of potential sources of such funding;
- the Company's use of proceeds from funding and financings;
- the Company's ability to recruit sufficient numbers of patients for future clinical trials;
- the implementation of the Company's business model and strategic plans, including strategic plans with respect to patent applications and collaborations;
- the Company's ability to develop and commercialize product candidates;
- the Company's commercialization, marketing and manufacturing capabilities and strategy;
- 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 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 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 the Company's 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:

- its ability to obtain positive results of clinical trials;
- its ability to obtain required regulatory approvals;
- its 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;
- its ability to attract and retain skilled staff;
- market competition;
- the products and technology offered by the Company's competitors;
- its ability to protect patents and proprietary rights; and
- its ability to repay debt.

If one or more of these risks or uncertainties or a risk that is not currently known to the Company, materialize, or if its 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 the Company's views as of the date of this document. While the Company may elect to update these forward-looking statements in the future, the Company has no current intention to do so except as to the extent required by applicable securities law. Investors are cautioned that forward-looking statements are not guarantees of future performance and are inherently uncertain. Accordingly, investors are cautioned not to put undue reliance on forward-looking statements. The Company advises you that these cautionary remarks expressly qualify in their entirely all forward-looking statements attributable to the Company or persons acting on its behalf.