



**FORM 51-102F1  
MANAGEMENT'S DISCUSSION AND ANALYSIS  
FOR THE SIX MONTHS ENDED MARCH 31, 2019 AND 2018**

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## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED MARCH 31, 2019 AND 2018

This management's discussion and analysis ("**MD&A**") of ESSA Pharma Inc. (the "**Company**" or "**ESSA**") for the six months ended March 31, 2019 and 2018 is dated as of May 8, 2019.

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 six months ended March 31, 2019 and 2018 and the audited consolidated financial statements for the years ended September 30, 2018, 2017 and 2016, 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 the United States Private Securities Litigation Reform Act and applicable Canadian securities laws. Please refer to the discussion of forward-looking statements set out under the heading "Cautionary Note Regarding Forward-Looking Statements" below. As a result of many factors, the Company's actual results may differ materially from those anticipated in these forward-looking statements.

As at March 31, 2019, the Company's common shares traded on the TSX Venture Exchange ("**TSX-V**") under the symbol "**EPI**" and the Nasdaq Capital Market ("**Nasdaq**") under the symbol "**EPIX**".

### 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 that may be expressed or implied by such forward-looking statements. Examples of such forward looking statements include, but are not limited to statements related to:

- the Company's ability to obtain funding for operations, including research funding, and the timing of potential sources of such funding;
- the initiation, timing, cost, location, progress and success of, strategy and plans with respect to, ESSA's research and development programs (including research programs and related milestones with regards to next-generation drug candidates and compounds), preclinical studies and clinical trials;
- the therapeutic benefits, properties, effectiveness, pharmacokinetic profile and safety of the Company's potential future product candidates, including the expected benefits, properties, effectiveness, pharmacokinetic profile and safety of the Company's next-generation Aniten compounds;
- the Company's ability to advance its potential future product candidates through, and successfully complete, clinical trials;
- the Company's ability to achieve profitability;
- the grant ("**CPRIT Grant**") under the Cancer and Prevention Research Institute of Texas ("**CPRIT**") and payments thereunder, including residual obligations;
- the Company's use of proceeds from funding and financings;
- the Company's ability to recruit sufficient numbers of patients for future clinical trials, and the benefits expected therefrom;
- the Company's ability to establish and maintain relationships with collaborators with acceptable development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts;
- the implementation of the Company's business model and strategic plans, including strategic plans with respect to patent applications and strategic collaborations partnerships;
- the Company's ability to identify, develop and commercialize product candidates;

- the Company's commercialization, marketing and manufacturing capabilities and strategy;
- the Company's ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others;
- the Company's expectations regarding federal, state, provincial and foreign regulatory requirements, including the Company's plans with respect to anticipated regulatory filings;
- whether the Company will receive, and the timing and costs of obtaining, regulatory approvals in the United States, Canada and other jurisdictions;
- the accuracy of the Company's estimates of the size and characteristics of the markets that may be addressed by the Company's potential future product candidates;
- the rate and degree of market acceptance and clinical utility of the Company's potential future product candidates, if any;
- the timing of, and the Company's ability and the Company's collaborators' ability, if any, to obtain and maintain regulatory approvals for the Company's potential future product candidates;
- the Company's expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- the Company's ability to engage and retain the employees required to grow its business;
- the compensation that is expected to be paid to the Company's employees;
- the Company's future financial performance and projected expenditures;
- developments relating to the Company's competitors and its industry, including the success of competing therapies that are or may become available; and
- estimates of the Company's financial condition, expenses, future revenue, capital requirements, its needs for additional financing and potential sources of capital and funding.

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 identify a product candidate or product candidates;
- the availability of financing on reasonable terms;
- its ability to repay debt;
- its ability to obtain regulatory and other approvals to commence a clinical trial involving future product candidates;
- its ability to obtain positive results from its research and development activities, including clinical trials;
- its ability to obtain required regulatory approvals;
- its ability to protect patents and proprietary rights;
- 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;
- its ability to attract and retain skilled staff;
- market competition; and
- the products and technology offered by the Company's competitors.

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 Annual Report on Form 20-F for the fiscal year ended September 30, 2018. Some of these risks and assumptions include, among others:

- uncertainty as to the Company's ability to raise additional funding;
- risks related to the Company's ability to raise additional capital on favorable terms;
- uncertainty as to the Company's ability to generate sufficient cash to service its indebtedness;
- risks that the Company may default on the residual obligations of the agreement providing for the CPRIT Grant, which may result in the Company not receiving the remaining CPRIT Grant funds and/or having to reimburse all of the CPRIT Grant, if such default is not waived by CPRIT;

- risks related to the Company's ability to continue as a going concern;
- risks related to the Company's incurrence of significant losses in every quarter since its inception and the Company's anticipation that it will continue to incur significant losses in the future;
- risks related to the Company's limited operating history;
- risks related to the Company's ability to identify a product candidate through preclinical studies and obtain regulatory approval of an IND application to commence a clinical trial;
- risks related to the Company's future success being dependent primarily on identification through preclinical studies, regulatory approval, and commercialization of a single product candidate;
- risks related to the Company's ability to continue to license its product candidates or technology from third parties;
- uncertainty related to the Company's ability to obtain required regulatory approvals for ESSA's proposed products;
- risks related to the Company's ability to successfully identify and develop potential future product candidates in a timely manner;
- risks related to the Company's ability to successfully commercialize future product candidates;
- the possibility that the Company's potential future product candidates may have undesirable side effects;
- risks related to clinical drug development;
- risks related to the Company's ability to conduct a clinical trial or submit a future NDA/NDS or IND/CTA (each, as defined herein);
- risks related to the Company's ability to enroll subjects in future clinical trials;
- risks that the FDA (as defined herein) may not accept data from trials conducted in such locations outside the United States;
- risks related to the Company's ongoing obligations and continued regulatory review;
- risks related to potential administrative or judicial sanctions;
- the risk of increased costs associated with prolonged, delayed or terminated clinical trials;
- risks related to the Company's failure to obtain regulatory approval in international jurisdictions;
- risks related to recently enacted and future legislation in the United States that may increase the difficulty and cost for the Company to obtain marketing approval of, and commercialize, its potential future products and affect the prices the Company may obtain;
- risks related to new legislation, new regulatory requirements, and the continuing efforts of governmental and third party payors to contain or reduce the costs of healthcare;
- the risk that third parties may not carry out their contractual duties;
- risks related to the possibility that the Company's relationships with academic institutions and clinical research organizations (as defined herein) may terminate;
- risks related to the Company's lack of experience manufacturing product candidates on a large clinical or commercial scale and its lack of manufacturing facility;
- the Company's reliance on proprietary technology;
- the Company may not be able to protect its intellectual property rights throughout the world;
- risks related to claims by third parties asserting that the Company, or its employees have misappropriated their intellectual property, or claiming ownership of what the Company regards as its intellectual property;
- risks related to the Company's ability to comply with governmental patent agency requirements in order to maintain patent protection;
- risks related to computer system failures or security breaches;
- risks related to business disruptions that could seriously harm the Company's future revenues and financial condition and increase ESSA's costs and expenses;
- risks related to the Company's dependence on the use of information technologies;
- risks related to the Company's ability to attract and maintain highly-qualified personnel;
- third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain the Company's future revenues;
- risks related to potential conflicts of interest between the Company and its directors and officers;
- risks related to competition from other biotechnology and pharmaceutical companies;
- risks related to movements in foreign currency exchange rates;
- risks related to the Company's ability to convince public payors and hospitals to include ESSA's potential future products on their approved formulary lists;

- risks related to the Company's ability to establish an effective sales force and marketing infrastructure, or enter into acceptable third-party sales and marketing or licensing arrangements;
- risks related to the Company's ability to manage growth;
- risks related to the Company's ability to achieve or maintain expected levels of market acceptance for its products;
- risks related to the Company's ability to realize benefits from acquired businesses or products or form strategic alliances in the future;
- risks related to collaborations with third parties;
- risks that employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for ESSA and harm its reputation;
- risks related to product liability lawsuits;
- risks related to compulsory licensing and/or generic competition;
- risks related to the increased costs and effort as a result of ESSA being a public company;
- risks inherent in foreign operations;
- laws and regulations governing international operations may preclude the Company from developing, manufacturing and selling certain product candidates outside of the United States and Canada and require ESSA to develop and implement costly compliance programs;
- risks related to laws that govern fraud and abuse and patients' rights;
- risks related to the Company's ability to comply with environmental, health and safety laws and regulations;
- risks related to the different disclosure obligations for a U.S. domestic reporting company and a foreign private issuer such as ESSA;
- risks relating to the Company's ability to maintain its status as a foreign private issuer in the future;
- the risk that the Company could become a "passive foreign investment company;"
- risks related to the Company's status as an emerging growth company;
- risks related to United States investors' ability to effect service of process or enforcement of actions against the Company;
- risks related to the Company's ability to maintain compliance with Nasdaq listing requirements;
- risks related to market price and trading volume volatility;
- risks related to the Company's dividend policy;
- risks associated with future sales of the Company's securities;
- risks related to the Company's ability to implement and maintain effective internal controls;
- risks related to the Company's ability to maintain an active trading market for its common shares;
- risks related to share price volatility associated with the Company's thinly traded common shares; and
- risks related to analyst coverage.

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 entirety all forward-looking statements attributable to the Company or persons acting on its behalf.

## OVERVIEW OF THE COMPANY

ESSA is a pharmaceutical company currently in preclinical stage 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 preclinical series of compounds can significantly expand the interval of time in which patients suffering from castration-resistant prostate cancer ("CRPC") can benefit from hormone-based therapies. Specifically, the compounds act by disrupting the androgen

receptor (“AR”) signaling pathway, the primary pathway that drives prostate cancer growth, by preventing AR activation through selective binding to the Tau-5 region of the N-terminal domain (“NTD”) of the AR. In this respect, ESSA’s compounds differ from classical anti-androgens, which interfere either with androgen synthesis, or with the binding of androgens to the ligand-binding domain (“LBD”), located at the opposite end of the receptor. A functional NTD is essential for activation of the AR; blocking the NTD inhibits AR-driven transcription and therefore androgen-driven biology. We believe that the transcription inhibition mechanism of ESSA’s preclinical series of compounds is unique, and has the advantage of bypassing identified mechanisms of resistance to the anti-androgens currently used in the treatment of CRPC. The Company has been granted by the United States Adopted Names (“USAN”) Council a unique USAN stem “-aniten” to recognize this new mechanistic class. The Company refers to this series of proprietary compounds, currently in development, as the “Aniten” series. In preclinical studies, blocking the NTD has demonstrated the capability to prevent AR-driven gene expression. A recently completed Phase I clinical trial of ESSA’s first-generation agent EPI-506 (as defined herein) demonstrated prostate-specific antigen (“PSA”) declines, a sign of inhibition of AR-driven biology, at higher dose levels.

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 or surgical castration; this approach is termed “androgen deprivation therapy”, or “ADT”. 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 have been generally treated with anti-androgens that block the binding of androgens (enzalutamide, apalutamide or bicalutamide) to the AR, or inhibit synthesis of androgens (abiraterone). More recently, important results have been achieved by utilizing this latest generation of anti-androgens in combination with ADT in newly diagnosed metastatic prostate cancer.

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 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. Generally, current drugs for the treatment of prostate cancer work by focusing on the first mechanism in combination with either (i) interfering with the production of androgen, or (ii) preventing androgen from binding to the LBD. However, over time, these approaches eventually fail, due to mechanisms of resistance which all involve the LBD, whether at the DNA (AR amplification or LBD mutations) or RNA level (emergence of AR splice variants).

Through their potential to directly and selectively block all known means of activating the AR, the Company believes the Aniten series of compounds hold the potential to be effective in cases where current therapies have failed. Both preclinical and clinical studies support this belief. In preclinical studies, the Aniten series of compounds has been shown to shrink benign prostate tissue in mice as well as prostate cancer xenografts, including tumors both sensitive and resistant to the current generation anti-androgens such as enzalutamide. Recent studies have also suggested the potential for combinations of ESSA’s Aniten compounds with anti-androgens to potentially inhibit AR-driven biology more completely in unique and complementary mechanisms by affecting opposite ends of the AR receptor.

The Phase I clinical trial of first-generation ralaniten acetate (“EPI-506”), has confirmed the safety and tolerability for this mechanism of transcription inhibition of AR-driven biology as patients tolerated doses of the drug at overall exposures consistent with those associated with efficacy in animal models. Possible proof of concept was shown with short duration PSA declines of up to 29% being observed in some patients highly refractory to current anti-androgens. However, unlike in animals, this first-generation drug was significantly metabolized in humans, leading to a very short half-life of circulating drug. Consequently, very high doses were required to achieve the desired overall exposures, with the relatively short half-life limiting the therapeutic level exposure of the drug within a 24-hour period. This limitation, together with unfavorable pharmaceutical properties, led to the Company’s decision to discontinue EPI-506 development in favor of focusing on the development of the next generation of Anitens. The Company is now focused on developing this next generation, including more potent drugs with potentially increased resistance to metabolism as well as improved pharmaceutical properties, including expected improvements to manufacturability, stability and likelihood of successful commercial formulation.



The NTD of the AR is flexible with a high degree of intrinsic disorder making it difficult for use in crystal structure-based drug design. The Company is not currently aware of any success by other drug development companies in finding drugs that bind specifically to this drug target. The nature of the highly specific binding of the Aniten compounds to the NTD, and the biological consequences of that binding, have been defined in recent scientific studies. The selectivity of the binding, based on *in vivo* imaging as well as *in vitro* studies, is consistent with the clean toxicological profile observed with the first-generation EPI-506 and the subsequent safety profile in the Phase I trial.

The incidence of both metastatic and non-metastatic CRPC continues to rise, and using a dynamic progression model, Scher et al<sup>†</sup> have projected a 2020 incidence of 546,955 and prevalence of 3,072,480. The Company expects that the Aniten series of compounds could be effective for many of those patients. In its early clinical development, the Company intends to initially focus on patients who have failed abiraterone or enzalutamide therapies for the following reasons:

- CRPC treatment remains a prostate cancer market segment with an apparent and significant unmet therapeutic need and is therefore a potentially large market;
- the Company believes that the unique mechanism of action of its Aniten compounds is well suited to treat those patients who have failed AR LBD focused therapies, and whose biological characterization reveals that their tumors are still largely driven by AR biology;
- the Company expects that the large number of patients with an apparent unmet therapeutic need in this area will facilitate timely enrollment in its clinical trials; and
- the Company believes that a successful Phase I clinical trial will facilitate the early study of the combination of ESSA's Aniten compound with anti-androgens such as enzalutamide or apalutamide.

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 initial series of compounds, which include EPI-002 and EPI-506. The Company licensed the original EPI-family of drugs from UBC and the BCCA. The Company is party to a license agreement with the BCCA and UBC dated December 22, 2010, as amended (the “**License Agreement**”), which provides the Company with exclusive world-wide rights to the issued patents and patent applications in respect of the EPI-series compounds, including the next generation Aniten compounds.

The Company believes that it has developed a strong and defensive intellectual property position for multiple EPI and Aniten structural classes, with 14 active patent families, covering different structural motifs/analogues.

Patent applications are pending in the United States and in contracting states to the Patent Cooperation Treaty for the Aniten next-generation NTD inhibitors, with expiry between 2037-2039.

### Completed Phase I Clinical Study of EPI-506

The Company conducted an initial proof-of-concept Phase I clinical study utilizing the first-generation Aniten compound, EPI-506. The objective of the EPI-506 Phase I clinical trial was to explore 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 (“**mCRPC**”) who were no longer responding to either abiraterone or enzalutamide treatments, or both. Efficacy endpoints, such as PSA reduction, and other progression criteria were evaluated. Details relating to the design of the Phase I/II clinical trial of EPI-506 are available on the U.S. National Institutes of Health clinical trials website (see <https://clinicaltrials.gov>).

The Investigational New Drug (“**IND**”) application to the U.S. Food and Drug Administration (“**FDA**”) for EPI-506, to begin a Phase I 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. Based on allometric scaling, an initial dose level of EPI-506 of 80 mg was determined. However, following the enrollment of the initial cohorts, it became apparent that levels of EPI-506 were much lower in humans than the projections from the animal studies. Supported by the large therapeutic index from toxicology studies, EPI-506 dosing was escalated aggressively to allow patients in the clinical study greater exposure to the drug. The highest

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<sup>†</sup> Scher HI, Solo K, Valant J, Todd MB, Mehra M (2015) Prevalence of Prostate Cancer Clinical States and Mortality in the United States: Estimates Using a Dynamic Progression Model. PLoS ONE 10(10): e0139440. doi:10.1371/journal.pone.0139440

dose patients ultimately received was 3600 mg of EPI-506, administered in a single dose or split into two doses daily. The initial data from the Phase I clinical trial was presented at the European Society of Medical Oncology ("ESMO") meeting in September 2017.

Conducted at five sites in the United States and Canada, the open-label, single-arm, dose-escalation study evaluated the safety, pharmacokinetics, maximum-tolerated dose and anti-tumor activity of EPI-506 in men with end-stage mCRPC who had progressed after prior enzalutamide and/or abiraterone treatment and who may have received one prior line of chemotherapy. Twenty-eight patients were available for analysis, with each patient having received four or more prior therapies for prostate cancer at the time of study entry. Patients self-administered oral doses of EPI-506 ranging from 80 mg to 3600 mg, with a mean drug exposure of 85 days (range of eight to 535 days). Four patients underwent prolonged treatment (with a median of 318 days; and a range of 219 to 535 days at data cut-off), following intra-patient dose escalation. PSA declines, an indication of efficacy, ranging from 4% to 29% were observed in five patients, which occurred predominantly in the higher dose cohorts ( $\geq 1280$  mg).

EPI-506 was generally well-tolerated with a favorable safety profile having been demonstrated across all doses up to 2400 mg. At a dose of 3600 mg, gastrointestinal adverse events (nausea, vomiting and abdominal pain) were observed in two patients: one patient in the once-daily ("QD") dosing cohort and one patient in the 1800 mg twice-daily dosing cohort, leading to study discontinuation and a dose-limiting toxicity ("DLT") due to more than 25% of doses being missed in the 28-day safety reporting period. A separate patient in the 3600 mg QD cohort experienced a transient Grade 3 increase in liver enzymes (AST/ALT), which also constituted a DLT, and enrollment was consequently concluded in this cohort.

Although the safety profile and possible signs of efficacy at higher-dose levels support the concept that inhibiting the AR NTD may provide a clinical benefit to mCRPC patients, the pharmacokinetic and metabolic studies revealed that the challenges encountered in achieving exposures similar to those associated with efficacy in the animal models were due to the greatly increased metabolism of EPI-506 in patients as compared to rodents. In light of these discoveries, ESSA concluded that prioritizing the development of one of its Aniten next-generation NTD inhibitors that, in the Company's discovery program, had demonstrated greater potency, reduced metabolism and other enhanced pharmaceutical properties offered a more compelling regulatory and commercial pathway forward. As a result, the Company announced on September 11, 2017 its decision to discontinue the further clinical development of EPI-506 and to implement a corporate restructuring plan to focus research and development resources on its next-generation Anitens targeting the AR NTD. The restructuring included a decrease in headcount and a reduction of operational expenditures related to the clinical program.

ESSA's next-generation Aniten compounds represent chemical scaffold changes to the first-generation drugs and appear to retain NTD inhibition of the AR. However, they have demonstrated an ability to improve upon a number of attributes of the first-generation compound, EPI-506. In *in vitro* assays measuring inhibition of AR transcriptional activity, these drugs demonstrate greater than 10 times higher potency than EPI-506 or its active metabolite, EPI-002. In addition, the compounds demonstrated resistance to metabolism in preclinical studies, is indicative of longer half-lives in humans. Lastly, the compounds demonstrated significantly improved pharmaceutical properties relative to EPI-506. They represent potential improvements in ease and cost of large-scale manufacture, drug product stability, and suitability for commercialization globally.

## Strategy

The Company's initial therapeutic goal is to develop a safe and effective therapy for prostate cancer patients whose tumors have progressed on current anti-androgen therapy. However, the action of the NTD-inhibiting Aniten compounds suggests that there may ultimately be additional therapeutic advantage to combining these agents with anti-androgens at an earlier stage of treatment. Therefore, while the first priority is to select and enter into Phase I development of an optional NTD inhibitor, in parallel the Company is also conducting preclinical studies of combination therapy with academic and industry collaborators.

### *Identifying an Aniten compound to take into clinical trials*

The purpose of the next-generation program has been to identify drug candidates with improved potency, reduced metabolic susceptibility and superior pharmaceutical properties compared to ESSA's first-generation compounds.



Structure-activity relation studies conducted on the chemical scaffold of ESSA's first-generation compounds have resulted in the generation of a new series of compounds that have demonstrated higher potency and predicted longer half-lives. Additional changes in the chemical scaffold have also been incorporated with the goal of improving ADME and pharmaceutical properties of the chemical class.

In preclinical models of AR inhibition, several candidate molecules have displayed greater than 10 times higher potency than EPI-002.

On March 26, 2019, the Company announced the nomination of EPI-7386 as its lead clinical candidate for the treatment of mCRPC through inhibition of the N-terminal domain of the androgen receptor. In preclinical studies, EPI-7386 has displayed activity *in vitro* in numerous prostate cancer models including models where current antiandrogens are inactive and compared to ESSA's first generation compound, ralaniten acetate, EPI-7386 is significantly more potent, metabolically stable and more effective in preclinical studies. In addition, EPI-7386 has demonstrated a favorable tolerability profile in all animal studies of the compound conducted to date.

At the Genitourinary Cancers Symposium on February 14, 2019 the Company presented a poster that showed that EPI-7386 demonstrates *in vitro* cellular potency against the androgen receptor in a similar range to the leading antiandrogens, bicalutamide and enzalutamide. Importantly, EPI-7386 shows activity in numerous *in vitro* models of antiandrogen resistance driven by the AR-V7 splice variant of the androgen receptor while enzalutamide is inactive. In addition, EPI-7386 is metabolically stable in liver microsome and hepatocyte preparations and shows a favorable pharmacokinetic profile in mice, exhibiting significant exposure and a long half-life. Also, EPI-7386 (60 mg/kg) displayed comparable activity to enzalutamide (30 mg/kg) in a prostate cancer LNCaP xenograft mouse model in which enzalutamide mouse exposure was estimated to be twice the clinical exposure of enzalutamide in humans.

IND-enabling studies are currently underway, and ESSA expects to enter clinical studies with EPI-7386 in the first calendar quarter of 2020.

#### *Advancing a potential future product candidate through clinical development and regulatory approval in CRPC patients*

Following IND approval of a development candidate, the Company intends to conduct a Phase I clinical trial to determine the safety, tolerability, maximum tolerated dose, pharmacokinetics and potential therapeutic benefits of the drug in mCRPC patients. Depending on the number of cohorts enrolled, the Phase I clinical trial is expected to take nine to twelve months. At this time, it is expected that the design of the Phase I clinical trial will be the standard three patients per dose cohort. All patients will be characterized biologically for underlying tumor genomic characteristics, for evidence of AR pathway activation and for dose-related pharmacological and pharmacodynamic effects. Once the Phase I clinical trial is complete, the Company plans to review the data, including the safety, tolerability, evidence of efficacy and pharmacological and biomarker data. This information will inform the final size, design, timing and clinical as well as biological characteristics of the patients to be entered into a potential Phase II clinical trial.

#### *Developing a potential future product candidate as an essential component of a new standard of care for the treatment of pre-CRPC and expanding usage earlier in the disease stage*

An activated AR is required for the growth and survival of most prostate cancer, and NTD inhibition of AR-directed biology occurs both in full length AR, vARs and in the setting of the multiple resistance mechanisms affecting the anti-androgens which work through the opposite end of the AR. The Company, therefore, believes that the AR NTD is an ideal target for next-generation hormone therapy. If ESSA's potential future product candidate is successful in treating CRPC patients, it is reasonable to expect that such clinical candidate may be effective in treating earlier stage patients. Therefore, the Company may conduct additional clinical studies potentially, leading to the approval of a clinical candidate for use in prostate cancer patients at an earlier disease stage likely in combination with anti-androgens. The Company is currently generating *in vitro* and *in vivo* data in collaboration with academic and industry investigators in this regard. Preliminary data indicates that there may be potential benefits to combining an NTD inhibitor, such as an Aniten compound, with an anti-androgen that works through inhibition of the LBD of the AR. Other emerging potential clinical applications for NTD inhibitors are in combination with other agents, such as poly ADP ribose polymerase inhibitors, as well as in the subset of metastatic breast cancer patients whose tumors have been demonstrated to have activation of the AR pathway.

*Evaluating strategic collaborations to maximize value*

The Company currently retains all commercial rights for its EPI and Aniten series drug portfolio. The Company continues to evaluate potential collaborations that could enhance the value of its prostate cancer program and allow it to leverage the expertise of such strategic collaborators.

**CORPORATE UPDATE AND OVERALL PERFORMANCE**

ESSA is a preclinical stage company and does not currently generate revenue. During the six months ended March 31, 2019, the Company recorded a comprehensive loss of \$6,140,554 (2018 - \$6,472,897). As of March 31, 2019, the Company had cash resources of \$8,597,639 (September 30, 2018 - \$14,829,144) and working capital of \$5,371,772 (September 30, 2018 - \$12,252,309).

Effective April 25, 2018, the Company consolidated its issued and outstanding common shares on the basis of one (1) post-consolidation common share for every twenty (20) pre-consolidation common shares. Unless otherwise stated, all share and per share amounts have been restated retrospectively to reflect this share consolidation.

This corporate update highlights significant events and transactions for the six months ended March 31, 2019 and for the subsequent period to the date of this MD&A.

**Corporate and Finance Highlights***Exercise of Pre-Funded Warrants*

On October 1, 2018, the Company issued 535,000 common shares to Omega Fund IV, L.P. upon the exercise of 535,000 pre-funded warrants originally issued in an equity financing in January 2018.

*Change to the Company's Board of Directors*

On October 18, 2018, Dr. Otello Stampacchia of Omega Fund Management, LLC, was appointed to the board of directors of the Company; concurrently, the Company granted 12,000 stock options, exercisable at \$3.58 per share for a period of ten years, to Dr. Stampacchia in relation to his appointment.

*Stock Option Grant*

On February 8, 2019, the Company granted a total of 238,000 stock options to directors, officers, employees and consultants, exercisable at either C\$5.06 or US\$3.81 for a period of 10 years.

**Research and Development Milestones***Progress in the selection of a potential future product candidate and filing an IND*

During the period from the fourth calendar quarter of 2017 to the first calendar half of 2019, the Company has conducted and will continue to conduct preclinical studies on the next-generation Aniten compounds. During such period, there are two key research and development milestones that the Company aims to achieve:

- First milestone: the selection of a most promising candidate from the Aniten compounds, which will need to meet specific criteria, for the Company to take into the clinical trial stage. The Company recently announced the selection of EPI-7386 as its IND candidate.
- Second milestone: the filing and approval with respect to the selected candidate of an IND with the FDA and a CTA with Health Canada. IND-enabling studies on EPI-7386 are currently underway and the Company expects to enter clinical studies with EPI-7386 in the first calendar quarter of 2020.

## DISCUSSION OF OPERATIONS

### Preclinical Studies

The Company is focused on the advancement of next-generation Aniten NTD inhibitors designed to improve upon the properties of the first-generation compound, EPI-002, and its prodrug EPI-506. A series of oral small molecule compounds have been identified which, while retaining the common mechanism of action to interfere with AR-mediated signaling, hold the promise of improved properties such as enhanced potency, reduced susceptibility to metabolism and improved drug-like properties. Several of these compounds are currently being characterized in more detail with the goal of selecting a next-generation development compound based on certain established criteria. The Company also continues to conduct preclinical combination studies.

These next-generation compounds were discovered through chemical modification of the first-generation drug, EPI-002. Specific chemical changes to the structure of EPI-002 have resulted in increased potency in an *in vitro* AR-based gene transcription assay, exhibiting greater than 10 times higher potency than EPI-002. The ability of the first in the series of these next-generation molecules to reduce tumor growth was confirmed in a human prostate cancer xenograft model. In this preclinical study, the next-generation compound reduced tumor growth compared to the control using low daily doses of the drug. This next-generation compound also inhibited *in vitro* cellular proliferation of an enzalutamide-resistant cell line.

In addition to higher potency, the next-generation compounds are designed to reduce the metabolism of these agents following oral dosing compared to EPI-002. Excessive metabolism of a drug candidate may reduce the effective exposure levels of a drug and necessitate frequent and excessive dosing requirements. Specific modifications in the chemical structure of these molecules were made in an attempt to block known sites of metabolism of EPI-002. A series of *in vitro* studies examining drug metabolism were conducted with the next-generation compounds. Results indicated that several of these compounds, with the additional chemical modifications, may be metabolized more slowly than EPI-002 in humans. Currently, the Company is conducting animal pharmacokinetic studies to verify the initial *in vitro* metabolism results. If this *in vitro* and *in vivo* data is replicated in patients, the reduced metabolism of the next-generation compounds may be expected to improve their pharmacokinetic profile and daily dose requirements following oral dosing compared to EPI-002.

Importantly, the next-generation compounds exhibiting less *in vitro* metabolism were tested against off-target screening. Significant off-target binding of drug candidates could lead to unanticipated toxicity. Broad characterization of these compounds has demonstrated minimal non-specific binding properties in this off-target screening, indicating a favorable selectivity profile for further development. Following the preclinical characterization of the most promising of these next-generation compounds, the Company selected EPI-7386 as its IND candidate.

### Future Clinical Development Program

#### *Phase I/II Clinical Trial Design for treating CRPC patients*

The Company recently selected EPI-7386 as its IND candidate. If the Company successfully attains approval of any IND or CTA, the Company will conduct a Phase I/II clinical trial to determine the safety, tolerability, maximum tolerated dose, pharmacokinetics, and efficacy of the compound in CRPC patients. In a Phase I study, it is expected the clinical trial will evaluate the safety, tolerability, pharmacokinetics, and maximum-tolerated dose of the compound, in multiple-dose escalations. Learnings from the Phase I clinical trial of EPI-506 will be incorporated into the design and conduct of potential future trials. The Company plans to include, for example, extensive biological characterization of the patients entered into the trial. If the Phase I portion of the clinical trial is successful, the Phase II portion (dose expansion) of the clinical trial will evaluate activity in a target group of biologically-characterized mCRPC patients.

#### *Early Conduct of a Combination Phase I/II Clinical Trial*

Given the evolution of prostate cancer therapeutics towards combination therapy strategies, the biological rationale for combining NTD and LBD inhibitors, and compelling early *in vitro* and preclinical animal model results, the

Company may perform combination studies of the next-generation Aniten compound with current generation anti-androgens.

### Phase III Clinical Trial

In order to ultimately obtain full regulatory approval, the Company expects that at least one Phase III clinical trial will be required, most likely in patients similar to the population of mCRPC patients that will have been enrolled in the planned Phase I/II clinical trial. However, the results of the Phase I/II clinical trial may also suggest modification of the initial patient population based on response and biomarker assessment. In a Phase III clinical trial, the key end-point is expected to be progression-free survival or overall survival relative to patients receiving the standard-of-care. It is expected that such a Phase III clinical trial would be conducted at numerous sites around the world.

## SELECTED QUARTERLY FINANCIAL INFORMATION

The following table summarizes selected unaudited consolidated financial data for each of the last eight quarters, prepared in accordance with IFRS. The Company has not earned any revenues or declared dividends as of March 31, 2019.

	For the Quarters Ended			
	March 31, 2019	December 31, 2018	September 30, 2018	June 30, 2018
Total assets	\$ 9,612,421	\$ 13,214,847	\$ 16,017,074	\$ 18,512,377
Long-term liabilities	2,215,701	2,824,827	3,520,664	4,134,529
Research and development expense	1,454,077	1,286,323	926,839	987,792
General and administration	1,762,212	1,247,108	1,211,159	1,579,420
Comprehensive loss	\$ (3,429,787)	\$ (2,710,767)	\$ (2,276,430)	\$ (2,880,113)
Basic loss per share	(0.54)	(0.43)	(0.39)	(0.50)
Diluted loss per share	(0.54)	(0.43)	(0.39)	(0.50)

	For the Quarters Ended			
	March 31, 2018	December 31, 2017	September 30, 2017	June 30, 2017
Total assets	\$ 22,334,083	\$ 3,433,234	\$ 5,607,044	\$ 8,405,965
Long-term liabilities	4,797,841	5,421,942	6,103,835	7,105,830
Research and development expense	1,989,107	969,597	1,165,917	2,920,181
General and administration	2,179,717	958,375	1,105,295	1,302,314
Comprehensive income (loss)	\$ (4,382,956)	\$ (2,089,941)	\$ (1,945,299)	\$ 3,592,404
Basic income (loss) per share	(0.83)	(1.44)	(1.34)	2.47
Diluted income (loss) per share	(0.83)	(1.44)	(1.34)	2.32

The Company's quarterly results have varied and may, in the future, vary depending on numerous factors, including the rate of expenditure relative to financial capacity and operational plans, the status and timing of CPRIT Grant funding, fluctuations in the Company's derivative liabilities, and whether the Company has granted any stock options. Certain of these factors may not be predictable to the Company. CPRIT Grant funding has been taken proportionately into income against research and development ("R&D") expenses incurred to date, which in some cases may have been incurred in previous quarters. Fluctuations on derivative liabilities are discussed below under the subheading "Derivative liabilities" section below. The granting of stock options results in share-based payment charges, reflecting the vesting of such stock options.

In the quarter ended September 30, 2018, the Company recorded the partial receipts of the third tranche of the CPRIT Grant of \$229,201, which was recognized as recoveries of R&D expenditures. The CPRIT Grant is detailed in the accompanying condensed consolidated interim financial statements and risks relating to the CPRIT Grant, including risk that the Company may default on the residual obligations of the agreement providing for the CPRIT Grant, are described under the heading “*Risk Factors*” in the Company’s Annual Report on Form 20-F for the fiscal year ended September 30, 2018, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on the EDGAR website at [www.sec.gov](http://www.sec.gov).

In the quarter ended March 31, 2018, the Company completed the January 2018 Financing (as defined below) for gross proceeds of approximately \$26,040,000 resulting in an increase in assets.

### Six months ended March 31, 2019 and 2018

The Company incurred a comprehensive loss of \$6,140,554 for the six months ended March 31, 2019 compared to a comprehensive loss of \$6,472,897 for the six months ended March 31, 2018.

Other significant changes in comprehensive loss are as follows:

#### *Research and Development*

- The overall R&D expense for the six months ended March 31, 2019 was \$2,740,400 compared to \$2,958,704 for the six months ended March 31, 2018. R&D expense in 2019 was incurred primarily in preclinical research on the Company’s next-generation Aniten compounds, which commenced in September 2017. R&D expense in 2019 also includes the costs of winding down the EPI-506 Phase I clinical trial, which was terminated in September 2017, and associated chemistry, manufacturing and controls costs.
- Consulting fees were \$169,151 for the six months ended March 31, 2019 compared to \$433,188 for the six months ended March 31, 2018 and include amounts paid to the Chief Scientific Officer and Chief Technical Officer for monthly consulting fees and bonuses pursuant to consulting agreements – see “*Related Party Transactions*” below. The prior period also included R&D consultants working on the winding down of the EPI-506 Phase I clinical trial, which was terminated in September 2017.
- Legal patents and license fees have increased to \$450,976 for the six months ended March 31, 2019 compared to \$263,981 for the six months ended March 31, 2018. The increase is due to the Company’s patent applications on its next-generation compounds as compared to the prior period which included the abandonment of the family of patents related to EPI-506 in relation to the Company’s termination of the clinical trial in September 2017. 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.
- Clinical costs of \$nil (2018 - \$1,165,072), manufacturing costs of \$3,312 (2018 - \$173,927), and pharmacology costs of \$nil (2018 - \$177,049) for the six months ended March 31, 2019 have decreased as a result of the Company’s winding down of the EPI-506 Phase I clinical trial, which was terminated in September 2017.
- Preclinical costs of \$1,261,436 (2018 - \$nil) for the six months ended March 31, 2019 were incurred in the development of the Company’s next-generation Aniten compounds. In the six months ended March 31, 2018, preclinical costs were primarily incurred internally and under the collaborative research agreements with the BCCA and UBC – see the discussion of research grants and administration costs below.
- Research grants and administration costs were \$152,416 (2018 - \$191,076) for the six months ended March 31, 2019 and relate to amounts payable pursuant to collaborative research agreements with the BCCA and UBC. Amounts incurred vary in relation to timing of milestone payments pursuant to such agreements.

- Salaries and benefits have increased to \$424,144 (2018 - \$367,196) for the six months ended March 31, 2019 as a result of increased preclinical and clinical staff involved in the development of the Company's next-generation Aniten compounds.

R&D expenses include the following major expenses for the three and six months ended March 31, 2019 and 2018:

	Three months ended March 31, 2019	Three months ended March 31, 2018	Six months ended March 31, 2019	Six months ended March 31, 2018
Clinical	\$ -	\$ 1,008,515	\$ -	\$ 1,165,072
Consulting	94,820	123,951	169,151	433,188
Legal patents and license fees	177,440	141,415	450,976	263,981
Manufacturing	2,000	80,512	3,312	173,927
Other	14,224	16,245	20,464	17,890
Pharmacology	-	134,350	-	177,049
Preclinical	603,575		1,261,436	
Research grants and administration	152,416	111,483	152,416	191,076
Royalties	65,405	66,929	65,405	66,929
Salaries and benefits	245,741	204,604	424,144	367,196
Share-based payments (Note 10*)	92,851	90,855	182,903	85,396
Travel	5,605	10,248	10,193	17,000
<b>Total</b>	<b>\$ 1,454,077</b>	<b>\$ 1,989,107</b>	<b>\$ 2,740,400</b>	<b>\$ 2,958,704</b>

\* See the Notes set out in the accompanying condensed consolidated interim financial statements for the six months ended March 31, 2019 and 2018.

Share-based payments of \$182,903 (2018 - \$85,396) for the six months ended March 31, 2019 relate to the value assigned to stock options granted to key management and consultants of the Company conducting research and development activities. The expense is recognized in relation to the grant and vesting of these equity instruments as measured by the Black-Scholes pricing model.

#### *General and administrative*

General and administration expenses for the six months ended March 31, 2019 increased to \$3,009,320 from \$3,138,092 in the comparative period in 2018. Significant components of such expenses in the current period included:

- Director fees of \$118,000 (2018 - \$112,083) were incurred in relation to various meetings held by the board of directors of the Company (the "**Board**") and various committees during the period; fees in the current period were paid to five directors, compared to four directors in the prior period.
- Investor relations expense of \$144,827 (2018 - \$143,282) was incurred in relation to investor relations consultants, shareholder communications and news releases.
- Professional fees for legal and accounting services of \$385,157 (2018 - \$429,876) were incurred in conjunction with the corporate activities in the current period, including additional preparatory work on financing strategy and the Company's annual regulatory filings.
- Rent expense has decreased to \$85,898 (2018 - \$216,298) as a result of reduced costs related to relocation to more cost-effective office space in Houston in June 2018.
- Salaries and benefits expense has increased to \$1,306,767 (2018 - \$1,261,925) due to corporate staffing such as the Chief Executive Officer, Chief Financial Officer, and Chief Operating Officer, as disclosed under the heading "Related Party Transactions", and additional general administrative support staff.



- Insurance expense of \$231,256 (2018 - \$228,530) relates to insurance coverage for directors and officers of the Company as a reporting issuer and publicly listed company in the United States, as well as general liability insurance.

General and administrative expenses include the following major expenses for the three and six months ended March 31, 2019 and 2018:

	Three months ended March 31, 2019	Three months ended March 31, 2018	Six months ended March 31, 2019	Six months ended March 31, 2018
Amortization	\$ 4,574	\$ 9,971	\$ 9,148	\$ 19,943
Consulting and subcontractor fees	25,239	37,001	51,404	55,908
Director fees	55,000	64,333	118,000	112,083
Insurance	116,978	113,696	231,256	228,530
Investor relations	103,540	98,428	144,827	143,282
Office, IT and communications	28,497	40,544	43,023	66,168
Professional fees	135,684	336,274	385,157	429,876
Regulatory fees and transfer agent	38,092	120,508	55,087	140,746
Rent	42,983	105,429	85,898	216,298
Salaries and benefits	935,458	906,629	1,306,767	1,261,925
Share-based payments (Note 10*)	223,556	293,264	469,721	387,111
Travel and entertainment	<u>52,611</u>	<u>53,640</u>	<u>109,032</u>	<u>76,222</u>
<b>Total</b>	<b>\$ 1,762,212</b>	<b>\$ 2,179,717</b>	<b>\$ 3,009,320</b>	<b>\$ 3,138,092</b>

\* See the Notes set out in the accompanying condensed consolidated interim financial statements for the six months ended March 31, 2019 and 2018.

Share-based payments expense of \$469,721 (2018 - \$387,111) for the six months ended March 31, 2019 relates to the value assigned to stock options granted to key management and consultants of the Company. The expense is recognized in relation to the grant and vest of these equity instruments as measured by the Black-Scholes pricing model.

#### *Derivative liabilities*

The Company has certain warrants treated as derivatives for financial reporting purposes. Consequently, the Company's financial results are impacted by fluctuations in the market price of the Company's common stock. These warrants, as well as some broker warrants, are measured at fair value, with changes recognized in the statement of loss and comprehensive loss at each reporting date. During the six months ended March 31, 2019, the Company recorded the resulting change in fair value, largely resulting from the increase in stock price during the period, of \$3,765 (2018 - \$97,813) 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 six months ended March 31, 2019 and 2018.

#### **Three months ended March 31, 2019 and 2018**

The Company incurred a comprehensive loss of \$3,429,787 for the three months ended March 31, 2019 compared to a comprehensive loss of \$4,382,956 for the three months ended March 31, 2018. The detailed changes in R&D and G&A expenses for the three months ended March 31, 2019 and 2018 are included in the tables above.

For the three months ended March 31, 2019, the Company incurred R&D costs in relation to the termination of its clinical studies of EPI-506 and continued its development of the next-generation Aniten compound, whereas in the comparative period in 2018 the Company was continuing its clinical studies of EPI-506; this is reflected in decreased clinical costs of \$nil (2018 - \$1,008,515), decreased manufacturing costs of \$2,000 (2018 - \$80,512), and decreased

pharmacology costs of \$nil (2018 - \$134,350) in relation to the clinical studies of EPI-506, offset by increased preclinical costs of \$603,575 (2018 - \$nil) relating to the Aniten compound development.

G&A expenses of \$1,762,212 (2018 - \$2,179,717) for the three months ended March 31, 2019 have decreased over the prior period, in particular for professional fees of \$135,684 (2018 - \$336,274) and regulatory and transfer agent fees of \$38,092 (2018 - \$120,508) in relation to the January 2018 financing, the annual general meeting held in March 2018, and the 1:20 share consolidation in April 2018. Salaries and benefits of \$935,458 (2018 - \$906,629) for the three months ended March 31, 2019 also reflect bonuses paid to senior management during the period.

### USE OF PROCEEDS

The Company did not complete any financings during the six months ended March 31, 2019.

During the year ended September 30, 2018, the Company received total net proceeds of \$23,654,101 from an equity financing of 4,321,000 common shares and 2,189,000 pre-funded warrants at a price of \$4.00 each, for total gross proceeds \$26,040,000 (the "**January 2018 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
<i>The development of EPI-506 Phase I/II clinical program through Phase I/ Preclinical development of next-generation Aniten compounds</i>	<p>The proceeds were initially used as intended to further the development of the EPI-506 Phase I/II clinical trial program while meeting administrative requirements, up until the fourth quarter of the fiscal year ended September 30, 2017, during which time the EPI-506 Phase I/II clinical trial program was terminated.</p> <p>During the six months ended March 31, 2019, the Company incurred \$2,557,497 in cash R&amp;D costs in relation to the preclinical costs of the Aniten next generation compound, as well as close-out costs related to the termination of the EPI-506 Phase I/II clinical trial program. An additional \$2,530,451 has been incurred for cash general and administrative costs in support of the Company's research and development activities. The Company also completed \$1,378,145 and \$227,231 in principal and interest payments, respectively, on a capital term loan with Silicon Valley Bank (the "SVB Term Loan"), pursuant to which the Company has currently drawn down \$8,000,000.</p> <p>During the year ended September 30, 2018, the Company incurred \$4,873,335 in cash R&amp;D costs, net of recoveries, in relation to the preclinical costs of the Aniten next generation compound, as well as close-out costs related to the termination of the EPI-506 Phase I/II clinical trial program. An additional \$5,928,671 has been incurred for cash general and administrative costs in support of the Company's research and development activities. The Company also completed \$1,991,378 and \$563,298 in principal and interest payments, respectively, on the SVB Term Loan.</p> <p>As at March 31, 2019, the Company has not yet fully expended the funds raised in its January 2018 Financing towards the preclinical development of its next-generation Aniten compounds.</p>

## LIQUIDITY AND CAPITAL RESOURCES

As at March 31, 2019, the Company has working capital of \$5,371,772 (September 30, 2018 - \$12,252,309). Operational activities during the six months ended March 31, 2019 were financed mainly by proceeds from the January 2018 Financing. At March 31, 2019, the Company had available cash reserves of \$8,597,639 (September 30, 2018 - \$14,829,144) and accounts receivable of \$243,660 (September 30, 2018 - \$297,349) related primarily to the final CPRIT Grant payment and GST input tax credits, to settle current liabilities of \$3,732,578 (September 30, 2018 - \$3,344,338). The Company believes that it will require additional funds to satisfy its obligations as they become due and execute its planned expenditures through the fiscal 2019 year, including the funding of a Phase 1 clinical study of a next-generation Aniten compound and to meet obligations under the SVB Term Loan.

Cash used in operating activities for the six months ended March 31, 2019 was \$4,605,736 (2018 - \$5,178,018). Working capital items provided cash of \$511,301 (2018 - \$415,242 cash generated).

There were no cash flows from investing activities for the six months ended March 31, 2019 and 2018.

Cash used in financing activities for the six months ended March 31, 2019 was \$1,605,376 (2018 - \$22,910,566), including \$1,378,145 (2018 - \$657,340) and \$227,231 (2018 - \$291,959) in principal and interest paid in relation to the SVB Term Loan. In the six months ended March 31, 2018, the Company received \$26,040,000 in gross proceeds received from the January 2018 financing, offset by \$2,180,135 in share issuance costs.

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 preclinical activities as well as possible unanticipated costs resulting from strategic opportunities that may arise in the future. 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 the funds necessary to continue the preclinical development of its next-generation Anitens targeting the AR NTD and for its other operational activities (see "Risk Factors").

## CONTRACTUAL OBLIGATIONS

As of March 31, 2019, 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.

Contractual obligations	2019	2020	2021	2022	2023	After 5 years
Minimum annual royalty per License Agreement (CAD) (1)	C\$ -	C\$ 85,000	C\$ 85,000	C\$ 85,000	C\$ 85,000	C\$ 680,000
Collaborative Research Agreement with BCCA (CAD)	<u>174,037</u>	-	-	-	-	-
Total (in CAD)	C\$ 174,037	C\$ 85,000	C\$ 85,000	C\$ 85,000	C\$ 85,000	C\$ 680,000
Total (in USD) (2)	\$ 130,238	\$ 63,608	\$ 63,608	\$ 63,608	\$ 63,608	\$ 508,868
SVB loan payments (USD)	\$ 1,605,377	\$ 4,045,744	\$ -	\$ -	\$ -	\$ -
Lease on U.S. office spaces (USD)	\$ 58,809	\$ 119,383	\$ 70,670	\$ -	\$ -	\$ -
Total (USD)	\$ 1,794,424	\$ 4,228,735	\$ 134,278	\$ 63,608	\$ 63,608	\$ 508,868

## Notes:

- (1) ESSA has the worldwide, exclusive right to develop products based on "Licensed IP", as defined in, and pursuant to, 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. Pursuant to the License Agreement, the Company was required to 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, would have been due upon the enrolment of the first patient in Phase II and Phase III of the EPI-506 clinical trial, respectively, which had been expected to occur in 2017 and 2018.
- (2) Converted based on the indicative exchange rate of the Bank of Canada of C\$1.00 = \$0.7483 as at March 31, 2019.

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

The Company has no material 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 business acquisitions or dispositions 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 six months ended March 31, 2019 and 2018 was as follows:

<b>Name and Relationship</b>	<b>Nature of compensation</b>	<b>2019</b>	<b>2018</b>
Richard Glickman, Director and Chairman of the Board	Director fees <sup>(1)</sup>	\$ 31,500	\$ 33,500
Gary Sollis, Director	Director fees <sup>(1)</sup>	24,000	26,000
Franklin Berger, Director	Director fees <sup>(1)</sup>	24,000	24,000
Scott Requadt, Director	Director fees <sup>(1)</sup>	22,000	24,000
Hugo Beekman, Former Director	Director fees <sup>(1)(2)</sup>	-	4,583
Dr. Otello Stampacchia, Director	Director fees <sup>(1)(2)</sup>	16,500	-
Dr. Marianne Sadar, Director and Chief Scientific Officer	Consulting fees and bonus <sup>(3)</sup>	68,731	201,163
Dr. Raymond Andersen, Director and Chief Technical Officer	Consulting fees and bonus <sup>(4)</sup>	68,731	121,607
Dr. David R. Parkinson, Chief Executive Officer	Salary and bonus <sup>(5)</sup>	389,641	439,697
David Wood, Chief Financial Officer	Salary and bonus <sup>(6)</sup>	188,333	227,696
Peter Virsik, Executive Vice-President and Chief Operating Officer	Salary and bonus <sup>(7)</sup>	344,464	329,412
Dr. Frank Perabo, former Chief Medical Officer	Salary and bonus <sup>(8)</sup>	-	230,928
Directors and officers	Share-based payments <sup>(9)</sup>	553,773	454,650
<b>Total compensation</b>		<b>\$ 1,731,673</b>	<b>\$ 2,117,236</b>

## Notes:

- (1) The Company compensates its independent directors as follows: annual retainer of \$25,000, additional annual retainer of \$25,000 for the Chairman of the Board, additional annual retainer of \$10,000 for committee chairs, \$1,500 per board meeting attended in person, and \$1,000 for all other board and subcommittee meetings.
- (2) Amounts are payable to Omega Funds Management LLC, a company in which Mr. Beekman was a Principal, and Dr. Stampacchia is the Managing Director.
- (3) On December 22, 2010, the Company and Dr. Marianne Sadar entered into a consulting agreement, subsequently amended February 1, 2013 and February 1, 2015, whereby Dr. Sadar received a monthly consulting fee of C\$15,000 and various bonuses payable on the achievement of milestones such as IND filings, contracted research objectives, publications and the filing of patents. The consulting agreement expired on January 31, 2018. Under a new consulting agreement, effective February 1, 2018, Dr. Sadar will receive an annual consulting fee of C\$180,000 (C\$15,000 monthly) for the first and second year of the term and an annual consulting fee of C\$120,000 (C\$10,000 monthly) for the third and fourth year of the term. Dr. Sadar is also eligible for a bonus of up to 25% of the annual consulting fee upon accomplishment of certain objectives as agreed upon by all parties.
- (4) On December 22, 2010, the Company and Dr. Raymond Andersen entered into a consulting agreement, subsequently amended February 1, 2013 and February 1, 2015, whereby Dr. Andersen received a monthly consulting fee of C\$10,000 and various bonuses payable on achievement of milestones such as IND filings, contracted research objectives, publications and the filing of patents. The consulting agreement expired on January 31, 2018. Under a new consulting agreement, effective February 1, 2018, Dr. Andersen will receive an annual consulting fee of C\$180,000 (C\$15,000 monthly) for the first and second year of the term and an annual consulting fee of C\$120,000 (C\$10,000 monthly) for the third and fourth year of the term. Dr. Andersen is also eligible for a bonus of up to 25% of the annual consulting fee upon accomplishment of certain objectives as agreed upon by all parties.
- (5) Dr. David R. Parkinson receives a base salary of \$474,346 per annum, increased from \$451,758 effective January 1, 2019, and a performance-based bonus per annum of up to 50% of his base salary.
- (6) David Wood receives a base salary of \$246,376 per annum, increased from \$236,900 effective January 1, 2019, and a performance-based bonus per annum of up to 40% of his base salary.
- (7) Peter Virsik receives a base salary of \$400,387 per annum, increased from \$375,950 effective January 1, 2019, and a performance-based bonus per annum of up to 40% of his base salary.
- (8) Dr. Frank Perabo received a base salary of \$447,372 per annum. Dr. Perabo resigned as the CMO of the Company effective January 31, 2018.
- (9) 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”); David Wood, Chief Financial Officer (“CFO”); Peter Virsik, Executive Vice-President and Chief Operating Officer (“COO”); Dr. Frank Perabo, CMO (who resigned from such role effective January 31, 2018); Dr. Marianne Sadar, Director; Dr. Raymond Andersen, Director; Richard Glickman, Director and Chairman of the Board; Gary Sollis, Director; Franklin Berger, Director; Scott Requadt, Director, Dr. Otello Stampacchia, Director (appointed October 18, 2018), and Hugo Beekman, Director (who resigned from such role effective May 30, 2018).

During the six months ended March 31, 2019, the Company modified nil (2018 – 73,000) options held by and granted 197,000 (2018 – 682,000) options to key management personnel. The vesting of options granted to key management personnel in prior periods was recorded as a share-based payments expense in the statement of income and comprehensive income at a value of \$556,579 for the six months ended March 31, 2019 (2018 - \$ 454,650).

Included in accounts payable and accrued liabilities as at March 31, 2019 is \$147,849 (September 30, 2018 - \$128,035) due to Richard Glickman, Gary Sollis, Franklin Berger, Scott Requadt, and Omega Funds Management, LLC 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. This amount increases to 18 months if the termination without cause occurs after a change of control event or within 60 days prior to a change of control event where such event was under consideration at the time of termination. Mr. Wood, CFO, is entitled to a payment of one year of base salary upon termination without cause, whether or not the termination was caused by a change of control event. Mr. Virsik, COO, is entitled to a payment of one year of base salary upon

termination without cause. 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, 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 six months ended March 31, 2019 and 2018 are consistent with those policies detailed in Notes 2 and 3 of the Company's annual consolidated financial statements for the years ended September 30, 2018, 2017 and 2016, except for the following:

#### *IFRS 9 Financial Instruments*

On October 1, 2018, the Company adopted IFRS 9 *Financial Instruments* ("IFRS 9"), which was issued by the IASB in October 2010. IFRS 9 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. There was no impact to the Company's financial instruments resulting from the adoption of IFRS 9.

#### *IFRS 15 Revenue from Contracts with Customers*

On October 1, 2018, the Company adopted IFRS 15 *Revenue from Contracts with Customers* ("IFRS 15"), which 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 did not have an impact on the Company's financial statements.

#### **New standards not yet adopted**

#### *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. On adoption of IFRS 16, the Company expects to capitalize leases currently disclosed in Note 16 resulting in an increase in lease liabilities and a corresponding right of use asset.

### 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 has met certain terms and conditions to qualify for the grant 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.

*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 these inputs. The Company makes reference to prices quoted on the TSX (prior to November 27, 2017) and the TSX-V (following November 27, 2017), as applicable, and Nasdaq. The assumptions and models used for estimating fair value for share-based payment transactions are discussed in Note 10 of the accompanying condensed consolidated interim financial statements. Share-based payments are recorded under R&D and G&A expenditures.

*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 Quarterly Financial Information - Derivative liabilities.*"

## FINANCIAL INSTRUMENTS AND RISKS

The Company's financial instruments consist of cash, receivables, accounts payable and accrued liabilities, long-term debt and derivative liabilities. The fair value of cash, receivables and accounts payable and accrued liabilities approximates their carrying values due to their short term to maturity. The fair value of the SVB Term Loan is approximately \$5,356,753 which includes the principal and financing costs assessed on settlement as at March 31, 2019. The SVB Term Loan bears an interest rate of the Wall Street Journal 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 the termination of the SVB Term Loan. The SVB Term Loan contains a voluntary prepayment option whereby the principal amount can be prepaid in whole or in part. 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 defaults in the event of a material adverse change. There are no financial covenants under the SVB Term Loan. The derivative liabilities are measured using level 3 inputs. During the six months ended March 31, 2019, the Company recognized a loss on derivative liability of \$3,675 (2018 – \$97,813 gain) 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 March 31, 2019, the Company had working capital of \$5,371,772. The SVB Term Loan is repayable over a 33 month period ending September 1, 2020. The Company does not generate revenue and will be reliant on external financing to fund operations and repay the SVB Term Loan. Management continues to seek sources of additional financing which would assure continuation of the Company's operations and research programs. However, there is no certainty that such financing will be provided or provided on favorable terms. Management plans to complete a financing in sufficient time to continue to execute its planned expenditures without interruption.

#### *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 March 31, 2019, 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 Wall Street Journal Prime Rate would result in an increase of \$18,552 or decrease of \$12,366 in the net loss realized for the period.

## (b) Foreign currency risk

The Company's foreign currency risk exposure relates to net monetary assets denominated in Canadian dollars. The Company maintains its cash in US dollars and converts on an as needed basis to discharge Canadian denominated expenditures. A 10% change in the foreign exchange rate between the Canadian and U.S. dollar would result in a fluctuation of \$17,513 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](http://www.sedar.com), the website of the SEC at [www.sec.gov](http://www.sec.gov) and the Company's website at [www.essapharma.com](http://www.essapharma.com). The Company's Annual Report on Form 20-F for the fiscal year ended September 30, 2018 also provides additional information on the Company, and can be accessed through SEDAR at [www.sedar.com](http://www.sedar.com) or the website of the SEC at [www.sec.gov](http://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	6,311,098
Stock options	1,149,961
Warrants	2,127,686

### 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 for the fiscal year ended September 30, 2018, which is posted on SEDAR at [www.sedar.com](http://www.sedar.com) and on the SEC's EDGAR website at [www.sec.gov](http://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 aforementioned Annual Report on Form 20-F to be the most significant to potential investors in the Company, but are not all of the risks associated with an investment in securities of the Company.

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

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

### Disclosure Controls and Procedures

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 March 31, 2019. 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 March 31, 2019, 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 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 United States Securities and Exchange Act of 1934, as amended, 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 January 1, 2019 to March 31, 2019 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 CEO and CFO, 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 is also 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.