



**FORM 51-102F1  
MANAGEMENT'S DISCUSSION AND ANALYSIS  
FOR THE YEARS ENDED SEPTEMBER 30, 2019, 2018 and 2017**

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## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FOR THE YEARS ENDED SEPTEMBER 30, 2019, 2018 AND 2017

This management's discussion and analysis ("**MD&A**") of ESSA Pharma Inc. (the "**Company**" or "**ESSA**") for the years ended September 30, 2019, 2018 and 2017 is dated as of December 18, 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 audited consolidated financial statements for the years ended September 30, 2019, 2018 and 2017, and the related notes thereto. The consolidated financial statements are prepared in accordance with International Financial Reporting Standards ("**IFRS**"). Financial information presented in this MD&A is presented in United States dollars ("**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.

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 product candidate and 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 product candidate and 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 Realm Acquisition and the Company's ability to effectively liquidate Realm (as such terms are defined herein) and assume the related obligations;
- the use of proceeds from the August 2019 Financing (as defined herein);
- 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 product candidate and 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 product candidate and 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:

- 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 product candidates in a timely manner;
- 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 (as such terms are defined herein);
- risks related to the Company's ability to successfully commercialize future product candidates;
- the possibility that the Company's product candidate and potential future product candidates may have undesirable side effects;
- 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;
- the risk that third parties may not carry out their contractual duties;
- risks related to the possibility that the Company's relationships with clinical research organizations (as defined herein) and academic institutions 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;
- 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 product candidate and 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;
- 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;
- risks related to the Realm Acquisition, the liquidation of Realm, and the assumption of related obligations;
- 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 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 reliance on proprietary technology;
- risks related to the Company's ability to protect its intellectual property rights throughout the world;
- risks related to claims by third parties asserting that the Company, or its employees or consultants 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 product candidate and 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 is 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 standard of care therapies, including second-generation anti-androgen drugs such as abiraterone, enzalutamide, apalutamide, and darolutamide. 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 anti-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 N-terminal domain (“NTD”) of the AR. In this respect, ESSA’s compounds differ from classical non-steroid 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 from the NTD (i.e. “lutamides”) or to androgen synthesis (i.e. abiraterone). 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 administered to patients with metastatic CRPC (“mCRPC”) refractory to current standard of care therapies.

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 (darolutamide, enzalutamide, apalutamide or bicalutamide) to the AR, or inhibit synthesis of androgens (abiraterone). More recently, significant improvements in progression-free survival 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 an 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 prostate cancer xenografts, including tumors both sensitive and resistant to the second-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 indicated 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 37% being observed in some patients whose disease was highly refractory to second-generation anti-androgens treatment. However, unlike in animals, this first-generation drug was significantly metabolized in humans, leading to a very short half-life of circulating drug and suboptimal drug exposures. Consequently, very high doses were required to achieve modest drug 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 of anitens, including more potent drugs with potentially increased resistance to metabolism as well as advanced pharmaceutical properties, including expected advancements in 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 1 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 second-generation anti-androgen therapies (i.e. abiraterone and/or lutamides) 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; and
- 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.

Furthermore, ESSA believes that a successful Phase I clinical trial will facilitate the early study of the combination of the ESSA Aniten compound with second-generation anti-androgens. The Company and its collaborators have developed preclinical *in vitro* and *in vivo* evidence supporting the combination of NTD inhibitors together with the LBD inhibiting anti-androgens. The application of two independent, complementary mechanisms of AR transcription inhibition may result in greater suppression of androgen activity and the delay or prevention of drug resistance. Recent progress in the clinical treatment of prostate cancer has resulted from the earlier utilization of anti-androgens in combination with classic androgen deprivation therapy ("ADT"), consistent with the premise that more effective androgen suppression yields clinical benefit. The introduction of NTD inhibitors would have the potential of further improving androgen suppression and delaying the emergence of resistance.

The Company is party to a license agreement with the British Columbia Cancer Agency ("BCCA") and the University of British Columbia ("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 related to the EPI-002 compound.

The Company believes that it has developed a strong and defensive intellectual property position for multiple EPI and Aniten structural classes, with 16 pending and maintained patent families 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 2036-2040.

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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

### 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 anti-tumor activity in asymptomatic or minimally symptomatic patients with mCRPC who were no longer responding to either abiraterone or enzalutamide treatments, or both. Efficacy endpoints, such as PSA reduction, and other disease 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 EPI-506 exposure was much lower in humans than projected. EPI-506 dosing was escalated aggressively to allow patients in the clinical study greater exposure to the drug. The highest 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 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 37% 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 anti-tumor activity 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 anti-tumor activity 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 multiple chemical scaffold changes to the first-generation drugs and appear to retain NTD inhibition of the AR. However, they have demonstrated an ability to advance 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 20 times higher potency than EPI-506 or its active metabolite, EPI-002. In addition, the compounds demonstrated resistance to metabolism in preclinical studies, suggesting likely longer half-lives in humans. Lastly, the compounds demonstrated significantly superior pharmaceutical properties relative to EPI-



506. They represent potential advancements in ease and cost of large-scale manufacture, drug product stability, and suitability for commercialization globally. From this series of next-generation compounds, EPI-7386 was selected as the IND candidate and preparations for IND filing are currently underway.

### 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 characterize 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 as well as exploring other potential applications for AR-NTD inhibitors, including breast cancer.

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

The purpose of the next-generation program has been to identify drug candidates with increased 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. Multiple 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 met these goals, and 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 NTD of the androgen receptor. In preclinical studies, EPI-7386 has displayed activity *in vitro* in numerous prostate cancer models including models where second-generation anti-androgens are inactive and compared to ESSA's first-generation compound, EPI-506, 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.

On October 28, 2019 at the 2019 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, an oral poster presentation titled "Treatment of castrated resistant prostate cancer, with EPI-7386, a second generation N-terminal domain androgen receptor inhibitor", presented a deeper preclinical characterization of EPI-7386. The poster showed that pre-clinical studies demonstrate that EPI-7386 (i) displays similar *in vitro* IC50 potency compared to the lutamide class of antiandrogens in an *in vitro* androgen receptor (AR) inhibition assay; (ii) shows *in vitro* activity in several enzalutamide-resistant prostate cancer cell models; (iii) exhibits a favorable metabolic profile across three preclinical animal species (which suggests that EPI-7386 will have high exposure and a long half-life in humans) (iv) provides similar antitumor activity to enzalutamide in the enzalutamide-sensitive LNCaP prostate cancer xenograft model, and (v) provides superior antitumor activity to enzalutamide, as a single agent or in combination with enzalutamide, in the enzalutamide emerging-resistant VCaP prostate cancer xenograft model, specifically showing AR inhibition with both an N-terminal domain inhibitor (EPI-7386) and a ligand binding domain inhibitor (enzalutamide), induces deeper and more consistent anti-tumor responses in the enzalutamide emerging-resistant VCaP xenograft model; (vi) antitumor activity in enzalutamide-resistant prostate cancer xenograft models, 22Rv1 and LNCaP95, with no antitumor activity, as expected, in a non-functional androgen receptor PC-3 prostate cancer xenograft model; (vii) wide therapeutic index as demonstrated by a broad dose response in the VCaP model; (viii) high plasma exposures in animal studies using a new suspension formulation.

IND-enabling studies are currently underway, and ESSA expects to file an IND in the first calendar quarter of 2020.

#### *Advancing a 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 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 anti-androgen hormone therapy. If ESSA's 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 second-generation 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 year ended September 30, 2019, the Company recorded a comprehensive loss of \$10,441,865 (2018 - \$11,629,440; 2017 - \$4,499,012). As of September 30, 2019, the Company had cash resources of \$53,322,723 (2018 - \$14,829,144) and working capital of \$48,724,264 (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 year ended September 30, 2019 and for the subsequent period to the date of this MD&A.

### Corporate and Finance Highlights

#### *Equity Financing*

On August 27, 2019, the Company closed a public offering of equity securities of the Company in Canada and a concurrent private placement of equity securities in the United States (the "**August 2019 Financing**"). The Company issued a total of 6,080,596 common shares in the capital of the Company and 11,919,404 pre-funded common share purchase warrants of the Company in lieu of common shares of the Company at a price of \$2.00 per security for aggregate gross proceeds of \$36,000,000. Each pre-funded warrant entitles the holder thereof to acquire one common share at a nominal exercise price for a period of five years. In connection with the August 2019 Financing, the Company paid total cash commissions of \$1,978,770 and incurred other financing costs of \$687,510.

The August 2019 Financing was led by Soleus Capital and includes RA Capital Management as a new investor. Existing investors, including BVF Partners LP, Omega Funds, and Eventide Funds, among others, also participated.

#### *SVB Term Loan Repayment*

On October 17, 2019, the Company repaid, early and at its option, its capital term loan under which the Company had received total net proceeds of \$7,779,063 from Silicon Valley Bank in the year ended September 30, 2017 (the "**SVB Term Loan**"). The Company repaid the balance of principal of \$2,953,968 and remaining finance costs of \$698,503.

#### *Stock Option Grants*

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.

On June 10, 2019, the Company granted 5,000 stock options to an employee, exercisable at \$2.20 for a period of 10 years.

On October 4, 2019, the Company granted 1,441,530 stock options to directors, officers, employees and consultants at an exercise price of \$3.23 for a period of 10 years. Additionally, the board of directors approved an amended stock option and amended restricted share unit plan to provide for a maximum of 6,251,469 common shares. The Company granted 2,551,470 stock options under the amended stock option plan to certain employees at a weighted average price of \$3.23 for a period of 10 years. Options granted under the amended stock option plan may not be exercised by the optionees until the amended plan is approved by the shareholders and regulators.

On October 17, 2019, the Company amended 42,000 stock options held by a former director such that they were immediately vested, and the expiry date was extended for a period of one year from date of resignation.

On October 30, 2019, the Company granted 225,000 stock options to non-executive members of the board of directors at an exercise price of \$4.67 for a period of 10 years.

#### *Acquisition of Realm Therapeutics plc*

On July 31, 2019, the Company completed the acquisition (the "**Realm Acquisition**") of Realm Therapeutics plc ("**Realm**") pursuant to a scheme of arrangement under Part 26 of the U.K. Companies Act 2006 ("**Scheme**") as sanctioned by the High Court of Justice in England and Wales, on July 29, 2019. Under the terms of the Realm Acquisition, ESSA acquired all of the issued and outstanding shares of Realm, and Realm shareholders received a total of 6,718,150 common shares of the Company ("**New ESSA Shares**") at a ratio of 0.5763 New ESSA Share per each one share of Realm (or 1.4409 New ESSA Shares for every one Realm ADS (as defined in the Scheme), representing 25 Realm shares), based on a 60-day volume-weighted average price of \$3.19 per share of ESSA on May 14, 2019.

At the closing of the Realm Acquisition, the Company acquired net assets of \$20,247,296 from Realm, including \$22,244,248 in cash. The Company is in the process of liquidating Realm and its subsidiary.

#### *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 at a price of \$0.002 per common share for gross proceeds of \$1,070, originally issued in the January 2018 Financing (as defined herein).

On June 26, 2019, the Company issued 1,652,530 common shares upon the cashless exercise of 1,653,999 pre-funded warrants originally issued in the January 2018 Financing.

On July 31, 2019, the Company issued 749,332 common shares upon the cashless exercise of 749,999 pre-funded warrants on June 26, 2019 to Biotechnology Value Fund and certain affiliated funds (collectively, "**BVF**"). BVF was, prior to the Scheme becoming effective, shareholders of both ESSA and Realm, and received 1,310,866 New ESSA

Shares upon the Scheme becoming effective. BVF holds 2,640,566 common shares of the Company, representing 17.99% of the issued and outstanding common shares of the Company.

#### *Changes 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. Dr. Stampacchia resigned October 17, 2019.

On June 26, 2019, Dr. Marianne Sadar did not stand for re-election to the board of directors of the Company.

On July 31, 2019, pursuant to the closing of the Realm Acquisition and the terms of the Scheme, Dr. Raymond Andersen resigned from the board of directors of the Company, and Mr. Alex Martin, Ms. Marella Thorell, and Mr. Sanford (Sandy) Zweifach were appointed to the board of directors of the Company.

On October 17, 2019, Dr. Ari Brettman, nominee of Clarus Lifsciences III, L.P., was appointed to the board of directors.

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

##### *Progress in the selection of a product candidate and filing an IND*

During the period from the fourth calendar quarter of 2017 to the first calendar quarter of 2020, 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 announced the selection of EPI-7386 as its IND candidate in March 2019.
- Second milestone: the filing and approval with respect to the selected candidate of an IND with the FDA. IND-enabling studies on EPI-7386 are currently underway and the Company expects to file an IND in the first calendar quarter of 2020.

### **DISCUSSION OF OPERATIONS**

#### **Preclinical Studies**

The Company is focused on the advancement of EPI-7386, a next-generation Aniten NTD inhibitor.

This next-generation compound was discovered through significant chemical structure-based activity efforts. In an *in vitro* AR-based gene transcription assay, EPI-7386 exhibited greater than 20 times higher potency than EPI-002. The ability of EPI-7386 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, EPI-7386 and other 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 dose administration. Specific modifications in the chemical structure were made in an attempt to block the known sites of metabolism of EPI-002. A series of *in vitro* studies examining drug metabolism were conducted with EPI-7386 and other next-generation compounds. Results indicated that several of these compounds, including EPI-7386, may be metabolized more slowly than EPI-002 in humans. The Company has conducted animal pharmacokinetic studies which verify the initial *in vitro* metabolism results and predict a drug half-life in patients over 24 hours.

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 EPI-7386 and other Anitens 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 and IND-preparation toxicology studies are being conducted.

### **Future Clinical Development Program**

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

The Company has selected EPI-7386 as its IND candidate and IND-preparatory studies are underway. If the Company successfully attains approval of any IND or CTA, the Company will conduct a Phase I 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 the Phase I and 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 and it is the Company's intent to conduct early studies of EPI-7386 in combination with anti-androgens.

#### *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 who 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 anti-tumor 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 ANNUAL FINANCIAL INFORMATION**

ESSA was incorporated on January 6, 2009 and did not engage in any material financial or commercial activity until commencing operations in 2010. The Company has not earned revenues or declared dividends as of September 30, 2018.

The following table sets forth selected consolidated financial information for the periods indicated. The selected consolidated financial information set out below for the years ended September 30, 2019, 2018, and 2017 has been derived from our audited consolidated financial statements and accompanying notes, in each case prepared in accordance with IFRS.

The selected consolidated financial information set out below may not be indicative of ESSA's future performance.

| <b>For the year ended September 30</b> | <b>2019</b> |              | <b>2018</b> |              | <b>2017</b> |             |
|--|-------------|--------------|-------------|--------------|-------------|-------------|
| Revenue                                | \$          | Nil          | \$          | Nil          | \$          | Nil         |
| Research and development expenses      |             | 6,696,234    |             | 4,873,335    |             | 5,726,366   |
| Total operating expenses               |             | 12,772,464   |             | 11,713,965   |             | 11,651,870  |
| Comprehensive loss                     |             | (10,441,865) |             | (11,629,440) |             | (4,499,012) |
| Loss per share – basic and diluted     |             | (1.24)       |             | (2.55)       |             | (3.09)      |
| Total assets                           |             | 54,773,824   |             | 16,017,074   |             | 5,607,044   |
| Total long-term liabilities            |             | 18,179       |             | 3,520,664    |             | 6,103,835   |
| Cash dividends declared per share      |             | Nil          |             | Nil          |             | Nil         |

### Years ended September 30, 2019, 2018 and 2017

The Company incurred a comprehensive loss of \$10,441,865 for the year ended September 30, 2019 compared to a comprehensive loss of \$11,629,440 for the year ended September 30, 2018 and \$4,499,012 for the year ended September 30, 2017. In the year ended September 30, 2019, the Company completed the Realm Acquisition which resulted in a non-recurring transaction gain of \$2,332,954. The Company recognized recoveries against research and development expenditures of \$nil, \$229,201, and \$5,192,799 in the years ended September 30, 2019, 2018, and 2017, respectively, resulting in reduced research and development expenses in those years. In addition, as part of the Company's January 2016 financing, the Company issued warrants, as well as warrants in connection with the SVB Term Loan, which are derivative liabilities carried at fair value under the Black Scholes valuation methodology. Consequently, a contributing disparity in comprehensive loss over the years presented is driven by a gain of \$1,469 (2018 – \$151,095; 2017 – \$7,305,746) with respect to the fair value measurement of the Company's derivative liabilities, which reflects the decrease in the Company's stock price over those periods.

Other significant changes in comprehensive loss are as follows:

#### *Research and Development*

- The overall Research and Development (“**R&D**”) expense for the year ended September 30, 2019 was \$6,696,234 compared to \$4,873,335 for the year ended September 30, 2018 and \$5,726,366 for the year ended September 30, 2017. The gross expense for the year was \$6,696,234 (2018 - \$5,102,536; 2017 - \$10,919,165) before recognition of qualifying CPRIT Grant funds of \$nil (2018 - \$229,201; 2017 - \$5,192,799). R&D expense in 2019 and 2018 was incurred primarily in preclinical research on the Company's next-generation Aniten compounds. R&D expense in 2018 and 2017 also includes the costs of the EPI-506 Phase I clinical trial, which commenced in November 2015 and terminated in September 2017, and associated winddown and chemistry, manufacturing and controls (“**CMC**”) costs.
- Clinical costs of \$80,021 in fiscal 2019 (2018 - \$1,177,179; 2017 - \$2,623,636) relate to clinical consulting work in preparation for the expected IND filing and Phase I clinical trial of EPI-7386. Clinical costs in 2018 and 2017 were incurred in relation to the Company's winddown and completion of the EPI-506 Phase I/II clinical trial, which was terminated in September 2017.
- Consulting fees were \$301,817 in fiscal 2019 (2018 - \$624,879; 2017 - \$935,151) which vary from the comparative periods in 2018 and 2017 due primarily to a reduction in R&D consultants, including clinical/medical monitoring, CMC, and regulatory consultants working on the EPI-506 Phase I clinical trial, which was terminated in September 2017. Consulting fees also include amounts paid to the Drs. Marianne Sadar and Raymond Andersen for monthly consulting fees and bonuses pursuant to consulting agreements – see “*Related Party Transactions*” below.
- Legal patents and license fees have increased to \$781,133 in fiscal 2019 (2018 - \$561,099; 2017 - \$834,295) compared to the comparative period in 2018 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.

- Preclinical costs of \$2,789,753 (2018 - \$446,748; 2017 - \$nil) and manufacturing costs of \$946,705 (2018 - \$219,526; 2017 - \$3,571,106) for the year ended September 30, 2019 were incurred in the development of the Company's next-generation Aniten compounds having selected to advance EPI-7386 in March 2019, including current Good Manufacturing Practice ("cGMP") manufacturing. Preclinical costs in 2018 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. Manufacturing costs in 2017 were incurred in relation to the Company's EPI-506 Phase I/II clinical trial, which terminated in September 2017.
- Research grants and administration costs were \$254,970 (2018 - \$385,085, 2017 - \$38,534 recovery) 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. In 2017, the Company incurred total costs of \$392,704, and also negotiated a new collaborative research agreements, which superseded the previous agreements and resulted in the write off of \$431,238 which had been overaccrued under the previous agreements while the new agreements were in negotiation.
- Salaries and benefits, related to preclinical and clinical staff, have increased to \$1,012,344 in fiscal 2019 (2018 - \$845,428; 2017 - \$2,213,655) as a result of increased preclinical and clinical staff involved in the development of the Company's next-generation Aniten compounds, including the appointment of the Company's Chief Medical Officer in July 2019. In 2018, salaries and benefits decreased compared to 2017 due to the corporate structuring in September 2017 that led to reduced clinical staff in Texas. In addition, the Company's former Chief Medical Officer resigned in January 2018.

R&D expenses include the following major expenses by nature for the years ended September 30, 2019, 2018, and 2017:

| For the year ended September 30                     | 2019                | 2018                | 2017                |
|---|---------------------|---------------------|---------------------|
| Clinical  | \$ 80,021           | \$ 1,177,179        | \$ 2,623,636        |
| Consulting  | 301,817             | 624,879             | 935,151             |
| Legal patents and license fees                      | 781,133             | 561,099             | 834,295             |
| Manufacturing                                       | 946,705             | 219,526             | 3,571,106           |
| Other   | 111,750             | 40,845              | 187,228             |
| Pharmacology  | -                   | 372,509             | 407,373             |
| Preclinical   | 2,789,753           | 446,748             | -                   |
| Research grants and administration                  | 254,970             | 385,085             | (38,534)            |
| Royalties   | 65,405              | 66,929              | 48,863              |
| Salaries and benefits                               | 1,012,344           | 845,428             | 2,213,655           |
| Share-based payments (Note 11*)                     | 304,786             | 324,528             | (3,870)             |
| Travel  | 47,550              | 37,781              | 140,262             |
| CPRIT Grant claimed on eligible expenses (Note 18*) | -                   | (229,201)           | (5,192,799)         |
| <b>Total</b>  | <b>\$ 6,696,234</b> | <b>\$ 4,873,335</b> | <b>\$ 5,726,366</b> |

\* See the Notes set out in the accompanying consolidated financial statements for the years ended September 30, 2019, 2018 and 2017.

Share-based payments of \$304,786 in fiscal 2019 (2018 - \$324,528, 2017 - \$3,870 recovery) relates to the value assigned to stock options granted to key management and consultants of the Company conducting research and development activities. The expense is recognized in relation to the grant and vesting of these equity instruments as measured by the Black-Scholes pricing model.

*General and administrative*

General and administration expenses for the year ended September 30, 2019 were comparable at \$5,473,486 from \$5,928,671 in the comparative period in 2018 and \$5,140,921 in the comparative period in 2017. Significant components of such expenses in the current period included:

- Director fees of \$252,000 in fiscal 2019 (2018 - \$196,472; 2017 - \$191,500) were incurred in relation to various meetings held by the board of directors of the Company (the “**Board**”) and various committees during the year. On July 31, 2019, in connection with the Realm Acquisition, the Company appointed three additional members to the Board.
- Investor relations expense of \$319,373 (2018 - \$235,416; 2017 - \$230,579) was incurred in relation to investor relations consultants, shareholder communications and news releases.
- Professional fees for legal and accounting services of \$675,412 in fiscal 2019 (2018 - \$860,435; 2017 - \$612,865) and regulatory fees and transfer agent costs of \$91,764 in fiscal 2019 (2018 - \$150,913; 2017 - \$74,600) were incurred in conjunction with ongoing corporate activities in the current year. Professional fees and regulatory fees incurred in fiscal 2018 include the voluntary downlisting from the Toronto Stock Exchange (the “**TSX**”) to the TSX-V, the 1:20 share consolidation, and the base shelf prospectuses filed in July 2018. Professional fees and regulatory fees incurred in fiscal 2017 related to the undertaking of a United States R&D tax credit study.
- Rent expense has decreased to \$192,479 in fiscal 2019 (2018 - \$415,744; 2017 - \$470,716) 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 \$2,072,746 in fiscal 2019 (2018 - \$2,010,613; 2017 - \$1,863,634) 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 \$471,852 (2018 - \$449,972; 2017 - \$395,690) 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 by nature for the years ended September 30, 2019, 2018, and 2017:

| <b>For the year ended September 30</b> | <b>2019</b>         | <b>2018</b>         | <b>2017</b>         |
|--|---------------------|---------------------|---------------------|
| Amortization                           | \$ 18,297           | \$ 34,488           | \$ 46,145           |
| Consulting and subcontractor fees      | 142,780             | 96,986              | 86,931              |
| Director fees                          | 252,000             | 196,472             | 191,500             |
| Insurance                              | 471,852             | 449,972             | 395,690             |
| Investor relations                     | 319,373             | 235,416             | 230,579             |
| Office, IT and communications          | 155,208             | 216,714             | 187,364             |
| Professional fees                      | 675,412             | 860,435             | 612,865             |
| Regulatory fees and transfer agent     | 91,764              | 150,913             | 74,600              |
| Rent                                   | 192,479             | 415,744             | 470,716             |
| Salaries and benefits                  | 2,072,746           | 2,010,613           | 1,863,634           |
| Share-based payments (Note 11*)        | 841,921             | 1,076,886           | 762,797             |
| Travel and entertainment               | <u>239,654</u>      | <u>184,032</u>      | <u>218,100</u>      |
| <b>Total</b>                           | <b>\$ 5,473,486</b> | <b>\$ 5,928,671</b> | <b>\$ 5,140,921</b> |

\* See the Notes set out in the accompanying consolidated financial statements for the years ended September 30, 2019, 2018 and 2017.



Share-based payments expense of \$841,921 in fiscal 2019 (2018 - \$1,076,886; 2017 - \$762,797) 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 issued and outstanding which are treated as derivative liabilities and increase the Company's exposure to fluctuations in the market price of the Company's common stock. Under a cashless exercise, these warrants are exercisable for a variable number of common shares of the Company, resulting in embedded derivatives for which the Company has recognized derivative liabilities. These warrants are measured at fair value, with changes recognized in the statement of loss and comprehensive loss at each reporting date. During the year ended September 30, 2019, the Company recorded the resulting change in fair value, largely resulting from the decrease in stock price during the year, of \$1,469 (2018 - \$151,095; 2017 - \$7,305,746) in the statement of loss and comprehensive loss.

Derivative warrant liabilities are discussed under the heading "*Critical Accounting Estimates*" and Note 9 of the accompanying consolidated financial statements for the years ended September 30, 2019, 2018 and 2017.

### 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 September 30, 2019.

#### For the Quarters Ended

|                                    | September 30,<br>2019 | June 30,<br>2019 | March 31,<br>2019 | December 31,<br>2018 |
|------------------------------------|-----------------------|------------------|-------------------|----------------------|
| Total assets                       | \$ 54,773,824         | \$ 7,072,204     | \$ 9,612,421      | \$ 13,214,847        |
| Long-term liabilities              | 18,179                | 1,413,047        | 2,215,701         | 2,824,827            |
| Research and development expense   | 2,004,750             | 1,951,084        | 1,454,077         | 1,286,323            |
| General and administration         | 1,251,000             | 1,213,166        | 1,762,212         | 1,247,108            |
| Comprehensive loss                 | \$ (999,527)          | \$ (3,301,784)   | \$ (3,429,787)    | \$ (2,710,767)       |
| Loss per share – basic and diluted | (0.07)                | (0.52)           | (0.54)            | (0.43)               |

#### For the Quarters Ended

|                                    | September 30,<br>2018 | June 30,<br>2018 | March 31,<br>2018 | December 31,<br>2017 |
|------------------------------------|-----------------------|------------------|-------------------|----------------------|
| Total assets                       | \$ 16,017,074         | \$ 18,512,377    | \$ 22,334,083     | \$ 3,433,234         |
| Long-term liabilities              | 3,520,664             | 4,134,529        | 4,797,841         | 5,421,942            |
| Research and development expense   | 926,839               | 987,792          | 1,989,107         | 969,597              |
| General and administration         | 1,211,159             | 1,579,420        | 2,179,717         | 958,375              |
| Comprehensive loss                 | \$ (2,276,430)        | \$ (2,880,113)   | \$ (4,382,956)    | \$ (2,089,941)       |
| Loss per share – basic and diluted | (0.39)                | (0.50)           | (0.83)            | (1.44)               |

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, 2019, the Company completed the Realm Acquisition, acquiring net assets of \$20,247,296, incurring professional fees of \$1,925,145 and recognizing a gain on acquisition of \$2,332,954. The Company also completed the August 2019 Financing for gross proceeds of \$36,000,000, resulting in an increase in assets.

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 consolidated 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, 2019, which is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on the SEC’s Electronic Data Gathering and Retrieval System, or “**EDGAR**” website at [www.sec.gov](http://www.sec.gov).

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

### Three months ended September 30, 2019 and 2018

The Company incurred a comprehensive loss of \$999,527 for the three months ended September 30, 2019 compared to a comprehensive loss of \$2,276,430 for the three months ended September 30, 2018. Significant differences between the periods include a gain on the Realm Acquisition of \$2,332,954 (2018 - \$nil), CPRIT Grant recoveries of \$nil (2018 - \$229,201) recognized against gross R&D expenditures of \$2,004,750 (2018 - \$1,156,040), and a loss in derivative liability of \$9,933 (2018 - \$20,787 gain). Other significant changes in comprehensive loss are as follows:

#### *Research and Development*

- The overall R&D expense for the three months ended September 30, 2019 was \$2,004,750 compared to \$926,839 for the three months ended September 30, 2018. R&D expense in 2019 was incurred primarily in preclinical work on the Company’s clinical candidate EPI-7386 which was selected in March 2019. In the three months ended September 30, 2018, the Company was continuing its research and development of its next-generation Aniten compounds in order to make a candidate selection.
- Clinical costs of \$80,021 in 2019 (2018 - \$9,844) relate to clinical consulting work in preparation for the expected IND filing and Phase I clinical trial of EPI-7386.
- Consulting fees were \$61,859 for the three months ended September 30, 2019 compared to \$93,879 for the three months ended September 30, 2018 and include amounts paid to the Chief Scientific Officer and Chief Technical Officer for monthly consulting fees and bonuses pursuant to their respective consulting agreements – see “*Related Party Transactions*” below. Consulting fees have reduced from the prior period as the Company has made its candidate selection and therefore has been utilizing internal staff to take the candidate forward.
- Legal patents and license fees have increased to \$110,413 for the three months ended September 30, 2019 compared to \$41,646 for the three months ended September 30, 2018. The increase is due to the Company’s patent applications on its next-generation compounds as compared to the prior period which followed 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.

- Preclinical costs of \$830,015 (2018 - \$366,248) and manufacturing costs of \$501,764 (2018 - \$10,850) for the three months ended September 30, 2019 were incurred in the development of the Company's next-generation Aniten compounds, including cGMP manufacturing of EPI-7386. Preclinical costs in 2018 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 \$nil (2018 - \$144,308) for the three months ended September 30, 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 \$319,055 (2018 - \$220,162) for the three months ended September 30, 2019 as a result of increased preclinical and clinical staff involved in the development of the Company's next-generation Aniten compounds, including the appointment of the Company's Chief Medical Officer in July 2019.

R&D expenses include the following major expenses for the three months ended September 30, 2019 and 2018:

| <b>For the three months ended September 30</b>      | <b>2019</b> |                  | <b>2018</b> |                |
|---|-------------|------------------|-------------|----------------|
| Clinical  | \$          | 80,021           | \$          | 9,844          |
| Consulting  |             | 61,859           |             | 93,879         |
| Legal patents and license fees                      |             | 110,413          |             | 41,646         |
| Manufacturing                                       |             | 501,764          |             | 10,850         |
| Other   |             | 36,695           |             | 15,790         |
| Pharmacology  |             | -                |             | 101,248        |
| Preclinical   |             | 830,015          |             | 366,248        |
| Research grants and administration                  |             | -                |             | 144,308        |
| Salaries and benefits                               |             | 319,055          |             | 220,162        |
| Share-based payments (Note 11*)                     |             | 49,577           |             | 143,485        |
| Travel  |             | 15,351           |             | 8,580          |
| CPRIT Grant claimed on eligible expenses (Note 18*) |             | -                |             | (229,201)      |
| <b>Total</b>  | <b>\$</b>   | <b>2,004,750</b> | <b>\$</b>   | <b>926,839</b> |

\* See the Notes set out in the accompanying consolidated financial statements for the years ended September 30, 2019, 2018 and 2017.

Share-based payments of \$49,577 (2018 - \$143,485) for the three months ended September 30, 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 three months ended September 30, 2019 increased to \$1,251,000 from \$1,211,159 in the comparative period in 2018. Significant components of such expenses in the current period included:

- Director fees of \$70,500 (2018 - \$35,750) were incurred in relation to various meetings held by the Board and various committees during the period. On July 31, 2019, in connection with the Realm Acquisition, the Company appointed three additional members to the Board.
- Investor relations expense of \$102,729 (2018 - \$39,421) was incurred in relation to investor relations consultants, shareholder communications and news releases. Increased costs for the current period relate to the Realm Acquisition and the August 2019 Financing.

- Professional fees for legal and accounting services of \$114,460 (2018 - \$154,507) were incurred in conjunction with the corporate activities in the current period.
- Rent expense of \$53,901 (2018 - \$54,407) is comparable to the previous period.
- Salaries and benefits expense has increased to \$387,793 (2018 - \$359,790) 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 \$124,262 (2018 - \$112,367) 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 three months ended September 30, 2019 and 2018:

| <b>For the three months ended September 30</b> | <b>2019</b>         | <b>2018</b>         |
|--|---------------------|---------------------|
| Amortization                                   | \$ 4,574            | \$ 4,575            |
| Consulting and subcontractor fees              | 65,900              | 19,621              |
| Director fees                                  | 70,500              | 35,750              |
| Insurance                                      | 124,262             | 112,367             |
| Investor relations                             | 102,729             | 39,421              |
| Office, IT and communications                  | 70,853              | 66,155              |
| Professional fees                              | 114,460             | 154,507             |
| Regulatory fees and transfer agent             | 8,585               | (24,025)            |
| Rent   | 53,901              | 54,407              |
| Salaries and benefits                          | 387,793             | 359,790             |
| Share-based payments (Note 11*)                | 189,141             | 346,303             |
| Travel and entertainment                       | <u>58,302</u>       | <u>42,288</u>       |
| <b>Total</b>                                   | <b>\$ 1,251,000</b> | <b>\$ 1,211,159</b> |

\* See the Notes set out in the accompanying consolidated financial statements for the years ended September 30, 2019, 2018 and 2017.

Share-based payments expense of \$189,141 (2018 - \$346,303) for the three months ended September 30, 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 three months ended September 30, 2019, the Company recorded the resulting change in fair value, largely resulting from the increase in stock price during the period, of \$9,933 (2018 - \$20,787 gain) in the statement of loss and comprehensive loss.

Derivative warrant liabilities are discussed under the heading "Critical Accounting Estimates" and Note 9 of the accompanying consolidated financial statements for the years ended September 30, 2019, 2018 and 2017.

### USE OF PROCEEDS

During the year ended September 30, 2019, the Company received total net proceeds of \$36,000,000 pursuant to the August 2019 Financing. The Company issued a total of 6,080,596 common shares and 11,919,404 pre-funded warrants in lieu of common shares of the Company at a price of \$2.00 per security. Each pre-funded warrant entitles the holder thereof to acquire one common share at a nominal exercise price for a period of five years.

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   |
|---|--|
| <p><i>Preclinical development of next-generation Aniten compounds</i></p> | <p>The proceeds under the January 2018 Financing were intended for use toward the advancement of the preclinical and clinical development of the Company's next-generation Aniten compounds. Additionally, the funds were intended for use for the interest and principal payments on the Company's SVB Term Loan and general corporate purposes. Having selected EPI-7386 in March 2019, the August 2019 Financing will be used primarily to complete the Phase 1 dose-escalation and extension studies, Phase 1 combination studies with recent anti-androgens and preliminary work on Phase II studies. In addition, the Company plans to conduct preclinical studies with EPI-7386 in additional prostate and breast cancer models as well as to continue the preclinical development of additional Aniten molecules. According to current plans, the net proceeds combined with the company's current cash reserves are expected to provide sufficient cash resources through 2022.</p> <p>During the year ended September 30, 2019, the Company incurred \$6,391,448 in cash R&amp;D costs in relation to the preclinical costs of the Aniten next generation compound. An additional \$4,613,268 has been incurred for cash general and administrative costs in support of the Company's research and development activities. The Company also completed \$2,808,823 and \$401,929 in principal and interest payments, respectively, on the SVB Term Loan, pursuant to which the Company initially drew 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 September 30, 2019, the Company has not yet fully expended the funds raised in its August 2019 Financing towards the preclinical development of its next-generation Aniten compounds.</p> |

### LIQUIDITY AND CAPITAL RESOURCES

As at September 30, 2019, the Company has working capital of \$48,724,264 (2018 - \$12,252,309; 2017 - \$1,281,551). Operational activities during the year ended September 30, 2019 were financed mainly by proceeds from the January

2018 Financing. At September 30, 2019, the Company had available cash reserves of \$53,322,723 (2018 - \$14,829,144; 2017 - \$3,957,185) and accounts receivable of \$360,800 (2018 - \$297,349; 2017 - \$29,475) related primarily to the final CPRIT Grant payment and GST input tax credits, to settle current liabilities of \$5,274,744 (2018 - \$3,344,338; 2017 - \$3,777,212). The Company believes that it has sufficient capital to satisfy its obligations as they become due and execute its planned expenditures through the fiscal 2022 year, provided there are no significant changes in capital structure and debt obligations.

Cash used in operating activities for the year ended September 30, 2019 was \$12,249,935 (2018 - \$10,218,046; 2017 - \$17,354,811). Working capital items used cash of \$1,257,852 (2018 - \$659,557; 2017 - \$1,918,043).

Cash used in investing activities for the year ended September 30, 2019 was \$45,507 (2018 - \$201,399; 2017 - \$nil), including \$246,906 paid on the termination of the Realm sublease, offset by \$201,399 in relation to the refund of a deposit paid on an office lease in the prior year.

Cash generated from in financing activities for the year ended September 30, 2019 was \$50,810,826 (2018 - \$21,310,498; 2017 - \$12,326,784), including \$22,244,248 acquired in the Realm Acquisition, less transaction costs paid of \$1,860,341, \$36,000,000 in gross proceeds from the August 2019 Financing offset by \$2,362,329 in share issuance costs, and \$2,808,823 and \$401,929 in principal and interest paid in relation to the SVB Term Loan. In the year ended September 30, 2018, the Company generated \$26,040,000 in gross proceeds received from the January 2018 financing, offset by \$2,174,826 in share issuance costs and \$1,991,378 and \$563,298 in principal and interest paid in relation to the SVB Term Loan. In the year ended September 30, 2017, the Company generated cash of \$12,326,784 from financing activities including \$5,192,799 as a partial receipt of the third and final tranche of the CPRIT Grant, \$8,000,000 in gross proceeds received from the SVB Term Loan, and \$2,939 in proceeds received on exercise of stock options, offset by \$220,937 in cash transaction costs, \$436,944 in interest paid in relation to the SVB Term Loan, and \$211,073 in deferred financing 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 and clinical 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 September 30, 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   | 2020         | 2021       | 2022       | 2023       | 2024       | After 5 years |
|---|--------------|------------|------------|------------|------------|---------------|
| Minimum annual royalty per License Agreement (CAD) <sup>(1)</sup> | C\$ 85,000   | C\$ 85,000 | C\$ 85,000 | C\$ 85,000 | C\$ 85,000 | C\$ 595,000   |
| Total (in CAD)  | C\$ 85,000   | C\$ 85,000 | C\$ 85,000 | C\$ 85,000 | C\$ 85,000 | C\$ 595,000   |
| Total (in USD) <sup>(2)</sup>                                     | \$ 64,185    | \$ 64,185  | \$ 64,185  | \$ 64,185  | \$ 64,185  | \$ 449,294    |
| SVB loan payments (USD)   | \$ 4,045,500 | \$ -       | \$ -       | \$ -       | \$ -       | \$ -          |
| Lease on U.S. office spaces (USD)                                 | \$ 119,383   | \$ 70,670  | \$ -       | \$ -       | \$ -       | \$ -          |
| Total (USD)   | \$ 4,229,068 | \$ 134,855 | \$ 64,185  | \$ 64,185  | \$ 64,185  | \$ 449,294    |

## 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 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 = \$0.7551 as at September 30, 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 years ended September 30, 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>             | \$ 61,000        | \$ 60,500        |
| Gary Sollis, Director  | Director fees <sup>(1)</sup>             | 49,000           | 45,000           |
| Franklin Berger, Director  | Director fees <sup>(1)</sup>             | 48,000           | 43,500           |
| Scott Requadt, Director  | Director fees <sup>(1)(2)</sup>          | 45,000           | 41,500           |
| Otello Stampacchia, Director                                       | Director fees <sup>(1)(3)</sup>          | 33,500           | -                |
| Alex Martin, Director  | Director fees <sup>(1)</sup>             | 5,167            | -                |
| Marella Thorell, Director  | Director fees <sup>(1)</sup>             | 5,167            | -                |
| Sanford Zweifach, Director   | Director fees <sup>(1)</sup>             | 5,167            | -                |
| Hugo Beekman, former Director                                      | Director fees <sup>(1)(3)</sup>          | -                | 5,972            |
| Dr. Marianne Sadar, former Director and Chief Scientific Officer   | Consulting fees and bonus <sup>(4)</sup> | 136,052          | 289,247          |
| Dr. Raymond Andersen, former Director and Chief Technical Officer  | Consulting fees and bonus <sup>(5)</sup> | 136,052          | 194,593          |
| Dr. David R. Parkinson, Chief Executive Officer                    | Salary and bonus <sup>(6)</sup>          | 626,814          | 665,576          |
| David Wood, Chief Financial Officer                                | Salary and bonus <sup>(7)</sup>          | 311,521          | 345,219          |
| Peter Virsik, Executive Vice-President and Chief Operating Officer | Salary and bonus <sup>(8)</sup>          | 544,659          | 517,387          |
| Dr. Alessandra Cesano, Chief Medical Officer                       | Salary and bonus <sup>(9)</sup>          | 100,000          | -                |
| Dr. Frank Perabo, former Chief Medical Officer                     | Salary and bonus <sup>(10)</sup>         | -                | 230,928          |
| Directors and officers   | Share-based payments <sup>(11)</sup>     | <u>1,006,143</u> | <u>1,429,053</u> |
| Total compensation   |  | \$ 3,113,239     | \$ 3,868,475     |

## 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 in 2018 were paid to Clarus Ventures LLC, a company in which Mr. Requadt was the Managing Director.
- (3) Amounts are payable to Omega Fund Management LLC, a company in which Mr. Beekman was a Principal, and Dr. Stampacchia is the Managing Director. Dr. Stampacchia resigned from the Board on October 17, 2019.
- (4) 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. Dr. Sadar did not stand for re-election to the board of directors of the Company at the annual general meeting held on June 26, 2019.
- (5) 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. Dr. Andersen resigned from the board of directors of the Company on July 31, 2019 upon the closing of the Realm Acquisition.
- (6) 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.
- (7) 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.
- (8) 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.
- (9) Dr. Alessandra Cesano receives a base salary of \$400,000 per annum, and a performance-based bonus per annum of up to 40% of her base salary. Dr. Cesano was appointed as the CMO of the Company effective July 1, 2019.
- (10) 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.
- (11) 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. Alessandra Cesano, CMO (appointed July 1, 2019), Dr. Frank Perabo, CMO (who resigned from such role effective January 31, 2018); Dr. Marianne Sadar, Director (who did not stand for re-election on June 26, 2019); Dr. Raymond Andersen, Director (who resigned upon the closing of the Realm Acquisition effective July 31, 2019); 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 resigned October 17, 2019), Alex Martin, Director (appointed upon the closing of the Realm Acquisition effective July 31, 2019); Marella Thorell, Director (appointed upon the closing of the Realm Acquisition effective July 31, 2019); Sanford Zweifach, Director (appointed upon the closing of the Realm Acquisition effective July 31, 2019); and Hugo Beekman, Director (who resigned from such role effective May 30, 2018).

During the year ended September 30, 2019, the Company modified nil (2018 – 73,000; 2017 – Nil) options held by and granted 202,000 (2018 – 682,000; 2017 - Nil) options to key management personnel. The vesting of these options



and options granted to key management personnel in prior periods were recorded as share-based payments expense in the statement of loss and comprehensive loss at a value of \$1,146,707 (2018 - \$1,401,414; 2017 - \$758,927).

Included in accounts payable and accrued liabilities as at September 30, 2019 is \$108,331 (2018 - \$128,035) due to David Parkinson, Peter Virsik, David Wood, Richard Glickman, Gary Sollis, Franklin Berger, Scott Requadt, Clarus Ventures, LLC, Omega Fund 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, Mr. Virsik, COO, and Dr. Cesano, CMO, are 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, COO, and CMO vest immediately upon a change of control.

### CHANGES IN OR ADOPTION OF ACCOUNTING POLICIES

The accounting policies adopted in the preparation of the consolidated financial statements for the years ended September 30, 2019, 2018 and 2017 are detailed in Notes 2 and 3 of the Company's annual consolidated financial statements for the years ended September 30, 2019, 2018 and 2017:

#### *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 18 of the consolidated financial statements resulting in an increase in lease liabilities and corresponding right-of-use assets of \$165,500.

## 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.

### *Long-term debt*

The Company has made certain estimates regarding the expected timing of and value of cash flows with respect to long-term debt. The estimates will fluctuate in accordance with changes in interest rates and any prepayments made, should the Company elect to do so.

### *Income tax*

The determination of income tax is inherently complex and requires making certain estimates and assumptions about future events. Changes in facts and circumstances as a result of income tax audits, reassessments, changes to corporate structure and associated domiciling, jurisprudence and any new legislation may result in an increase or decrease the provision for income taxes. The value of deferred tax assets is evaluated based on the probability of realization; the Company has assessed that it is improbable that such assets will be realized and has accordingly not recognized a value for deferred taxes.

*Functional Currency*

The functional currency of the Company and its subsidiaries is the currency of their respective primary economic environment, and the Company reconsiders the functional currency if there is a change in events and conditions, which determined the primary economic environment. The functional currencies of the Company's entities have been judged as detailed in Note 2 of the accompanying consolidated financial statements.

*Acquisition of Realm*

The acquisition of Realm required management to make a judgment as to whether Realm constituted a business combination or an asset acquisition under the definitions of IFRS 3 *Business Combinations*. The assessment required management to assess the inputs, processes and ability of Realm to produce outputs at the time of acquisition. Pursuant to the assessment, Realm was considered an asset acquisition (Note 4 of the accompanying consolidated financial statements).

*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 has applied estimates with respect to the valuation of pre-funded warrants issued for cash. Pre-funded warrants are valued at an amount equal to the cash proceeds received.

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 11 of the accompanying consolidated 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 9 of the accompanying 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 was approximately \$3,926,075 which included the principal and financing costs assessed on settlement as at September 30, 2019. The SVB Term Loan bore 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 required 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 contained a voluntary prepayment option whereby the principal amount can be prepaid in whole or in part. The SVB Term Loan was 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 was subject to standard events of default including defaults in the event of a material

adverse change. There were no financial covenants under the SVB Term Loan. The SVB Term Loan was repaid in full on October 17, 2019. The derivative liabilities are measured using level 3 inputs. During year ended September 30, 2019, the Company recognized a gain on derivative liability of \$1,469 (2018 – \$151,095; 2017 - \$7,305,746) 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 September 30, 2019, the Company had a working capital of \$48,724,264. The SVB Term Loan was repayable over a 33-month period ending September 1, 2020, and was repaid in full on October 17, 2019. Debt and equity financings are dependent on market conditions and may not be available on favorable terms.

#### *Market risk*

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

##### (a) Interest rate risk

As at September 30, 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 \$11,371 or decrease of \$40,146 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 \$21,465 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, 2019 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       | 20,762,374 |
| Stock options       | 5,314,000  |
| Warrants            | 12,393,092 |

### 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, 2019, which is posted on SEDAR at [www.sedar.com](http://www.sedar.com) and on EDGAR 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 consolidated financial statements was properly recorded, processed, summarized and reported to the Company's Board and Audit Committee. The Company's certifying officers conducted or caused to be conducted under their supervision an evaluation of the disclosure controls and procedures as required under Canadian securities laws, as at September 30, 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 September 30, 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 (the "**Audit Committee**") is comprised of Franklin Berger (chair), Gary Sollis, and Sanford Zweifach, 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 July 1, 2019 to September 30, 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.