

# FORM 51-102F1 MANAGEMENT DISCUSSION AND ANALYSIS FOR THE SIX MONTHS ENDED MARCH 31, 2015 AND 2014

## **ESSA Pharma Inc.**

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## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FOR SIX MONTHS ENDED MARCH 31, 2015 AND 2014

This management discussion and analysis ("MD&A") of ESSA Pharma Inc. (the "Company" or "ESSA") for the six months ended March 31, 2015 and 2014 is as of May 22, 2015.

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 interim consolidated financial statements and notes thereto for the six months ended March 31, 2015 and 2014 as well as the audited consolidated financial statements for the year ended September 30, 2014, nine months ended September 30, 2013 and year ended December 31, 2012, and the related notes thereto. The consolidated financial statements are prepared in accordance with International Financial Reporting Standards ("IFRS").

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 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 trades on the TSX Venture Exchange ("TSXV") under the symbol "EPI".

## OVERVIEW OF THE COMPANY

ESSA is a development-stage pharmaceutical company focused on the development of small molecule drugs for the treatment of castrate-resistant prostate cancer ("CRPC"). The Company is developing drugs which selectively block the amino terminus domain ("NTD") of the androgen receptor ("AR"), potentially overcoming the known AR-dependent mechanisms of CRPC and providing CRPC patients with the potential for increased progression-free and overall survival.

In 1999, Dr. Marianne Sadar, a Distinguished Scientist at the British Columbia Cancer Agency (the "BC Cancer Agency") elucidated a unique drug target on the AR: the NTD. In 2003, Dr. Sadar and Dr. Raymond Andersen, a Professor at the University of British Columbia ("UBC") known for his natural product libraries and medicinal chemistry experience and expertise, began a collaboration focused on discovery of small-molecule inhibitors of the AR NTD. By mid-2008, they together discovered a family of compounds that selectively inhibit the NTD target on the AR and demonstrated the efficacy of those molecules in recognized laboratory models of prostate cancer. These compounds are potential drugs for treatment of CRPC.

Drs. Sadar and Andersen incorporated ESSA in January 2009 under the laws of British Columbia, Canada. In 2010, Robert Rieder and Dr. Richard Glickman, both CEOs of NASDAQ-traded biopharmaceutical companies, completed the founding team at ESSA. Mr. Rieder was appointed CEO of the Company and Dr. Glickman was appointed Chairman of the board of directors of the Company (the "Board").

ESSA began substantive operations in 2010 with the licensing of intellectual property related to the research of Drs. Sadar and Andersen from the BC Cancer Agency and UBC (the "**Licensed IP**") pursuant to a licensing agreement (the "**License Agreement**") between the Company, UBC and the BC Cancer Agency. The Company began to invest in research activities in 2011 which were necessary for the selection of a variant of ESSA's lead compound, EPI-001, that would be suitable to take forward into clinical development and to the Investigational New Drug ("**IND**") phase.

ESSA has continued its efforts to identify and test a more-potent variant of our lead compound. This led to testing of a compound named EPI-506, a pro-drug of EPI-002. In vitro testing of EPI-506 showed that it was approximately two-fold more potent than EPI-002. In vivo experiments in established models of CRPC suggested an even higher increase in potency of EPI-506 over EPI-002 by oral dosing. In early 2014, as a result of data from various studies that showed that EPI-506 was well tolerated in both mice and canines, the Company decided to commence a work program focused on receiving regulatory approval to commence clinical testing of EPI-506 in CPRC patients.



## **Overview of Recurrent Prostate Cancer**

Adenocarcinoma of the prostate represents approximately 95% of all prostate cancers and is dependent on androgen for survival and proliferation. This dependency of prostate cells on androgen forms the basis for androgen deprivation therapy (surgical or pharmaceutical castration) as the gold standard for systemic therapy for recurrent prostate cancer. In adult males, the testes produce the majority of androgens with minor amounts contributed from the adrenal glands and other tissues.

The AR is a ligand-activated transcription factor that mediates the biological effects of androgen. Without a functional full-length AR, the addition of androgen has no biological effects. The AR has distinct functional domains that include a C-terminal ligand-binding domain, DNA-binding domain, the N-terminal domain and a hinge region. All current FDA-approved therapies that target the AR are directly or indirectly focused on its C-terminal ligand-binding domain. Androgens such as testosterone and dihydrotestosterone bind to the ligand-binding domain of the AR which result in changes in conformation and post-translational modifications, nuclear translocation and ultimately binding to the regulatory regions of DNA of target genes called androgen response elements. Thus, AR regulates the transcription of genes involved in prostate tissue growth and survival.

#### **Castration-Resistant Prostate Cancer**

Approximately one-third of all prostate cancer patients who have been treated for local disease will subsequently have biochemical failure: rising serum levels of prostate-specific antigen ("PSA") which is an indication of recurrent disease. Patients with advanced disease tend to go on to androgen ablation therapy (surgical or pharmacological castration). Pharmacological castration using analogues of luteinizing hormone releasing hormone ("LHRH") or surgical castration are effective and comprise the current gold standard of treatment.

Drugs which competitively bind in the ligand-binding pocket of the ligand-binding domain of the AR prevent both the binding of androgen and interaction of the AR with co-regulatory proteins, and therefore also prevent AR transcription activity. Such drugs (called "Antiandrogens") are effective in inhibiting the growth of prostate cancer tumors. Current antiandrogens used for prostate cancer include bicalutamide, flutamide, nilutamide, cyproterone acetate, enzalutamide, and the investigational drugs ARN-509, TOK-001 (Galeterone) and ODM-201.

A complete discussion of castration-resistant prostate cancer is detailed in the Company's final long form prospectus dated December 5, 2014 filed at www.sedar.com.

## **ESSA's Products and Programs**

ESSA's EPI-Series Drugs

ESSA has licensed a family of drugs which have been shown to prevent AR transcriptional activity by a variety of mechanisms. ESSA's 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 has been done with EPI-002. The clinical candidate compound that is being developed (EPI-506) is a pro-drug of EPI-002. That means that EPI-506 metabolizes to EPI-002 once it is dosed orally. Together, EPI-001, EPI-002, EPI-506, and other active analogues of EPI-001 are referred to as the "EPI-series drugs".

#### **Development Program**

Cancer therapeutics can typically be developed using relatively short-term pre-clinical experiments, shorter clinical studies with fewer patients than non-oncological indications, and less resources, and less time compared to experimental therapies in many other therapeutic areas. ESSA intends to initially focus its development efforts on obtaining regulatory approval to treat CRPC patients.



## **Pre-clinical Development**

ESSA is focused on developing EPI-506 as its clinical development candidate. EPI-506 has been shown by ESSA to be more potent than most other EPI-series drugs by oral dosing and has the appropriate pharmacological properties to be developed. *In vivo* efficacy of EPI compounds has been demonstrated using a variety of human prostate cancer xenograft models.

The Company's initial work to support the CRPC indication has consisted of efficacy studies, bioanalytical development and pharmacokinetic studies in four species, as well as non-GLP toxicology studies in four species. To date, EPI-506 appears to be well-tolerated after daily oral administration. Formulation development work and bioanalytical development for pre-clinical studies have been conducted at BRI Biopharmaceutical Research Inc. 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 studies in rodents and non-rodents, dose-ranging studies that lead to 28-day GLP toxicology studies. In addition, *in vitro* mutagenesis assay(s) and hERG potassium channel testing are expected to be performed. Consistent with the development of other oncology therapies at this early stage, no reproductive toxicology studies are required, given the patient population to be treated. The toxicology studies are expected to incorporate toxicokinetics in order to correlate potential toxic effects with EPI-506 exposure. *in vitro* metabolism data using hepatocytes have been conducted. A radiolabeled form of EPI-506 is being used for further metabolism and distribution work *in vivo*.

The Company expects to address FDA-mandated Chemistry, Manufacturing and Control ("CMC") requirements by using a combination of in-house expertise and contractual arrangements. The Company has engaged Naeja Pharmaceutical Inc. ("Naeja") in Edmonton, Alberta to produce non-Good Manufacturing Practice ("GMP") material for its IND-enabling toxicology studies. Chemical processes developed at Naeja, and in the laboratory of ESSA co-founder Dr. Raymond Andersen at UBC, are being transferred to the Southwest Research Institute in San Antonio, Texas for GMP manufacture of EPI-506 for early clinical trials. Formulation of the final drug product for clinical trials is expected to be performed by a fill/finish company experienced in gel capsule development.

## CORPORATE UPDATE AND OVERALL PERFORMANCE

ESSA is a development stage company and does not currently generate revenue. During the six months ended March 31, 2015, the Company incurred a comprehensive loss of \$6,158,938 (2014 - \$398,809). As at March 31, 2015, the Company had cash resources of \$13,238,618 (September 30, 2014 - \$4,146,938) and working capital of \$11,933,521 (September 30, 2014 - \$3,630,874).

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

### Research and Development Milestones

Filing of Investigational New Drug Application for EPI-506

On March 31, 2015, the Company filed with the Food and Drug Administration ("**FDA**" or the "**Agency**") in the US an Investigational New Drug ("**IND**") application related to the Company's proposed clinical trial of EPI-506 in prostate cancer patients. Approval of the IND application is required in order for ESSA to commence human testing of EPI-506 in the US.

The IND application is a complete description of the chemistry, non-clinical pharmacodynamics and pharmacokinetics, animal toxicology, manufacturing, and other relevant information related to EPI-506 as a potential treatment for patients with advanced prostate cancer.

On April 30, 2015, subsequent to filing the application, the Company received notification from the FDA in the US that the Company's IND application has been placed on clinical hold pending receipt by the FDA of additional chemistry and pharmaceutical data related to the stability of the drug substance and drug product and a Certificate of Analysis on drug product.



The Company will submit the required data as soon as available for the Agency's review. The delay caused by this circumstance is not expected to be significant, because the availability of those data had already been built in to the timelines prior to the IND submission.

If the FDA review process results in approval to commence human testing of EPI-506, ESSA expects to recruit the first patient into its proposed Phase 1/2 clinical trial of EPI-506 in the fourth quarter of fiscal 2015. The Company also intends to seek approval from the Health Protection Branch ("**HPB**") in Canada to include Canadian sites in the Phase 1/2 study, and plans to file a Clinical Trial Authorization application ("**CTA**") with the HPB in order to obtain that approval.

In its upcoming 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 or both.

## Significant Events and Transactions

Appointment of Mr. Franklin Berger

Mr. Franklin Berger has been appointed to the board of directors of ESSA as an independent director. A resident of New York, Mr. Berger's background includes strategic advisory work with top-tier venture capital firms and international biopharmaceutical companies.

Mr. Berger is an investor in the Company and spent 12 years in sell-side equity research, most recently as Managing Director, U.S. Equity Research at J. P. Morgan Securities, Inc. ("JPM") from May 1998 to March 2003. During his five years at JPM, he was involved with the issuance of over \$12 billion in biotechnology company equity or equity-linked securities. The majority of these transactions were book-run and lead-managed by the JPM biotech team. He was associated with several notable financings in the biotechnology sector including the Genentech Inc. initial public offering, the first large Celgene Corporation financings as well as financings of several large-cap biotechnology companies in their rapid growth phase. His team covered 26 publicly-traded biotechnology companies. Mr. Berger began his career as a sell-side analyst at Josephthal & Co. in 1991, subsequently moving to Salomon Smith Barney in 1997 serving as Director, Equity Research and Senior Biotechnology Analyst.

Mr. Berger currently serves on the board of directors of three other public biotechnology companies: Five Prime Therapeutics, Inc., Immune Design Corp. and Bellus Health, Inc. Previous public company board service included 11 years with Seattle Genetics, Inc., seven years with VaxGen, Inc., and seven years with Aurinia Pharmaceuticals Inc. (previously Isotechnika Pharma Inc.), based in Canada. He also serves or has served on private biotech company boards of directors including iTherX Pharma, Inc., Caprion Proteomics Inc. (sold in July 2012), and ViroChem Pharma, Inc. which was purchased by Vertex Pharmaceuticals, Inc. for \$400 million in 2009. Mr. Berger has led multiple M&A analyses resulting in greater than \$1 billion in transaction value.

## October 2014 Special Warrant Financing

In October 2014, the Company issued 679,640 special warrants (the "2014 Special Warrant Financing") at a price of \$2.00 per 2014 Special Warrant for gross proceeds of \$1,359,280. Each 2014 Special Warrant was deemed exercised for, without payment of any additional consideration, one Class A Preferred share in the capital of the Company (each a "Preferred Share") on December 15, 2014, being the fifth business day after the date on which a receipt for the final prospectus of the Company qualifying the distribution of the Preferred Shares issuable on exercise of the 2014 Special Warrants had been issued. On January 27, 2015, the Preferred Shares were converted into common shares of the Company (See *Listing on the TSX Venture Exchange*).



In connection with the 2014 Special Warrant Financing, the Company paid agent and finders' fees at 7% of proceeds raised by those parties being \$40,361, a cash fee to the Agent of \$30,000 plus applicable taxes and estimated other expenses of \$70,594. In addition, the Agent, and associated selling group, were issued 22,675 special broker warrants (the "**Special Broker Warrants**"), representing 7% of the number of 2014 Special Warrants sold by the Agent and the finders were issued 2,680 Special Broker Warrants, representing 7% of the number of 2014 Special Warrants sold to purchasers introduced to the Company by such finders. Each Special Broker Warrant was deemed exercised for, without payment of any additional consideration, one broker warrant (the "**Broker Warrants**"). Each Broker Warrant is exercisable to acquire one common share, subject to adjustment in certain circumstances, at a price of \$2.00 until October 22, 2015. The Special Broker Warrants were valued at \$49,960 using the Black-Scholes model with a risk-free interest rate of 1.00%, term of 1 year, volatility of 80% and dividend rate of 0%.

## January 2015 Special Warrant Financing

In January 2015, the Company issued 4,363,634 special warrants (the "2015 Special Warrant Financing") at a price of US\$2.75 per 2015 Special Warrant for gross proceeds of approximately US\$12,000,000. Each 2015 Special Warrant is exercisable for, without payment of any additional consideration, one common share at any time by the holder thereof and all of the 2015 Special Warrants will be deemed to be exercised on the earlier of: (i) October 16, 2015 and (ii) the date on which the common shares first begin to trade on either (i) the Nasdaq Global Select Market, the Nasdaq Global Market or the Nasdaq Capital Market securities trading platforms of the NASDAQ Stock Market or (ii) the NYSE MKT securities trading platform of the New York Stock Exchange (the "U.S. Listing Date"). Should the U.S. Listing Date not occur on or prior to October 16, 2015, instead of one common share, each 2015 Special Warrant shall entitle the holder thereof to receive 1.5 common shares upon exercise or deemed exercise thereof.

In connection with the 2015 Special Warrant Financing, Bloom Burton & Co. and Roth Capital Partners, LLC, as Agents, and selling group members, received cash commission equal to approximately US\$706,800 and 257,018 broker warrants. Each broker warrant is exercisable to purchase one common share until January 16, 2017 at a price of US\$2.75 per broker warrant. The warrants were valued at \$334,396 using the Black-Scholes model with a risk-free interest rate of 0.87%, term of 2 years, volatility of 72.3%, and dividend rate of 0%.

## Listing on the TSX Venture Exchange

The Company completed its listing on the TSXV on January 27, 2015 ("**Date of Listing**") and began trading under the symbol "EPI".

Immediately prior to the listing, all of the Company's 2,382,540 issued and outstanding Preferred Shares were converted into common shares.

Escrow, Lock-Up, and Supplementary Lock-Up Restrictions

Certain of the Company's 15,687,534 common shares outstanding at September 30, 2014 have been and continue to be subject to various trading restrictions, including (i) a voluntary contractual lock-up agreement ("Voluntary Lock-Up"), (ii) a supplementary contractual lock-up agreement ("Supplementary Lock-Up") and (iii) escrow restrictions imposed by the TSXV ("TSXV Escrow"). As at March 31, 2015, 14,098,212 of the Company's outstanding common shares were subject to trading restrictions, including 3,615,678 common shares subject only to Voluntary Lock-Up, 1,012,534 common shares subject only to TSXV Escrow and 9,470,000 common shares subject to Voluntary Lock-Up, Supplementary Lock-Up and TSXV Escrow.

14,562,500 common shares were initially subject to Voluntary Lock-Up. 712,950 common shares were released from Voluntary Lock-Up on the Date of Listing, 763,872 common shares were released on March 5, 2015, and the remaining common shares will be released in 17.2% increments on October 27, 2015, January 27, 2016, April 27, 2016 and July 27, 2016 and 2.2% on October 27, 2016.

9,470,000 common shares are subject to Supplementary Lock-Up. 1,325,800 common shares will be released from Supplementary Lock-Up on July 27, 2015, and the remaining common shares will be released on October 27, 2015.



10,595,034 common shares were initially subject to TSXV Escrow. 112,500 common shares were released from TSXV Escrow on the Date of Listing and the remaining common shares will be released in 15% increments every 6 months beginning July 27, 2015.

Submission of Draft Registration Statement on Form 20F with the SEC

The Company has submitted to the United States Securities and Exchange Commission ("SEC") a registration statement on Form 20-F ("Registration Statement") to register its common shares under the U.S. Securities Exchange Act of 1934. The submission is an initial step in the process of seeking a U.S. stock exchange listing. The Company's objective is to expand and diversify the shareholder base and further enhance access to international markets.

The Registration Statement will be subject to a full review by the SEC and may require several amendments before it is declared effective. The listing of the Company's common shares on a U.S. stock exchange will be subject to the SEC declaring the Registration Statement effective and the Company satisfying the applicable listing requirements of the exchange. The Registration Statement, when publicly filed with the SEC, will be available on the SEC's website at www.sec.gov/edgar.shtml.

## **Events Subsequent to March 31, 2015**

Other than as disclosed elsewhere in this report, there were no other significant events subsequent to March 31, 2015 and prior to the date of this report.

#### DISCUSSION OF OPERATIONS

Clinical Development

## 1 - Phase 1/2 Clinical Trial Design for treating CRPC patients

The Company, along with its key advisors (most of whom are physicians who are currently treating CRPC patients), expects to execute a Phase 1/2 study, based on a protocol submitted to the FDA, to determine the safety, tolerability, maximum-tolerated-dose, pharmacokinetics and potential therapeutic benefits of EPI-506 in CRPC patients. The Phase 1 portion of the study is expected to enroll up to 30 patients with CRPC. Following single-dose evaluation, patients are expected to then receive daily dosing for 28 days to assess safety for dose escalation, however, patients will continue to receive the study drug for 12 weeks or longer to assess efficacy. The primary function of this part of the study will be to assess safety and pharmacokinetics of EPI-506. It is also possible that some patients will respond to treatment. Such a response to treatment would be measured by decreased PSA levels and/or a reduction in metastatic lesions. ESSA expects to conduct this Phase 1 portion of the study at 5-6 sites in the U.S. and Canada and expects it to be completed in approximately mid-2016 depending on the enrollment rate and number of dose escalation steps.

The Phase 2 portion is initially expected to enroll up to 120 CRPC patients. Additional patient cohorts may be added to address relevant questions on patients' tumor response and molecular profile (e.g. splice variant status). This study is currently expected to focus on CRPC patients who have failed enzalutamide and/or abiraterone acetate. 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 response.

The Company expects to collect circulating tumor cells so that the status of AR splice variant and other relevant biologic markers related to AR signaling can be determined. We expect to conduct this study at 25-30 sites in the U.S. and Canada.



The Company is wholly-focused at present on the development of EPI-506. R&D expenditures relate to the preclinical and clinical work discussed in this document. Detailed discussion of R&D expenditures in provided below in "Quarter Financial Information" and are being incurred in accordance with the anticipated timelines presented herein. The Company anticipates that an additional investment of \$15,451,000 will be required for R&D expenditures for preclinical and clinical work through the fourth quarter of fiscal 2016 which will mark the first read of the Phase 1 data.

#### 2 – Phase 3 studies

In order to obtain regulatory approval, the Company will be required to carry out at least one Phase 3 study. At this time, we expect that these patients will be the same population of CRPC patients that were enrolled in the Phase 1/2 study. However, it may be that the results of the Phase 1/2 study suggest a different patient population. In the Phase 3 studies, the key end-point will be overall survival relative to patients receiving the current standard-of-care. We expect to conduct the study at many sites around the world.

## Development Timeline

It is currently expected that ESSA will accomplish the development of EPI-506 to completion of Phase 1/2 clinical proof-of-concept with the expectation to recruit the first patient into its proposed Phase 1/2 clinical trial of EPI-506 in fiscal 4Q/2015. The Phase 1/2 clinical trial will continue through fiscal 3Q/2017.

There can be no guarantee that the Company will complete each stage of development in accordance with the timelines set out above, or at all. The timelines are contingent, in addition to other factors, upon the approval of the FDA to commence clinical trials.

#### **Our Business Strategy**

Our goal is to provide CRPC patients with a clinically meaningful increase in overall survival as well as progression-free survival relative to current therapies. In order to accomplish that objective, ESSA intends initially to complete the above-described Phase 1/2 clinical trial in CRPC patients. The Company also intends to explore earlier application of the EPI-506 in patients who are candidates for current hormone therapies.

Pre-clinical Research and Development ("R&D") Collaborations

At this stage, the Company is not focused on pursuing pre-clinical R&D collaborations. However, should such an offer be made, ESSA would consider the offer on its specific merits, giving weight to the benefits that such a collaboration could bring to our development program, and the risk-adjusted benefits that such a collaboration could provide to ESSA shareholders.

## Clinical Development Collaborations

ESSA has a high level of interest in later stage clinical development collaborations and commercialization partnerships. In the past decade, three companies have been at least partially successful in proving the efficacy of hormone therapy agents for treating CRPC. Two of them (Cougar Biotechnology Inc. and Aragon Pharmaceuticals Inc.) were acquired by a large pharmaceutical company (Johnson & Johnson) following or during their Phase 2 development. The third company (Medivation Inc.) partnered with Astellas following Phase 2 clinical studies.

Because of this recent history, ESSA may seek liquidity following completion of its Phase 1/2 clinical trial, or could further the development of its drug program alone or via collaboration with a larger pharmaceutical industry partner.

#### **Financing**

The Company intends to obtain a listing on the NASDAQ Capital Market ("NASDAQ") to ensure that the Company has access to global financial markets. There can be no assurances that the Company will be successful in obtaining a listing on the NASDAQ. The Company has filed its Registration Statement with the SEC which is currently under review.



ESSA's financial strategy to date has been to raise sufficient funds from private equity investors in order to fund specific programs within a focused budget. As the program development costs increase and the Company begins to incur manufacturing and clinical study costs, ESSA may need to raise additional capital. The Company has been successful in reaching out to larger investors pursuant to the October 2014 Special Warrant Financing and January 2015 Special Warrant Financing; however, there is no certainty that funds will be available on preferable terms in the future.

## 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 th               | e Q | uarters Ended      |                  |
|----------------------------------|-------------------|----------------------|-----|--------------------|------------------|
|                                  | March 31,<br>2015 | December 31,<br>2014 |     | September 30, 2014 | June 30,<br>2014 |
| Total assets                     | \$<br>13,906,485  | \$<br>4,621,182      | \$  | 4,709,415          | \$<br>766,156    |
| Long-term liabilities            | 1,115,262         | 344,521              |     | 1,838,507          | · <u>-</u>       |
| Research and development expense | 3,121,607         | 720,880              |     | (126,671)          | 653,681          |
| General and administration       | 436,125           | 746,232              |     | 605,488            | 341,450          |
| Comprehensive loss               | (4,621,458)       | (1,537,480)          |     | (509,303)          | (1,046,992)      |
| Basic and diluted loss per share | (0.24)            | (0.10)               |     | (0.03)             | (0.07)           |

|                                  |                   | For th               | ıe Ç | Quarters Ended     |                  |
|----------------------------------|-------------------|----------------------|------|--------------------|------------------|
|                                  | March 31,<br>2014 | December 31,<br>2013 |      | September 30, 2013 | June 30,<br>2013 |
| Total assets                     | \$<br>547,963     | \$<br>549,440        | \$   | 677,309            | \$<br>684,726    |
| Long-term liabilities            | -                 | -                    |      | -                  | -                |
| Research and development expense | 31,448            | 147,556              |      | (5,561)            | 342,428          |
| General and administration       | 112,069           | 99,005               |      | 118,086            | 104,265          |
| Comprehensive loss               | (152,476)         | (246,335)            |      | (112,309)          | (446,693)        |
| Basic and diluted loss per share | (0.01)            | (0.02)               |      | (0.04)             | (0.03)           |

Share-based payments expense for prior quarters has been reclassified in the statement of loss and comprehensive loss to be assigned to the functional expense (research and development, general and administrative, or financing) to which the underlying optionee relates. Consequently, the total expense for the functional expense items has been amended from the previous quarter's management's discussion and analysis. The allocation of share-based payments expense is detailed in note 9 of the accompanying condensed consolidated interim financial statements.

From the quarters ended June 30, 2013 through 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 the Cancer Prevention and Research Institute of Texas ("CPRIT") of US\$2,792,533 which was recorded as a long-term liability for recognition against qualifying expenditures as those expenditures are made. The CPRIT Product Development and Relocation Grant is detailed in the accompanying unaudited condensed consolidated interim financial statements.

Also in the three months ended September 30, 2014, the Company completed financing involving the issuance of 1,185,400 Preferred Shares at a price of \$2.00 per Preferred Share for gross proceeds of \$2,370,800 which supplemented the Company's financial resources. In the three months ended December 31, 2014, the Company completed the 2014 Special Warrant Financing described above for gross proceeds of \$1,359,280. In the three months ended March 31, 2015, the Company completed the 2015 Special Warrant Financing described above for gross proceeds of \$14,215,155. 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 was filed on March 31, 2015.

## Six months ended March 31, 2015 and 2014

The Company incurred a comprehensive loss of \$6,158,938 for the six months ended March 31, 2015 compared to a comprehensive loss of \$398,809 for the six months ended March 31, 2014.

Significant changes are as follows:

## Research and Development

- The overall R&D expense for the six months ended March 31, 2015 was \$3,842,487 compared to \$179,004 for the six months ended March 31, 2014. The gross expense for 2015 was \$5,591,440 (2014 \$179,004) before recognition of qualifying CPRIT grant funds of \$1,748,953 (2014 \$nil). This signifies a significantly higher investment in research and development activities, inclusive of preclinical work, from the \$179,004 expended in the comparative period.
- 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 the ESSA Houston office. Overall, R&D activity is higher than in the comparative period as financing secured in late fiscal 2014 and early fiscal 2015 permitted a more robust research program compared to the prior period when the Company was focusing on achieving the CPRIT grant and financing objectives.
- Consulting fees have increased to \$644,058 (2014 \$83,574) as the Company has engaged qualified professionals to conduct specific R&D services for the Company in addition to regular payments made to the Company's Chief Scientific Officer and Chief Technical Officer over the two periods.
- Legal patents and license fees have increased to \$311,321 (2014 \$140,685) 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. This amount also includes the 2014 \$40,000 annual royalty under the License Agreement.
- Analytical studies, formulation and testing costs of \$1,688,486 (2014 \$68,274) and manufacturing costs of \$1,376,657 (2014 \$11,400) have increased compared to the six months ended March 31, 2014. These costs relate to contracted lab facilities to conduct testing and experimentation on the Company's EPI-series drugs. The investment for the current 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. In the comparative period, the Company also recovered \$235,470 in Scientific Research & Development ("SRED") tax credits from the province against these costs.
- Salaries and benefits relate to establishment of payroll for the Company's Chief Medical Officer, Executive
  VP of Research and additional preclinical and clinical staff in Texas. The Company has invested
  significantly over the past six months 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 and six month period ended March 31, 2015 and 2014:

|                                     | T   | hree months  | Т  | hree months  |    | Six months   |     | Six months   |
|-------------------------------------|-----|--------------|----|--------------|----|--------------|-----|--------------|
|                                     | 3.6 | ended        |    | ended        |    | ended        | 3.6 | ended        |
|                                     | Mai | rch 31, 2015 | Ma | rch 31, 2014 | Ma | rch 31, 2015 | Ma  | rch 31, 2014 |
| Analytical studies, formulation and |     |              |    |              |    |              |     |              |
| testing                             | \$  | 919,196      | \$ | 69,902       | \$ | 1,688,486    | \$  | 108,274      |
| Consulting                          |     | 474,113      |    | 38,261       |    | 644,058      |     | 83,574       |
| Legal patents and license fees      |     | 171,537      |    | 76,357       |    | 311,321      |     | 140,685      |
| Manufacturing                       |     | 992,014      |    | -            |    | 1,376,657    |     | 11,400       |
| Other                               |     | 6,416        |    | -            |    | 6,771        |     | -            |
| Salaries and benefits               |     | 478,843      |    | -            |    | 802,070      |     | -            |
| Share-based payments                |     | 232,449      |    | 18,889       |    | 521,382      |     | 60,976       |
| Travel                              |     | 115,528      |    | 7,493        |    | 240,695      |     | 9,565        |
| SRED tax credits                    |     | -            |    | (179,454)    |    | -            |     | (235,470)    |
| CPRIT grant claimed on eligible     |     |              |    |              |    |              |     |              |
| expenses                            |     | (268,489)    |    | <u> </u>     |    | (1,748,953)  |     | <u> </u>     |
| Total                               | \$  | 3,121,607    | \$ | 31,448       | \$ | 3,842,487    | \$  | 179,004      |

Share-based payments expense of \$521,382 (2014 - \$60,976) 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 vesting of these equity instruments as measured by the Black-Scholes pricing model.

## General and administrative

General and administration expenses for the six months ended March 31, 2015 increased to \$1,182,357 from \$211,074 in 2014. Significant components of the expense in the current period included:

- Consulting and subcontractor fees of \$106,885 (2014 \$125,595). In the current period, the costs related to
  ongoing administrative support and intellectual property consulting, and one-time professional recruiting
  services. In the prior period, costs were related to the CEO and CFO who have since been converted to full
  time employees included in salaries and benefits.
- Professional fees for legal and accounting services of \$997,149 (2014 \$42,257) were incurred in conjunction with the corporate activities in fiscal 2015. These services have been engaged to support the Company's financing activities and work toward listing on the TSXV (occurred in January 2015) and the NASDAQ (in progress). The Company has worked expediently with its professional service providers to develop corporate structures and compliance standards to meet new and developing reporting requirements as a public company.
- Salaries and benefits expense of \$616,020 (2014 \$nil) relates primarily to the establishment of the CEO and CFO as full time employees of the organization.
- Foreign exchange fluctuations have increased due to the spread between the Canadian and US dollars, primarily in relation to the US\$12,000,000 in proceeds on the 2015 Special Warrant Financing during the period. The Company is also exposed to foreign exchange fluctuations due to activities ongoing in Texas and the CPRIT grant. The foreign exchange rate applied at the date of 2015 Special Warrant Financing was 1.18 CAD/USD which fluctuated to 1.27 CAD/USD as at the reporting date of March 31, 2015; consequently, the Company recognized a significant gain on foreign exchange for the current period.
- 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 and six month periods ended March 31, 2015 and 2014:

|                                    | Т  | hree months<br>ended |    | Three months ended |    | Six months ended |    | Six months ended |
|------------------------------------|----|----------------------|----|--------------------|----|------------------|----|------------------|
|                                    | Ma | rch 31, 2015         | M  | arch 31, 2014      | Ma | rch 31, 2015     | Ma | arch 31, 2014    |
|                                    |    |                      |    |                    |    |                  |    |                  |
| Amortization                       | \$ | 9,214                | \$ | 6,331              | \$ | 17,960           | \$ | 12,662           |
| Consulting and subcontractor fees  |    | 31,488               |    | 59,195             |    | 106,885          |    | 125,595          |
| Director fees                      |    | 44,000               |    | -                  |    | 44,000           |    | -                |
| Foreign exchange                   |    | (1,185,286)          |    | 3,788              |    | (1,229,303)      |    | 5,323            |
| Investor relations                 |    | 74,096               |    | -                  |    | 87,572           |    | -                |
| Office, IT and communications      |    | 107,060              |    | 2,974              |    | 147,242          |    | 6,157            |
| Professional fees                  |    | 637,534              |    | 31,544             |    | 997,149          |    | 42,257           |
| Regulatory fees and transfer agent |    | 51,025               |    | -                  |    | 58,749           |    | -                |
| Rent                               |    | 47,238               |    | 8,117              |    | 61,542           |    | 15,512           |
| Salaries and benefits              |    | 429,161              |    | -                  |    | 616,020          |    | -                |
| Share-based payments               |    | 182,673              |    | -                  |    | 307,270          |    | -                |
| Travel and entertainment           |    | 108,023              |    | 120                |    | 112,581          |    | 3,568            |
| CPRIT grant claimed on eligible    |    |                      |    |                    |    |                  |    |                  |
| expenses                           |    | (100,101)            |    | <u>-</u>           |    | (145,310)        |    |                  |
|                                    |    | 10 1 15 -            |    |                    |    |                  |    | • • • • • • •    |
| Total                              | \$ | 436,125              | \$ | 112,069            | \$ | 1,182,357        | \$ | 211,074          |

Share-based payments expense of \$307,270 (2014 - \$nil) 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.

## Three months ended March 31, 2015 and 2014

The Company incurred a comprehensive loss of \$4,621,458 for the three months ended March 31, 2015 compared to a comprehensive loss of \$152,476 for the three months ended March 31, 2014.

The detailed changes for the research and development and general and administrative expenses for the three months ended March 31, 2015 and 2014 are included in the tables above. Most significantly, the Company made significant increased investment in research and development costs, including analytical studies, formulation and testing costs of \$919,196 (2014 - \$69,902) and manufacturing costs of \$992,014 (2014 - \$nil). In the current period, the Company worked toward the IND application filing which was completed with the support of research and lab service partners at the end of March 31, 2015. In general, the Company has increased R&D activity as it leverages momentum from pre-clinical development work discussed above and financings completed in the current fiscal year.

General and administrative expenses have increased over the prior period as the context of the Company has changed significantly. The Company completed its TSXV listing in the current period and is working toward a U.S. listing which has resulted in a higher overall corporate burden and engagement of professional services. The Company established formal payroll in August 2014 for its key executives which has led to a recurring salaries and benefits expense.

The 2015 Special Warrant Financing has increased the Company's net financial assets denominated in US dollars and exposure to fluctuations in the US/Canadian exchange rate. In conjunction with the 2015 Special Warrant Financing, the Company issued 257,018 broker warrants exercisable at a price of USD\$2.75 per common share. As these broker warrants are denominated in US dollars and are exercisable into the Company's common shares which are listed in 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 period ended March 31, 2015, the Company recorded a loss of \$780,866 with respect to the derivative liability.



#### **USE OF PROCEEDS**

During the six months ended March 31, 2015 and up to the date of this report, the Company received total net proceeds of \$14,220,585 from the following financings:

- In October 2014, the Company received net proceeds of \$1,218,325 in relation to the 2014 Special Warrant Financing.
- In January 2015, the Company received net proceeds of \$13,002,260 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 ½ clinical program while meeting administrative requirements.   |
|  | During the six months ended March 31, 2015, the Company incurred \$3,842,487 in research and development costs in relation to the development of the EPI-506 Phase 1/2 clinical program. An additional \$1,182,357 has been incurred for general and administrative costs in support of the Company's research and development activities. The Company intends to use the remaining funds towards the completion of the Phase 1/2 clinical program. |

## LIQUIDITY AND CAPITAL RESOURCES

Operational activities during the period ended March 31, 2015 were financed mainly by proceeds from equity financings completed in July and October 2014, January 2015, and the CPRIT Grant. At March 31, 2015, the Company had available cash reserves of \$13,238,618 and \$111,392 in accounts receivable related to the refund of GST input tax credits to settle current liabilities of \$1,486,553. This compares to cash reserves of \$4,146,938 and \$72,295 in accounts receivable related to refund of GST input tax credits at September 30, 2014 to settle current liabilities of \$658,305.

Cash used in operating activities for the three months ended March 31, 2015 was \$5,223,541 (2014 - \$114,446). Working capital items generated cash of \$793,198 (2014 - \$201,766), as accounts payable increased aligned with the increase of administration and research and development activities.

Cash used in investing activities for the three months ended March 31, 2015 was \$77,341 (2014 - \$nil) as the Company invested in equipment in the ongoing establishment of its Houston office.

Cash provided by financing activities for the three months ended March 31, 2015 was \$14,703,476 (2014 - \$nil). The Company received gross proceeds of \$1,359,280 and \$14,215,155 (US\$12,000,000) from the 2014 Special Warrant Financing and 2015 Special Warrant Financing, respectively, each as previously described above under "Corporate Update and Overall Performance", offset by \$1,019,455 in share issuance costs. The Company also received \$148,496 in proceeds on the exercise of warrants during the period.



As of September 30, 2014, the Company had working capital of \$3,359,834. With the addition of the 2015 Special Warrant Financing and expected future CPRIT advances, the Company has assessed that the cash position will be sufficient to finance operational and capital needs for the following 18 months. Management maintains operating budgets and actively reviews cash flows.

Future cash requirements may vary materially from those now expected due to a number of factors, including the costs associated with pre-clinical studies, formulation studies and preparations in order to initiate clinical trials 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, in the future it may be necessary to raise additional funds. 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 March 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   |    | 2015    |    | 2016    |    | 2017    |    | 2018    |    | 2019    |
|---|----|---------|----|---------|----|---------|----|---------|----|---------|
| Minimum annual royalty per License<br>Agreement with UBC/BC<br>Cancer Agency <sup>(1)</sup> | \$ | 65,000  | \$ | 65,000  | \$ | 85,000  | \$ | 85,000  | \$ | 85,000  |
| Lease on Vancouver office space   | _  | 22,100  | _  | 46,800  | _  | 46,800  | _  | 46,800  | _  | 46,800  |
| Total   | \$ | 87,100  | \$ | 111,800 | \$ | 131,800 | \$ | 131,800 | \$ | 131,800 |
| Lease on US office space (In USD)   | \$ | 106,365 | \$ | 244,230 | \$ | 251,192 | \$ | 258,206 | \$ | 307,361 |

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 is 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 is material to investors.

#### RELATED PARTY TRANSACTIONS

Key management personnel of the Company include Robert Rieder, the Chief Executive Officer, David Wood, Chief Financial Officer, Dr. Frank Perabo, Chief Medical Officer, Paul Cossum, Executive VP of Research and Development, Dr. Marianne Sadar, Chief Scientific Officer and Director, Dr. Raymond Andersen, Chief Technology Officer and Director, Richard Glickman, Director and Chairman of the Board, Gary Sollis, Director, and Franklin Berger, Director. Compensation paid to key management personnel for the six months ended March 31, 2015 and 2014 are as follows:



<sup>(1)</sup> ESSA has the worldwide, exclusive right to develop products based on the Licensed IP pursuant to the License Agreement. 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.

|  | 2015                     | 2014                    |
|--|--------------------------|-------------------------|
| Salaries and consulting fees<br>Share-based payments | \$<br>968,334<br>707,248 | \$<br>160,000<br>59,445 |
| Total compensation                                   | \$<br>1,675,582          | \$<br>219,445           |

During the six months ended March 31, 2015, the Company granted 200,000 options (2014 – nil) to key management personnel. The vesting of these options and options granted to key management personnel in prior periods were recorded as share-based payments expense in the statement of loss and comprehensive loss at a value of \$707,248 (2014 - \$59,445). The balance of the share-based payments expense included in related party compensation in the period relates to the vesting of stock options granted in prior periods.

Included in accounts payable and accrued liabilities at March 31, 2015 is \$55,520 (September 30, 2014 – \$24,331) 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.

Mr. Rieder is entitled to a payment of one year of base salary upon termination without cause, increasing to two years 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 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. Stock options held by the CEO and CFO 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 consistent with those followed in the preparation of the Company's annual consolidated financial statements for the year ended September 30, 2014, except for the adoption of new standards and interpretations effective as of October 1, 2014.

#### **Embedded derivatives**

Derivatives may be embedded in other financial instruments (the "host instrument"). Embedded derivatives are treated as separate derivatives when their economic characteristics and risks are not clearly and closely related to those of the host instrument, the terms of the embedded derivative are the same as those of a stand-alone derivative, and the combined contract is not held for trading or designated at fair value. These embedded derivatives are measured at fair value with subsequent changes recognized in gains or losses on derivative instruments in the statement of loss and comprehensive loss.

## New standards, interpretations and amendments adopted

The following standards, amendments to standards and interpretations have been adopted for the fiscal year beginning October 1, 2014:

| IFRS 2 (Amendment)  | Revised definitions for 'vesting conditions' and 'market condition' related to share |
|---------------------|--|
|                     | based compensation   |
| IFRS 13 (Amendment) | Revised disclosure requirements for contracts under the scope of IFRS 9/IAS 39       |
| IAS 24 (Amendment)  | New definitions for 'related party' encompassing key management personnel            |
| IAS 38 (Amendment)  | Revised valuation methods for the 'revaluation model' for intangible assets          |
| IAS 39              | New standard for financial instruments including embedded derivatives                |
|                     | IFRS 13 (Amendment) IAS 24 (Amendment) IAS 38 (Amendment)                            |

The application of these standards, amendments and interpretations has not had a material impact on the result and financial position of the Company.



## 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 financial instruments has not yet been determined.

#### 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 March 31, 2015, the Company had a cash balance of \$13,238,618 to settle current liabilities of \$1,486,553. All of the Company's financial liabilities have contractual maturities of 30 days or due on demand and are subject to normal trade 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

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

The Company is exposed to foreign currency risk on fluctuations related to accounts payable and accrued liabilities that are denominated in United States dollars. As at March 31, 2015, the Company had cash of US\$10,367,856 and accounts payable and accrued liabilities of US\$801,137. The Company anticipates that, pursuant to the product development and relocation grant disclosed in Note 14 of the accompanying unaudited condensed consolidated interim financial statements, the transactions of the Company will be increasingly subject to fluctuations in the US dollar. Additionally, the Company has broker warrants outstanding which are denominated in United States dollars (Note 7 of the accompanying unaudited condensed consolidated interim financial statements).

A 10% change in the foreign exchange rate between the Canadian and US dollar would result in a fluctuation of \$1,211,721 in the net loss realized for the period.

## (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.

#### **BUSINESS RISKS**

The Company's risks are detailed in the final prospectus filed on Sedar on December 5, 2014. Subsequent to filing the prospectus, the Company has identified the following additional risks:

## The Company remains subject to the restrictions and conditions of the CPRIT Agreement.

Failure to comply with the CPRIT Agreement may adversely affect ESSA's financial condition and results of operations. The Company relies on the CPRIT Grant to fund its ongoing operations. The CPRIT Grant is subject to the Company's compliance with the scope of work outlined in the CPRIT Agreement and demonstration of its progress towards achievement of the milestones set forth in the CPRIT Agreement (Note 14 of the accompanying unaudited condensed consolidated interim financial statements).

If the Company fails to comply with the terms of the CPRIT Agreement, it may not receive the remaining tranches of the CPRIT Grant or it may be required to reimburse some or the entire CPRIT Grant. Further, the CPRIT Grant may only be applied to a limited number of allowable expenses. Failure to obtain the remaining tranches of the CPRIT Grant or being required to reimburse all or a portion of the CPRIT Grant may cause a halt or delay in ESSA's ongoing operations, which may adversely affect the Company's financial condition and results of operations. If the Company fails to comply with the terms of the CPRIT Agreement, CPRIT will have the option to pursue the transfer and assignment of the Company's rights, title and interest in the intellectual property rights and technologies developed as a result of the CPRIT Grant. Failure to maintain ownership over the Company's intellectual property and technologies may adversely affect the Company's financial condition and results of operations.

If ESSA is unable to implement and maintain effective internal controls over financial reporting in the future, ESSA may not be able to report financial results accurately or prevent fraud. In that case, investors may lose confidence in the accuracy and completeness of ESSA's financial reports and the market price of ESSA's common shares may be negatively affected.

Maintaining effective internal control over financial reporting is necessary for ESSA to produce reliable financial reports and is important in helping to prevent financial fraud. If ESSA is unable to maintain adequate internal controls, ESSA's business and operating results could be harmed. ESSA is not currently required to comply with National Instrument 52-109—Certification of Disclosure in Issuers' Annual and Interim Filings of the Canadian Securities Administrators ("NI 52-109") with respect to the establishment and maintenance of internal controls. As a result, ESSA is not currently required to make an assessment of the effectiveness of our internal controls, or to deliver a report that assesses the effectiveness of ESSA's internal control over financial reporting.



ESSA has begun to evaluate how to document and test internal control procedures to satisfy the requirements of NI 52-109, which require, among other things, ESSA's management to assess annually the effectiveness of ESSA's internal control over financial reporting. During the course of this documentation and testing, ESSA may identify weaknesses or deficiencies that ESSA may be unable to remedy before any requisite deadline for those reports.

Preparing ESSA's consolidated financial statements involves a number of complex manual and automated processes which are dependent on individual data input or review and require significant management judgment. One or more of these elements may result in errors that may not be detected and could result in a material misstatement of ESSA's consolidated financial statements.

The process of designing and implementing effective internal controls and procedures, and expanding ESSA's internal accounting capabilities, is a continuous effort that requires ESSA to anticipate and react to changes in ESSA's business and the economic and regulatory environments and expend significant resources to establish and maintain a system of internal controls that is adequate to satisfy ESSA's reporting obligations as a public company. The standards that must be met for management to assess the internal control over financial reporting as effective are complex, and require significant documentation, testing and possible remediation to meet the detailed standards. ESSA cannot be certain at this time whether the Company will be able to successfully complete the continuing implementation of controls and procedures or the certification and attestation requirements of NI 52-109.

If a material misstatement occurs in the future, ESSA may fail to meet our future reporting obligations, ESSA may need to restate our financial results and the price of our common shares may decline. Any failure of ESSA's internal controls could also adversely affect the results of the periodic management evaluations and any annual independent registered public accounting firm attestation reports regarding the effectiveness of ESSA's internal control over financial reporting that may be required. Effective internal controls are necessary for ESSA to produce reliable financial reports and are important to helping prevent financial fraud. If ESSA cannot provide reliable financial reports or prevent fraud, ESSA's business and results of operations could be harmed, investors could lose confidence in ESSA's reported financial information, and the trading price of ESSA's common shares could drop significantly.

## Risk Related to ESSA Not Becoming Listed on NASDAO before the U.S. Listing Date

Although the Company has applied to list the common shares on the NASDAQ, a listing on the NASDAQ may not be obtained before the U.S. Listing Date and the Company may become subject to certain penalty provisions in the 2015 Special Warrants. Each 2015 Special Warrant is exercisable for, without payment of any additional consideration, one common share at any time by the holder thereof and all of the 2015 Special Warrants will be deemed to be exercised on the earlier of: (i) October 16, 2015 and (ii) the U.S. Listing Date . Should the U.S. Listing Date not occur on or prior to October 16, 2015, instead of one common share, each 2015 Special Warrant shall entitle the holder thereof to receive 1.5 common shares upon exercise or deemed exercise thereof.

There is a risk that the Company is or could become a passive foreign investment company ("PFIC") which would likely result in materially adverse U.S. federal income tax consequences for U.S. investors.

The Company believes that it may have been classified as a PFIC for the taxable year ending September 30, 2014, and the Company believes it may be classified as a PFIC for the current taxable year and in future taxable years. However, the determination as to whether the Company is a PFIC for any taxable year is based on the application of complex U.S. federal income tax rules that are subject to differing interpretations. If the Company is a PFIC for any taxable year during which a U.S. Holder (as defined under "Taxation—U.S. Federal Income Tax Considerations") holds the Common Shares, it would likely result in adverse U.S. federal income tax consequences for such U.S. Holder. U.S. Holders should carefully read "Taxation—U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Rules" for more information and consult their own tax advisors regarding the likelihood and consequences of the Company being treated as a PFIC for U.S. federal income tax purposes, including the advisability of making a "qualified electing fund" election (including a protective election), which may mitigate certain possible adverse U.S. federal income tax consequences but may result in an inclusion in gross income without receipt of such income.



## ADDITIONAL INFORMATION

Additional information can be found on Sedar at <u>www.sedar.com</u> and the Company's website <u>www.essapharma.com</u>.

## **OUTSTANDING SHARE CAPITAL**

| Equity instruments outstanding as of the date of this MD&A: |            |
|---|------------|
|   |            |
| Common shares   | 18,157,077 |
| Stock options   | 3,427,619  |
| Warrants  | 311,949    |
| Special warrants <sup>(1)</sup>                             | 4,363,634  |

<sup>(</sup>i) Convert to one common share at any time by the holder thereof and all of the 2015 Special Warrants will be deemed to be exercised on the earlier of: (i) October 16, 2015 and (ii) the U.S. Listing Date. Should the U.S. Listing Date not occur on or prior to October 16, 2015, instead of one common share, each 2015 Special Warrant shall entitle the holder thereof to receive 1.5 common shares upon exercise or deemed exercise thereof.

## FORWARD-LOOKING AND OTHER STATEMENTS

This MD&A, including the documents incorporated by reference herein, contains forward-looking statements or forward-looking information under applicable Canadian securities legislation that may not be based on historical fact, including, without limitation, statements containing the words "believe," "may," "plan," "will," "estimate," "continue," "anticipate," "intend," "expect," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words and similar expressions. Forward-looking statements are necessarily based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as the factors we believe are appropriate. Forward-looking statements in this MD&A and the documents incorporated by reference herein include, but are not limited to, statements relating to:

- the intention to complete the listing of the common shares on a U.S. stock exchange, completion and acceptance of the Registration statement and all transactions related thereto;
- the intention to file a CTA (as defined above) application in Canada, and expectations regarding the timing of such applications;
- the initiation, timing, cost, progress and success of our research and development programs, pre-clinical studies and clinical trials;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit sufficient numbers of patients for our future clinical trials;
- our ability to achieve profitability;
- our ability to obtain funding for our operations, including research funding;
- 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 our business model and strategic plans;
- our ability to develop and commercialize product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our expectations regarding federal, provincial and foreign regulatory requirements;
- whether the Company will receive, and the timing and costs of obtaining, regulatory approvals in the U.S., Canada, the European Union and other jurisdictions;
- the therapeutic benefits, effectiveness and safety of our product candidates;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our products and product candidates;
- the rate and degree of market acceptance and clinical utility of our future products, if any;



- the timing of, and our ability and our collaborators' ability, if any, to obtain and maintain regulatory approvals for our product candidates;
- our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- our ability to engage and retain the employees required to grow our business;
- the compensation that is expected to be paid to employees of the Company;
- our future financial performance and projected expenditures;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available; and
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing.

Such statements reflect our 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, while considered reasonable by ESSA as of the date of such statements, 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. In making the forward looking statements included in this MD&A, the Company has made various material assumptions, including but not limited to (i) obtaining positive results of clinical trials; (ii) obtaining regulatory approvals; (iii) general business and economic conditions; (iv) the Company's ability to successfully out-license or sell its current products and in-license and develop new products; (v) the availability of financing on reasonable terms; (vi) the Company's ability to attract and retain skilled staff; (vii) market competition; (viii) the products and technology offered by the Company's competitors; and (ix) the Company's ability to protect patents and proprietary rights.

In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including the risks outlined under the heading "Risk Factors" in the Company's prospectus filed on Sedar (www.sedar.com) on December 5, 2014 and included in "Business Risks" in this document. Should one or more of these risks or uncertainties, or a risk that is not currently known to us materialize, or should assumptions underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this MD&A or, in the case of documents incorporated by reference in this MD&A, as of the date of such documents, and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by applicable securities laws. 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.

