UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended September 30, 2020
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number: 001-37410

ESSA Pharma Inc.

(Exact name of registrant as specified in its charter)

British Columbia, Canada **(State or other jurisdiction of incorporation or organization)**	**47-2569713** **(I.R.S. Employer Identification Number)**

Suite 720, 999 West Broadway
Vancouver, BC V5Z 1K5
(Address of principal executive offices, including zip code)
Registrant's telephone number, including area code: (778) 331-0962
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares	**EPIX**	**Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common shares held by non-affiliates of the registrant, based on the closing sale price of the registrant's common shares on the last business day of its most recently completed second fiscal quarter, as reported on the Nasdaq was approximately $83.3 million.

The number of outstanding common shares of the registrant, no par value per share, as of December 15, 2020 was 33,600,122.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement in connection with the registrant's 2021 annual meeting of shareholders, which will be filed with the Securities and Exchange Commission (the "SEC") subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days following the end of the registrant's fiscal year ended September 30, 2020.

ESSA PHARMA INC.

FORM 10-K

For the Fiscal Year Ended September 30, 2020

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTOR SUMMARY

This Annual Report on Form 10-K includes "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and "forward-looking information" within the meaning of Canadian securities laws, or collectively, forward-looking statements. Forward-looking statements include statements that may relate to our plans, objectives, goals, strategies, future events, future revenue or performance, capital expenditures, financing needs and other information that is not historical information. Many of these statements appear, in particular, under the headings "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations". Forward-looking statements can often be identified by the use of terminology such as "subject to", "believe," "anticipate," "plan," "expect," "intend," "estimate," "project," "may," "will," "should," "would," "could," "hope," "can," the negatives thereof, variations thereon and similar expressions, or by discussions of strategy. 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:

- our ability to maintain operations, development programs, preclinical studies, clinical trials and raise capital as a result of the recent coronavirus disease 2019 ("COVID 19") outbreak;
- our ability to advance our product candidate and potential future product candidates through, and successfully complete, clinical trials;
- our ability to recruit sufficient numbers of patients for future clinical trials, and the benefits expected therefrom;
- our ability to obtain funding for operations, including research funding, and the timing and potential sources of such funding;
- the initiation, timing, cost, location, progress and success of, strategy and plans with respect to our 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 our product candidate and potential future product candidates, if any, including the expected benefits, properties, effectiveness, pharmacokinetic profile and safety of our next-generation aniten compounds;
- our ability to achieve profitability;
- the grant ("CPRIT Grant") under the Cancer Prevention and Research Institute of Texas ("CPRIT") and payments thereunder, including any residual obligations;
- our use of proceeds from funding and financings;
- our ability to effectively liquidate Realm (as defined herein), and assume the related obligations;
- our intended use of proceeds from the acquisition of Realm and the past and future offerings of our securities;
- our ability to establish and maintain relationships with collaborators with acceptable development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts;
- the implementation of our business model and strategic plans, including strategic plans with respect to patent applications and strategic collaborations and partnerships;
- our ability to identify, develop and commercialize product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our expectations regarding federal, state, provincial and foreign regulatory requirements, including our plans with respect to anticipated regulatory filings;
- whether we will receive, and the timing and costs of obtaining, regulatory approvals in the United States, Canada and other jurisdictions;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our product candidate and potential future product candidates, if any;

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

Such statements reflect our current views with respect to future events, are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements, including those described under "Risk Factors". In making the forward-looking statements included in this Annual Report on Form 10-K, we have made various material assumptions, including but not limited to:

- our ability to maintain operations as a result of the recent COVID-19 outbreak;
- our ability to conduct a clinical study involving our product candidate and to identify any future product candidates;
- the availability of financing on reasonable terms;
- our ability to obtain regulatory and other approvals to commence a clinical trial involving any future product candidates;
- our ability to obtain positive results from research and development activities, including clinical trials;
- our ability to obtain required regulatory approvals;
- our ability to protect patents and proprietary rights;
- our ability to successfully out-license or sell future products, if any, and in-license and develop new products;
- favorable general business and economic conditions;
- our ability to attract and retain skilled staff;
- market competition; and
- the products and technology offered by our competitors.

In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including the risks outlined under the heading "Risk Factors" within this document. Some of these risks and assumptions include, among others.

- risks related to our ability to maintain operations and execute on our business plan as a result of the recent COVID-19 outbreak or other health epidemics;
- risks related to clinical trial development and our ability to conduct the clinical trial of our product candidate and the predictive value of our current or planned clinical trials;
- risks related to our future success being dependent primarily on identification through preclinical studies, clinical studies, regulatory approval for commercialization of a single product candidate;
- risks related to our ability to continue to license our product candidates or technology from third parties;
- uncertainty related to our ability to obtain required regulatory approvals for our proposed products;
- risks related to the Company's ability to conduct a clinical trial or submit a future NDA/NDS or IND/CTA (each, as defined herein);
- risks related to our ability to successfully commercialize future product candidates;

- risks related to the possibility that our product candidate and potential future product candidates, if any, may have undesirable side effects;
- risks related to our ability to enroll subjects in clinical trials;
- risks that the FDA may not accept data from trials conducted in locations outside the United States;
- risks related to our 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 our relationships with clinical research organizations or academic institutions may terminate;
- risks related to our lack of experience manufacturing product candidates on a large clinical or commercial scale and our lack of manufacturing facility;
- risks related to our 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 us to obtain marketing approval of, and commercialize, our product candidate and potential future products, if any, and affect the prices our 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 our ability to raise additional funding;
- risks related to our ability to raise additional capital on favorable terms and impact of dilution from incremental financing;
- risks related to the acquisition of Realm, the liquidation of Realm, and the assumption of related obligations;
- risks that we may default on any residual obligations of the agreement providing for the CPRIT Grant, which may result in us 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 our incurrence of significant losses in every quarter since inception and our anticipation that it will continue to incur significant losses in the future;
- risks related to our limited operating history;
- risks related to our reliance on proprietary technology;
- risks related to our ability to protect our intellectual property rights throughout the world;
- risks related to claims by third parties asserting that we, or our employees or consultants have misappropriated their intellectual property, or claiming ownership of what we regard as our intellectual property;
- risks related to our 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 our future revenues and financial condition and increase our costs and expenses;
- risks related to our dependence on the use of information technologies;
- risks related to our ability to attract and maintain highly-qualified personnel;
- risks relating to the possibility that third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues;
- risks related to potential conflicts of interest between us and our 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 our ability to convince public payors and hospitals to include our product candidate and potential future products, if any, on their approved formulary lists;
- risks related to our 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 our ability to manage growth;
- risks related to our ability to achieve or maintain expected levels of market acceptance for our products;

- risks related to our 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 us and harm our 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 us being a public company;
- risks inherent in foreign operations;
- risks related to the possibility that laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and Canada and require us to develop and implement costly compliance programs;
- risks related to laws that govern fraud and abuse and patients' rights;
- risks related to our ability to comply with environmental, health and safety laws and regulations;
- risks related to the additional costs and expenses associated with being a U.S. domestic issuer as opposed to a foreign private issuer;
- risks related to us being 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 us;
- risks related to our ability to maintain compliance with Nasdaq listing requirements;
- risks related to market price and trading volume volatility;
- risks related to our dividend policy;
- risks associated with future sales of our securities;
- risks related to our ability to implement and maintain effective internal controls;
- risks related to our ability to maintain an active trading market for our common shares (the "Common Shares");
- risks related to share price volatility associated with our 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 us, materialize, or if our underlying assumptions prove to be incorrect, actual results may vary significantly from those expressed or implied by forward-looking statements. The forward-looking statements represent our views as of the date of this document. While we may elect to update these forward-looking statements in the future, we have no current intention to do so except as to the extent required by applicable 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. We advise you that these cautionary remarks expressly qualify in their entirely all forward-looking statements attributable to us or persons acting on our behalf.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States, Canada, and all European countries. On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic. COVID-19 has had a broad adverse impact on the global economy across many industries and has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business shutdowns, as well as significant volatility in global financial markets. Although COVID-19 has not yet had any material impact on our business, operations or financial condition, there can be no assurances that it will not have an impact on our business, operations or financial condition going forward. See "*Risk Factors - Risks Relating to COVID-19*" below.
We express all amounts in this Annual Report on Form 10-K in U.S. dollars, except where otherwise indicated. References to "$" and "US$" are to U.S. dollars and references to "C$" are to Canadian dollars.

Except as otherwise indicated, references in this Annual Report on Form 10-K to "ESSA," "the Company," "we," "us" and "our" refer to ESSA Pharma Inc. and its subsidiaries.

PART I

Item 1. Business

Overview

ESSA is a clinical stage pharmaceutical company, focused on developing novel and proprietary therapies for the treatment of prostate cancer in patients whose disease is progressing despite treatment with current standard of care therapies, including second-generation anti-androgen drugs such as abiraterone, enzalutamide, apalutamide, and darolutamide. The Company believes its latest series of investigational compounds, including its product candidate EPI-7386, have the potential to significantly expand the interval of time in which patients with castration-resistant prostate cancer ("CRPC") can benefit from anti-hormone-based therapies. Specifically, the compounds are designed to disrupt the androgen receptor ("AR") signaling pathway, the primary pathway that drives prostate cancer growth and prevent AR activation through selective binding to the N-terminal domain ("NTD") of the AR. In this respect, the Company's compounds are designed to differ from classical non-steroid anti-androgens. These anti-androgens 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.

The Company believes that the transcription inhibition mechanism of its preclinical compounds is unique and has the potential 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 first-in-class mechanistic class. The Company refers to this series of proprietary investigational compounds as the "Aniten" series. In preclinical studies, blocking the NTD has demonstrated the capability to prevent AR-driven gene expression. A previously completed Phase I clinical trial of ESSA's first-generation agent, ralaniten acetate ("EPI-506") administered to patients with metastatic CRPC ("mCRPC") refractory to current standard of care therapies demonstrated prostate-specific antigen ("PSA") declines, a sign of inhibition of AR-driven biology. This inhibition, however, was neither deep nor sustained enough to confer clinical benefit and the Company made the decision to develop a more potent next generation drug which would also have a longer half-life. The Company has done so and is now in clinical trial with this next generation Aniten, EPI-7386.

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 initial androgen ablation therapy using analogues of luteinizing hormone releasing hormone or surgical castration; this approach is termed "androgen deprivation therapy" ("ADT"). Most advanced prostate cancer patients initially respond to this 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 earlier in the disease, in newly diagnosed metastatic prostate cancer.

Since the mid 20th century it has been recognized that the growth of prostate tumors is in large part 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 variants of AR that lack an LBD, are constitutively activated, and consequently do not require androgen for activation. A third mechanism, of less certain clinical significance, may involve certain signaling pathways that activate AR independent of androgen activity. Generally, current drugs for the treatment of prostate cancer are directed against the first mechanism by either (i) interfering with the production of androgen, or (ii) preventing androgen from binding to the LBD. Over time, these approaches eventually fail due to mechanisms of resistance which all involve the LBD end of the receptor, whether at the DNA (AR amplification or LBD mutations) or RNA level (emergence of AR splice variants).

Through their potential to block androgen-driven gene transcription through a unique mechanism involving the NTD and thereby bypassing these known mechanisms of resistance to current anti-androgens, the Company believes the Aniten series of compounds hold the potential to be effective in cases where current therapies have failed. The results from both extensive preclinical studies and the initial clinical experience support the Company's belief. In preclinical studies, the Aniten series of compounds has been observed to shrink prostate cancer xenografts, including tumors both sensitive and resistant to the second-generation anti-androgens such as enzalutamide. PSA declines were observed in the initial Phase I study as described below. Importantly with respect to the potential clinical application of NTD inhibition, recent studies by the Company and its collaborators have also suggested the potential advantage for combinations of the Company's Aniten compounds with current anti-androgens to inhibit AR-driven biology more completely than inhibition of the receptor from either end of the receptor alone.

The Phase I clinical trial of the first generation Aniten EPI-506 provided evidence regarding the safety and tolerability for the potential mechanism of transcription inhibition of AR-driven biology. Patients generally tolerated doses of EPI-506 at overall exposures consistent with those associated with therapeutic activity in animal models. Possible proof of concept was observed 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, this first-generation drug was demonstrated to have poor pharmaceutical properties. The drug was rapidly 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 exposure of the drug within a 24-hour period. This limitation, together with other demonstrated unfavorable pharmaceutical properties, led to the Company's decision to discontinue EPI-506 development in favor of focusing on the development of a next generation of Anitens. This next generation includes significantly more potent drugs designed also to exhibit increased resistance to metabolism and therefore a longer predicted circulating half-life. The Company's lead product candidate EPI-7386 has demonstrated these and other favorable characteristics in extensive preclinical characterization studies which the Company has presented in a series of poster presentations at scientific meetings over the last year.

While the potential importance of the NTD as a drug target has been appreciated for more than two decades, for technical reasons this has been a difficult target for therapeutic agent development. The NTD of the AR is flexible with a high degree of intrinsic disorder making it difficult for use in classic crystal structure-based drug design. The Company is not currently aware of any success by other drug development companies in developing 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, has been consistent with the favorable toxicological results observed in preclinical studies of the first-generation EPI-506 and the subsequent safety results observed in the Phase I trial of EPI-506. The Company is currently conducting, together with external academic and industry collaborators, extensive biophysical and biological studies to reveal more precisely the nature of EPI-7386 binding, and the specific consequent effects on prostate cancer biology.

The incidence of both metastatic and non-metastatic CRPC continues to rise, and using a dynamic progression model, Scher et al[1] have projected a 2020 incidence of 546,955 and prevalence of 3,072,480. The Company believes that the Aniten series of compounds could hold potential 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, the Company believes that a successful Phase I clinical trial will facilitate the early study of the combination of EPI-7386 with second-generation anti-androgens. The Company and its collaborators have developed preclinical *in vitro* and *in vivo* evidence supporting further evaluation of the combination of NTD inhibitors together with the LBD inhibiting anti-androgens. The Company believes that 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 ADT, consistent with the premise that more effective androgen suppression may yield clinical benefit. The Company believes that the introduction of NTD inhibitors such as EPI-7386 therefore has potential to improve androgen suppression, delay the emergence of resistance, and result in improved clinical benefit.

The Company is party to a license agreement with the British Columbia Cancer Agency and the University of British Columbia 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 active compound of the previous clinical candidate EPI-506.

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 which cover multiple EPI- and Aniten structural classes of compounds with 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.

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 IND to the 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 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.

[1] 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.013944

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, a measure of potential efficacy, ranging from 4% to 37% were observed in five patients, which occurred predominantly in the higher dose cohorts (≥1280 mg).

EPI-506 was generally well-tolerated with favorable safety results observed 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 Company believes that the safety results and possible signs of anti-tumor activity observed 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 the limitations of the first generation agent EPI-506. Through its discovery research the Company had concluded that it should be feasible to develop a next generation of NTD inhibitor which would demonstrate greater potency, reduced metabolism and other improved pharmaceutical properties. 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.

The Company's family of next-generation investigational Aniten compounds incorporate multiple chemical scaffold changes to the first-generation drugs which in preclinical studies retain NTD inhibition of the AR. In addition, they have shown improvement in a range of attributes when compared to the first-generation compound, EPI-506, in preclinical studies. In *in vitro* assays measuring inhibition of AR transcriptional activity, these product candidates demonstrated 20 times higher potency than EPI-506 or its active metabolite, EPI-002. In addition, the compounds have demonstrated increased metabolic stability in preclinical studies, suggesting the potential for longer half-lives in humans. Lastly, the compounds have demonstrated more favorable pharmaceutical properties relative to EPI-506. The Company believes that these product candidates, if successfully developed and approved, may offer 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 lead candidate for clinical development and an IND was submitted to the FDA on March 30, 2020 and was allowed by the FDA on April 30, 2020. A CTA was filed with Health Canada in April 2020 and clearance was subsequently received. The Phase I clinical trial of EPI-7386 "Oral EPI-7386 in Patients With Metastatic Castration-Resistant Prostate Cancer (EPI-7386)" was started in June 2020 with the first patient dosed in July 2020 and is currently actively enrolling patients (www.clinicaltrials.gov).

Our 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, preclinical and clinical studies that have evaluated the NTD inhibition of the Company's Aniten compounds suggest the potential to increase therapeutic activity by combining these agents with anti-androgens at an earlier stage of treatment. Therefore, while the Company's first priority is to continue Phase I clinical development of EPI-7386 as a single agent, in parallel the Company has also been conducting preclinical studies and planning clinical studies to evaluate EPI-7386 in combination with other agents. These preclinical studies are being conducted in collaboration with academic institutions. In addition, the Company has engaged in discussions with the relevant pharmaceutical companies in the prostate cancer space regarding potential collaborative clinical trials of combination therapy in earlier line patients. In future preclinical studies, the Company intends to further explore other potential applications for AR-NTD inhibitors, including breast cancer and other AR-associated cancers.

The identification and characteristics of the IND candidate EPI-7386

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 (absorption, distribution, metabolism, and excretion) and pharmaceutical properties of the chemical class.

Several next-generation aniten molecules met prespecified preclinical target product profile goals regarding potency, stability, selectivity and pharmaceutical properties. 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. In addition, EPI-7386 is significantly more potent, metabolically stable and more effective in preclinical studies compared to ESSA's first-generation compound, EPI-506. Lastly, EPI-7386 has demonstrated a favorable tolerability profile in all animal studies of the compound conducted to date.

Following IND-enabling studies, ESSA filed an IND for EPI-7386 in mCRPC at the end of the first calendar quarter of 2020, and following the receipt of clearance by the FDA and allowance by Health Canada, commenced clinical testing of EPI-7386 in July 2020, allowing for accommodations to the planned timeline as a result of the impact of the COVID-19 situation at individual clinical trial sites (see "Risk Factors - Risks Relating to COVID-19" below).

The Company has presented preclinical scientific data in a number of poster presentations at scientific meetings in the past year.

Most recently at the 32nd EORTC-NCI-AACR Annual Symposium on Molecular Targets and Cancer Therapeutics ("ENA") on October 24th, 2020, an oral poster presentation titled, "The preclinical characterization of the N-terminal domain androgen receptor inhibitor, EPI-7386, for the treatment of prostate cancer", presented new information about EPI-7386 including: (i) in an *in vitro* cellular thermal shift assay (CETSA), EPI-7386 was shown to physically interact with the both the full-length and the splice variant (AR-V7) form of the androgen receptor ("AR") (ii) in an *in vitro* full-length AR-driven cellular model (LNCaP), RNAseq data was analyzed by pathway enrichment analysis. EPI-7386 demonstrates largely similar modulation of AR-regulated genes compared to enzalutamide, but with additional unique elements; and (iii) EPI-7386 exhibits superior activity to enzalutamide in the AR-V7-driven cellular models LNCaP95 and 22Rv1 by modulating AR-driven gene expression with or without the addition of an external androgen.

Previously, *in vitro* data had been presented demonstrating that EPI-7386 binds to the full-length androgen receptor and can inhibit the transcription of AR-regulated genes. The new data demonstrate that EPI-7386 can also physically interact with the splice variant form, AR-V7, of the androgen receptor and inhibit its activity. The importance of this interaction with AR-V7 is seen through the superior transcriptional inhibition of AR-regulated genes by EPI-7386 compared to enzalutamide in the AR-V7-driven cell models LNCaP95 and 22Rv1. Together, these data provide insights into mechanistic aspects related to the binding and utility of EPI-7386 against AR-V7 splice-variant driven prostate cancer models. The data supports the Company's rationale for studying EPI-7386 in men with prostate cancer resistant to current anti-androgens.

Advancing EPI-7386 through clinical development and regulatory approval in CRPC patients

The Company is conducting 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. The design of the Phase I clinical trial includes the standard three patients per dose cohort. Patients will be selected clinically, on the basis of having progressive metastatic CRPC as exemplified by rising PSA values despite latest generation anti-androgen treatment. However, all patients will be also be characterized biologically for underlying tumor genomic characteristics, for evidence of AR pathway activation and during the conduct of the trial, for dose-related biological, 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 subsequent Phase II and additional clinical trials, including trials of combination aniten/lutamide therapy in earlier line patients.

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. Unlike current anti-androgen therapies which can only inhibit full-length AR, NTD inhibition of AR-directed biology occurs both in full length AR and splice variant ARs. Therefore, the Company 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. Preclinical studies suggest particular value to the use of anitens in combination with the currently-widely used anti-androgens. As a result, 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 continues to develop *in vitro* and *in vivo* data in collaboration with academic and industry investigators in this regard. Preliminary data strongly indicates 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 ("PARP") 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.

Future Clinical Development Program

Phase I/II Clinical Trial Design for treating CRPC patients

With the allowance by the FDA of the IND and clearance of the CTA by Health Canada for EPI-7386, the Company is conducting a Phase I clinical trial to determine the safety, tolerability, maximum tolerated dose, pharmacokinetics, and efficacy of the compound in CRPC patients at clinical sites in the US and Canada. In the 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. The clinical trial is expected to enroll approximately 18 patients at multiple medical institutions in a standard 3+3 trial design with an approximate 10 additional patients enrolled in the dose expansion cohort. The Company is working with clinicals sites so patients can be enrolled ensuring compliance with COVID-19 risk management guidance as provided by FDA (see "*Risk Factors - Risks Relating to COVID-19*" below). Learnings from the Phase I clinical trial of EPI-506 have been incorporated into the design and conduct of the Phase I study. The Company has included in the study design, 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 of the clinical trial will evaluate activity in a larger group of biologically-characterized mCRPC patients.

Early Conduct of a Combination Phase I/II Clinical Trial

Given the evolution of prostate cancer therapeutics towards combination therapy strategies, the biological rationale for combining NTD and LBD inhibitors, and compelling early *in vitro* and preclinical animal model results, the Company intends to perform combination studies of the next-generation Aniten compound with current generation anti-androgens following the Phase 1 dose escalation and expansion studies. Since these combination studies will involve earlier lines of therapy i.e. often prior to receiving a late-stage anti-androgen, they will commence only after sufficient experience with safety, tolerability, and efficacy has been accumulated with single agent EPI-7386 therapy in later line of therapy patients. The Company currently estimates that these studies might commence within the third calendar quarter of 2021.

Phase III Clinical Trial

In order to ultimately obtain full single agent 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.

Competition

The competition in the prostate cancer market is very high, many of the companies against which we compete or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Several pharmaceutical therapies already have approved and many new molecules are being tested for their effect in this patient population. In addition, generic forms of Zytiga (abiraterone acetate) are now approved and commercially available in the U.S.

Currently approved therapies include:

GENERIC/PROGRAM NAME	BRAND NAME	COMPANY NAME(S)	STAGE
Enzalutamide	Xtandi	Astellas and Pfizer	Marketed
Abiraterone acetate	Zytiga	Johnson & Johnson	Marketed
Sipuleucel-T	Provenge	Valeant	Marketed
Docetaxel	n/a	Sanofi and various	Marketed
Cabazitaxel	Jevtana	Sanofi	Marketed
Radium-233	Xofigo	Bayer	Marketed
Apalutamide (ARN-509)	Erlead	Johnson & Johnson	Marketed
Darolutamide	Nubeqa	Bayer	Marketed
Pembrolizumab	Keytruda	Merck	Marketed
Olaparib	Lynparza	AstraZeneca	Marketed
Rucaparib	Rubraca	Clovis Oncology	Marketed

In this market, ESSA believes that its competitive position is strong because its product candidate, if successful, involves a mechanistically unique, differentiated approach to prostate cancer involving the therapeutic approach that has been shown to make the biggest difference to the survival of recurrent prostate cancer patients: blocking AR activation. Since EPI compounds have been shown to directly block the AR-NTD, they have the potential to overcome the AR-dependent resistance pathways (discussed above) that may develop as a result of treatment with current hormone-related therapies that target the AR LBD. If successful, ESSA believes this could represent a significant step forward in the treatment of prostate cancer. To ESSA's knowledge, no other antagonist to the AR-NTD is currently undergoing clinical trials for prostate cancer or any other indication. Other approaches to interfering with AR signaling include strategies to degrade the AR such as that being pursued by Arvinas, Inc.

Patents and Proprietary Rights

License Agreement with UBC and the BCCA

ESSA has in-licensed intellectual property embodied in issued patents, pending patents applications and know-how relating to compounds that modulate AR activity created through research work done at UBC and the BCCA (together, the "Licensors") under the direction of Dr. Raymond Andersen and Dr. Marianne Sadar, respectively. ESSA refers to these intellectual property rights as the "Licensed IP".

Pursuant to an agreement among ESSA and the Licensors dated as of December 22, 2010 and amended on February 10, 2011 and on May 27, 2014 (the "License Agreement"), ESSA has been granted a worldwide, exclusive license to develop and commercialize products based on the Licensed IP. ESSA paid a minimum annual royalty of C$40,000 in the 2014 calendar year, increasing to C$65,000 in each of 2015 and 2016 and C$85,000 in 2017, 2018, and 2019 and must continue to pay a minimum of C$85,000 for each year thereafter. For a First Compound entering clinical development, an additional C$50,000 and C$900,000 must be paid upon enrollment of a patient in a Phase II and Phase III clinical trial, respectively.

The Licensors may terminate the License Agreement upon ESSA's insolvency, or the License Agreement may be terminated by either party for certain material breaches by the other party. ESSA has already spent more than C$5,000,000 in connection with the commercialization of products relating directly to the Licensed IP, as required under the License Agreement. ESSA is required to allocate reasonable time to the development and commercialization of the Licensed IP and to use reasonable efforts to promote, market and sell products covered by the Licensed IP. The terms of the License Agreement required ESSA to issue to the Licensors, in lieu of payment of an initial license fee, 1,000,034 pre-Consolidation Common Shares. If ESSA develops products covered by the Licensed IP in the future, it will be required to pay certain development and regulatory milestone payments up to an aggregate of C$2.4 million for the first drug product developed under the license and up to an aggregate of C$510,000 for each subsequent product. ESSA must also pay the Licensors low single-digit royalties based on aggregate worldwide net sales of products covered by the Licensed IP and a percentage of sublicensing revenue in the low teens. ESSA is also required to reimburse costs incurred by the Licensors related to the prosecution and maintenance of patents embodying the Licensed IP. The License Agreement will expire on the later of 20 years after the date of the License Agreement or the expiry of the last issued patent included in the Licensed IP.

ESSA's Intellectual Property Strategy

Both ESSA and the broader pharmaceutical industry attach significant importance to patents for the protection of new technologies, products and processes. Accordingly, ESSA's success depends, in part, on its ability to obtain patents or rights thereto, to protect commercial secrets and carry on activities without infringing the rights of third parties. See "Risk Factors" in Item 1A elsewhere in this Annual Report. Where appropriate, and consistent with management's objectives, patents are pursued once concepts have been validated through appropriate laboratory work. To that end, ESSA will continue to seek patents in relation to those components or concepts that it perceives to be important.

Patent Applications

ESSA has licensed certain patent rights, with respect to some of its compounds that modulate AR activity, from the Licensors, jointly. ESSA has the right to acquire ownership of the licensed patents and patent applications upon specified payment to the Licensors, and providing that payments required under the License Agreement continue to be made.

ESSA currently has 16 pending and maintained patent families which cover multiple EPI- and Aniten structural classes of compounds with different structural motifs/analogues, that provide a strong and defensive intellectual property portfolio.

Regulatory Environment

The production and manufacture of ESSA's product candidate and potential future product candidates and its R&D activities are subject to regulation for safety, efficacy, quality and ethics by various governmental authorities around the world. In the United States, drugs and biological products are subject to regulation by the FDA. In Canada, these activities are regulated by the Food and Drugs Act and the rules and regulations thereunder, which are enforced by the TPD. Drug approval laws require registration of manufacturing facilities, carefully controlled research and testing of product candidates, government review and approval of experimental results prior to giving approval to sell drug products. Regulators also require that rigorous and specific standards such as cGMP, GLP and GCP are followed in the manufacture, testing and clinical development respectively of any drug product. See "Risk Factors" in Item 1A. elsewhere in this Annual Report.

The process of obtaining regulatory approvals and the corresponding compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of extensive nonclinical, sometimes referred to as preclinical laboratory tests, and preclinical animal trials in compliance with applicable requirements for the humane use of laboratory animals and formulation studies, including GLPs;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as GCP regulations and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed drug product for its intended use;
- preparation and submission to the FDA of a New Drug Application ("NDA");
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies ("REMS") and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies are conducted *in vitro* and in animals to evaluate pharmacokinetics, metabolism and possible toxic effects to provide evidence of the safety of the product candidate prior to its administration to humans in clinical studies and throughout development. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Initiation of Human Testing

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. In Canada, this application is called a CTA. An IND/CTA application must be filed and accepted by the FDA or TPD, as applicable, before human clinical trials may begin. In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations.

Two key factors influencing the rate of progression of clinical trials are the rate at which patients can be enrolled to participate in the research program and whether effective treatments are currently available for the disease that the drug is intended to treat. Patient enrollment is largely dependent upon the incidence and severity of the disease, the treatments available and the potential side effects of the drug to be tested and any restrictions for enrollment that may be imposed by regulatory agencies.

Phase I Clinical Trials

Phase I clinical trials for cancer therapeutics are typically conducted on a small number of patients to evaluate safety, dose limiting toxicities, tolerability, pharmacokinetics and to determine the dose for Phase II clinical trials in humans.

Phase II Clinical Trials

Phase II clinical trials typically involve a larger patient population than Phase I clinical trials and are conducted to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of a product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

Phase III Clinical Trials

Phase III clinical trials typically involve testing an experimental drug on a much larger population of patients suffering from the targeted condition or disease – in ESSA's case, CRPC. These studies involve testing the experimental drug in an expanded patient population at geographically dispersed test sites (multi-center trials) to establish clinical safety and effectiveness. These trials also generate information from which the overall risk-benefit relationship relating to the drug can be determined.

In most cases FDA requires two adequate and well controlled Phase III clinical trials to demonstrate the efficacy of the drug. A single Phase III trial with other confirmatory evidence may be sufficient in rare instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

New Drug Application

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA, or the TPD as part of an NDS, requesting approval to market the drug product for one or more indications. The NDS or NDA is then reviewed by the applicable regulatory body for approval to market the drug.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as Active Pharmaceutical Ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2,500,000 and the manufacturer or sponsor under an approved new drug application are also subject to significant annual program and establishment user fees. These fees are typically increased annually.

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, significant changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Orphan Designation and Exclusivity

ESSA may, in the future, seek orphan drug designation for its product candidates. Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product generally will receive orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Human Capital Resources

As of the date of this Annual Report, ESSA has a total of approximately 25 employees and consultants on a full-time or part-time basis. ESSA has in the past, and may in the future, retain additional expert consultants on an ad-hoc basis if required in connection with the Company's development program.

We believe that our future success will depend, in part, on our ability to continue to attract, hire, and retain qualified personnel. We continue to seek additions to our science and technical staff. Through our experience with technological innovation, we appreciate the importance of retention, growth and development of our employees. We believe we offer competitive compensation (including salary, incentive bonus, and equity) and benefits packages. None of our employees is represented by a labor union, and we have never experienced a work stoppage.

General Development of the Business

Significant Business Developments for the Year Ended September 30, 2020

In March 2020, the Company filed an IND application to the FDA to evaluate its lead product candidate, EPI-7386, in a Phase 1 clinical study for the treatment of patients with metastatic castration-resistant prostate cancer. In April 2020, the FDA notified the Company that it may proceed with its proposed clinical investigation of EPI-7386. A CTA was filed and subsequently cleared with Health Canada. The clinical trial is expected to enroll approximately 18 patients at multiple medical institutions in a standard 3+3 trial design with an approximate 10 additional patients enrolled in the dose expansion cohort.

On July 15, 2020, the Company dosed the first patient in a Phase 1 clinical trial designed to evaluate the safety and tolerability of EPI-7386 in mCRPC patients who failed standard of care treatments, including second generation anti-androgens. On September 14, 2020, the Company announced that the FDA granted Fast Track Designation to EPI-7386 for the treatment of adult male patients with mCRPC resistant to standard-of-care treatment.

Financing and Capital

On October 9, 2019, the Company filed a registration statement on Form F-3 (the "2019 Form F-3") with the SEC, allowing the resale of 20,491,618 in Common Shares of the Company. On November 5, 2019, the Company filed an amendment to the 2019 Form F-3 with the SEC, which declared the 2019 Form F-3 effective on November 5, 2019.

On October 17, 2019, the Company repaid the SVB Term Loan, originally maturing on September 1, 2020, in full totaling $3,652,471, comprising $2,953,968 in principal, $10,503 in accrued interest, and the final payment of $688,000.

Effective as of April 13, 2020, the Company entered into an Open Market Sale Agreement (the "ATM Sales Agreement") with Jefferies LLC. Under the ATM Sales Agreement, ESSA may sell its Common Shares in the capital of the Company from time to time for up to $35.0 million in aggregate sales proceeds in "at-the-market" transactions.

On July 31, 2020, the Company closed an underwritten public offering of 7,100,000 Common Shares of the Company at a public offering price of US$6.00 per share, before underwriting discounts, for an aggregate offering of approximately US$42.6 million (the "July 2020 Offering"). ESSA granted the underwriters a 30-day option to purchase up to an additional 1,065,000 Common Shares (the "Option"), and the underwriters exercised the Option on July 29, 2020. The proceeds to ESSA from the July 2020 Offering, including the exercise of the Option, were approximately US$45.0 million after deducting underwriting discounts and commissions (such commission being equal to 6% of the aggregate gross proceeds of the July 2020 Offering) and other estimated offering expenses. Existing investors participated in the financing along with new investors Pfizer Inc. (NYSE: PFE), Avidity Partners, CAM Capital, Point72, Ridgeback Capital, Sphera Healthcare and Vivo Capital.

Recent Developments

On October 14, 2020, the Company issued 1,493,504 Common Shares upon the cashless exercise of 1,493,504 pre-funded warrants.

On October 26, 2020, ESSA Pharma Inc. announced its strategic decision to voluntarily delist its Common Shares from the TSX Venture Exchange in Canada (the "TSX-V").

On November 25, 2020, the Company filed a Registration Statement on Form S-3 with the SEC to replace the existing Registration Statement on Form F-3, which, once effective, will allow the Company to raise up to $200 million worth of the securities listed therein.

On December 3, 2020, the Company issued 42,207 Common Shares for stock options exercised for gross proceeds of $153,701.

Corporate Structure

The Company was incorporated under the name "ESSA Pharma Inc." pursuant to the Business Corporations Act (British Columbia) on January 6, 2009. The Company's articles of incorporation (the "Articles") were amended on December 16, 2010 to attach certain special rights and restrictions to the Common Shares, on April 22, 2014 to authorize the creation of a new class of preferred shares in the capital of the Company, issuable in one or more series, and again on July 28, 2014 to create the class A preferred shares in the capital of the Company (the "Preferred Shares") and attach certain special rights and restrictions to such Preferred Shares.

The Company's registered and records office is located at Suite 2600, 595 Burrard Street, Vancouver, British Columbia, Canada V7X 1L3. The Company's head office is located at Suite 720, 999 West Broadway, Vancouver, British Columbia, Canada V5Z 1K5.

Since July 9, 2015, the Company's Common Shares have traded on the Nasdaq under the symbol "EPIX". The Company's Common Shares traded under the symbol "EPI" on the Toronto Stock Exchange (the "TSX") from July 28, 2015 until November 24, 2017. On November 27, 2017, the Company delisted its Common Shares from the TSX and began trading on the TSX-V under the same symbol, "EPI". On October 26, 2020, the Company announced its decision to voluntarily delist its Common Shares from the TSX-V.

The Company has the following wholly owned subsidiaries:

- ESSA Pharmaceuticals Corp. ("ESSA Texas"), existing under the laws of the State of Texas. The head office of ESSA Texas is located at Suite 1300, 700 Milam Street, Houston, Texas, USA 77002; and
- Realm Therapeutics plc. ("Realm"), existing under the laws of the England and Wales, and its wholly owned subsidiary Realm Therapeutics Inc., existing under the laws under the State of Delaware, which were both acquired on July 31, 2019 and are being liquidated with final certificates being awaited.

Available Information

This Annual Report on Form 10-K, our quarterly reports on Form 10-Q or Form 6-K, our current reports on Form 8-K or Form 6-K, and any amendments to these reports are filed, or will be filed, as appropriate, with the SEC and the Canadian Securities Administrators ("CSA"). These reports are available free of charge on our website, www.essapharma.com, as soon as reasonably practicable after we electronically file such reports with or furnish such reports to the SEC and the Canadian regulatory authorities. Information contained on, or accessible through, our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this document is an inactive textual reference.

Additionally, our filings with the SEC may be accessed through the SEC's website at www.sec.gov and our filings with the CSA may be accessed through the CSA's System for Electronic Document Analysis and Retrieval ("SEDAR") at www.sedar.com. Our annual report on Form 20-F from the year ended September 30, 2019, which includes a full discussion of the general development of our business, can be found at https://www.sec.gov/Archives/edgar/data/1633932/000110465919074530/tm1919820d1_20f.htm.

Item 1A. Risk Factors

Risk Factor Summary

We are providing the following summary of the risk factors contained in this Annual Report on Form 10-K to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review the full risk factors contained in this Annual Report on Form 10-K in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky. These risks and uncertainties include, but are not limited to, the following:

- We are subject to risks related to COVID-19;
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome;
- Our future success is dependent primarily on the regulatory approval for commercialization of a single product candidate, which is in the clinical development stage;
- We may not be able to obtain required regulatory approvals for our proposed products;
- We may not be able to successfully commercialize our Aniten series of compounds;
- Our product candidate and potential future product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales;
- Even if we obtain marketing approval for any product candidate and potential future products, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense;
- We may fail to comply with applicable legal and regulatory requirements, which may result in administrative or judicial sanctions;
- We have limited experience manufacturing product candidates on a large clinical or commercial scale and have no manufacturing facility
- We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, this could substantially harm our business because we may not be able to obtain regulatory approval for or commercialize product candidates in a timely manner or at all;

- Our business may be materially adversely affected by new legislation, new regulatory requirements and the continuing efforts of governmental and third-party payors to contain or reduce the costs of healthcare through various means;
- We will have significant additional future capital needs for future clinical trials and there are uncertainties as to the Company's ability to raise additional funding;
- We may not be able to raise additional capital on favorable terms, which may result in dilution to our existing shareholders, restrictions on our operations or the requirement for us to relinquish rights to technologies or any future product candidates;
- We have incurred significant losses in every quarter since our inception and anticipate that we will continue to incur significant losses in the future and may never generate profits from operations or maintain profitability;
- We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability;
- We rely on proprietary technology, the protection of which can be unpredictable and costly;
- We may not be able to protect our intellectual property rights throughout the world;
- We may be subject to claims by third parties asserting that we, or our employees or consultants have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property;
- Our business and operations would suffer in the event of computer system failures or security breaches;
- We face intense competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively;
- We have never marketed a drug before, and if we are unable to establish an effective sales force and marketing infrastructure, or enter into acceptable third-party sales and marketing or licensing arrangements, we may be unable to generate any revenue;
- Our product candidate and potential future products may, if approved for sale, not achieve or maintain expected levels of market acceptance, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our securities to decline;
- Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and Canada and require us to develop and implement costly compliance programs;
- We are and there is a risk that we may continue to be a "passive foreign investment company" which would likely result in materially adverse U.S. federal income tax consequences for U.S. investors; and
- The market price and trading volume of our Common Shares may be volatile, which could result in rapid and substantial losses for our shareholders or securities litigation.

Risk Factors

You should consider carefully the following risk factors, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and notes thereto. If any of the events described in the following risks actually occur, our business, financial conditions, results of operations and prospects could be materially adversely affected. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "Cautionary Note Regarding Forward-Looking Statements." The risks below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations, and/or prospects.

Risks Relating to COVID-19

In December 2019, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States, Canada, and all European countries. On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic. COVID-19 has had a broad adverse impact on the global economy across many industries and has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business shutdowns, as well as significant volatility in global financial markets. Although COVID-19 has not yet had any material impact on our business, operations or financial condition, there can be no assurances that it will not have an impact on our business, operations or financial condition going forward. In March 2020, the Company made the decision to transition employees to primarily remote working arrangements. This continues to the present, but the Company has taken steps to maintain internal communication, and operations have thus far continued on schedule and with minimal interruption. In particular, the Company has been able to continue to move towards activating initial clinical trial sites; with patients being dosed, and with additional patients in screening. The potential still remains that we may experience future delays with third party vendors operations being impacted by COVID-19 and delays in clinical trial activities relating to the diversion of global healthcare resources to higher priority COVID-19 related response activities. Therefore COVID-19-related effects have not yet had a material impact on our business, operations, financial condition, liquidity or strategic long-term development and commercialization plans.

While the Company will continue to work to minimize any emerging complications, the extent to which COVID-19 may cause more significant disruptions to our business and operations will depend on future developments, which are highly uncertain and cannot be definitively predicted. These uncertainties include the duration of the outbreak, the extent of travel restrictions and social distancing measures, the continued severity of the virus outbreak and the ability to treat it, the ability to collect sufficient data to track the virus, the collective actions taken to curb the spread of the virus, and the effectiveness of actions taken to contain and treat the disease and to address its impact, including its impact on global financial markets.

If the COVID-19 pandemic worsens or continues for a prolonged period of time, we could experience disruptions that could significantly impact our current and planned clinical trials, preclinical studies and our business activities including:

- delays or difficulties in initiating clinical trial sites;
- delays or difficulties in enrolling patients in our current and potential future clinical trials of EPI-7386;
- disruption to and delays in preclinical research and analysis activities due to an extended temporary closure of contract lab facilities;
- disruptions in supply, logistics or other activities related to the procurement of materials, which could have a negative impact on our ability to conduct preclinical studies, initiate or complete our clinical trials or commercialize our product candidates;
- diversion of healthcare resources away from the conduct of clinical trials;
- interruption of key preclinical studies and clinical trial activities, due to limitations on travel imposed or recommended by federal, state, provincial or municipal governments, employers and others;
- limitations in resources that would otherwise be focused on the conduct of our business or our current or planned preclinical studies or clinical trials, including due to sickness, restrictions on travel, prolonged stay-at-home or shelter-in-place orders and other COVID-19 related concerns;
- changes in regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our preclinical studies and clinical trials are conducted and incur unexpected costs, or requires us to discontinue our preclinical research or clinical trials altogether;
- delays in receiving regulatory approvals;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or furlough of government or contractor personnel; and
- limitations on our ability to recruit preclinical research, clinical, regulatory and other professional staff on the timeframe required to support our research and development programs.

In addition, COVID-19 could result in continued significant disruption of global financial markets, reducing our ability to access capital, which could have negative future impacts on our liquidity and financial condition. Financial volatility has adversely affected, and may continue to adversely affect, the value of our Common Shares.

The extent of the impact of the COVID-19 pandemic on our business, operations and financial condition is uncertain, and a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, operations and financial condition. We will continue to monitor the effectors of COVID-19 on an ongoing basis.

ESSA's Product Candidate and Regulatory Matters

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results and ESSA's product candidate and potential future product candidates may not have favorable results in later trials or in the commercial setting or satisfy the requirements of the FDA or non-US regulatory authorities.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. ESSA's planned clinical trials may produce negative or inconclusive results, and ESSA or any of its current and future collaborators may decide, or regulators may require ESSA, to conduct additional clinical or preclinical testing. The results of preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. Preclinical tests and Phase I and Phase II clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Favorable results in early trials may not be repeated in later trials. The Company cannot assure you that the FDA, TPD or EMA or other similar government bodies will view the results as the Company does, or that any future trials of ESSA's proposed products for other indications will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials.

A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any current or future clinical trial results for ESSA's proposed products may not be successful. Similarly, preclinical interim results of a clinical trial do not necessarily predict final results. A number of factors could contribute to a lack of favorable safety and efficacy results for ESSA's proposed products for other indications. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and due to varying patient characteristics including demographic factors and health status. There can be no assurance that the Company's clinical trials will demonstrate sufficient safety and efficacy for the FDA EMA to approve ESSA's potential products for the treatment of CRPC, or any other indication that the Company may consider in any additional NDA or NDS submissions for ESSA's potential products.

The Company will be required to demonstrate through large scale clinical trials that any product candidate and potential future product candidate is safe and effective for use in a diverse population before ESSA can seek regulatory approvals for its commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical and post-approval trials. If ESSA's potential products fail to demonstrate sufficient safety and efficacy in ongoing or future clinical trials, the Company could experience potentially significant delays in, or be required to abandon development of a product candidate.

In addition, clinical trials and nonclinical studies performed by research organizations and other independent third parties may yield negative results regarding the effect of ESSA's potential products on CRPC, either in absolute terms or relative to other products.

ESSA's future success is dependent primarily on the regulatory approval for commercialization of a single product candidate, which is in the clinical development stage.

The Company does not have any products that have obtained regulatory approval for commercialization. Currently, ESSA is engaged in the clinical testing of a product candidate, EPI-7386, to take forward from its Aniten series of compounds through clinical development to determine the safety, tolerability, maximum tolerated dose, pharmacokinetics and potential therapeutic benefits of such candidate in patients with CRPC, and to ultimately receive regulatory approval. As a result, the Company's near-term prospects, including its ability to finance its operations and generate revenue, are substantially dependent on its ability to develop, obtain regulatory approval for, and, if approved, to successfully commercialize a product candidate in a timely manner. ESSA cannot commercialize its product candidates in the United States without first conducting multiple preclinical and clinical trials to establish the product's safety and efficacy and obtaining regulatory approval for the product from the FDA; similarly, ESSA cannot commercialize its product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA development and review process typically varies in time and may take years to complete and approval is not guaranteed. Developing, obtaining regulatory approval for and successfully commercializing ESSA's product candidates will depend on many factors, including, but not limited to, the following:

- successfully completing formulation and process development activities;
- completing multiple clinical trials that demonstrate the efficacy and safety of ESSA's product candidates;
- receiving marketing approval from applicable regulatory authorities;
- establishing commercial manufacturing capabilities;
- launching commercial sales, marketing and distribution operations;
- acceptance of ESSA's product candidates by patients, the medical community and third-party payors;
- a continued acceptable safety profile following approval; and
- competing effectively with other therapies, including with respect to the sales and marketing of ESSA's product candidates, if approved.

Many of these factors are wholly or partially beyond ESSA's control, including clinical development, the regulatory submission process and changes in the competitive landscape. If ESSA does not achieve one or more of these factors in a timely manner, it could experience significant delays or an inability to develop ESSA's product candidates at all.

If the Company breaches any of the agreements under which the Company licenses rights to its technology from third parties, the Company could lose license rights that are important to ESSA's business. ESSA's current license agreement may not provide an adequate remedy for its breach by the licensor.

ESSA entered into a License Agreement with UBC and the BC Cancer Agency that covers certain Aniten compound candidates. The Company is subject to a number of risks associated with the Company's collaboration with UBC and the BC Cancer Agency, including the risk that UBC or the BC Cancer Agency may terminate the License Agreement upon the occurrence of certain specified events. ESSA's License Agreement requires, among other things, that the Company make certain payments and use reasonable commercial efforts to meet certain clinical and regulatory milestones. See "Patents and Proprietary Rights" in Item 4 of this Annual Report. If ESSA fails to comply with any of these obligations or otherwise breaches this or similar agreements, UBC, the BC Cancer Agency or any future licensors may have the right to terminate the license. ESSA could also suffer the consequences of non-compliance or breaches by licensors in connection with ESSA's license agreements. Such non-compliance or breaches by such third parties could in turn result in ESSA's breaches or defaults under the Company's agreements with the Company's other collaboration partners, and the Company could be found liable for damages or lose certain rights, including rights to develop and/or commercialize a product or product candidate. Loss of ESSA's rights to the Licensed IP or any similar license granted to ESSA in the future, or the exclusivity rights provided therein, could harm ESSA's financial condition and operating results.

The Company may not be able to obtain required regulatory approvals for the Company's proposed products.

The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products developed by ESSA or ESSA's future collaborative partners, if any, is subject to extensive regulation by federal, provincial, state and local governmental authorities and those regulations differ from country to country. ESSA's product candidate and potential future product candidates will be principally regulated in the United States by the FDA, in the European Union by the EMA and the regulators in the individual European Union member countries, in Canada by the TPD, and by other similar regulatory authorities in Japan and other jurisdictions. Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling products. Following several widely publicized issues in recent years, the FDA and similar regulatory authorities in other jurisdictions have become increasingly focused on product safety. This development has led to requests for more clinical trial data, for the inclusion of a significantly higher number of patients in clinical trials and for more detailed analysis of trial results. Consequently, the process of obtaining regulatory approvals, particularly from the FDA, is time-consuming and has become more costly than in the past. Any product developed by ESSA or ESSA's future collaborative partners, if any, must receive all relevant regulatory approvals or clearances from the applicable regulatory authorities before it may be marketed and sold in a particular country.

ESSA will not be permitted to market any potential products in the United States, Europe, Japan, Canada or in other countries where ESSA intends to market its product candidate and potential future product candidates until such product candidate receives approval of a NDA from the FDA or similar approval in other countries as restrictions apply. In the United States, the FDA generally requires the completion of preclinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. This process takes many years and requires the expenditure of substantial resources and may include post-marketing studies and surveillance. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Other than the INDs submitted for EPI-506 and EPI-7386, the Company has not submitted an IND or an NDA to date for any of the Company's potential products to the FDA or comparable applications to other regulatory authorities. If the Company's development efforts for potential products are not successful for the treatment of CRPC and regulatory approval is not obtained in a timely fashion or at all, the Company's business will be adversely affected.

The receipt of required regulatory approvals for the Company's product candidate and potential future product candidate(s) is uncertain and subject to a number of risks, including the following:

- the FDA, IRBs or comparable foreign regulatory authorities may disagree with the design or implementation of the Company's clinical trials;
- the Company may not be able to provide acceptable evidence of the safety, efficacy or quality of its potential products;
- the results of the Company's clinical trials may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval;
- the dosing of the Company's potential products in a particular clinical trial may not be at an optimal level;
- patients in the Company's clinical trials may suffer adverse effects for reasons that may or may not be related to the Company's potential products;
- the data collected from the Company's clinical trials may not be sufficient to support the submission of an NDA for the Company's potential products or to obtain regulatory approval in the United States, Europe, Japan, Canada, or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which the Company contracts for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering the Company's clinical data insufficient for approval.

The FDA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that the Company's data is insufficient for approval and require additional clinical trials, or other studies. In addition, varying interpretations of the data obtained from preclinical studies and clinical trials could delay, limit or prevent regulatory approval of the Company's potential products. ESSA, or ESSA's future collaborative partner, if any, must obtain and maintain regulatory authorization to conduct clinical trials. ESSA's preclinical research is subject to GLP and other requirements and ESSA's clinical research is subject to good clinical practice and other requirements. Failure to adhere to these requirements could invalidate ESSA's data. In addition, the relevant regulatory authority or independent review board may modify, suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Further, the process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the prescription product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. If regulatory approval is obtained in one jurisdiction, it does not necessarily mean that ESSA's potential products will receive regulatory approval in all jurisdictions in which the Company may seek approval, or any regulatory approval obtained may not be as broad as what was obtained in other jurisdictions. However, the failure to obtain approval for ESSA's potential products in one or more jurisdictions may negatively impact the Company's ability to obtain approval in a different jurisdiction. Accordingly, despite ESSA's expenditures and investment of time and effort, it may be unable to receive required regulatory approvals for product candidates developed by it. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained, or any approved products are not commercially successful, ESSA's business, financial condition and results of operations may be materially harmed.

As an organization, ESSA has never submitted an NDA/NDS and may be unable to do so for any future products ESSA develops.

ESSA is currently undergoing a Phase I clinical trial for EPI-7386. ESSA will need to conduct Phase II and Phase III clinical trials, which it has not previously undertaken. The conduct of Phase III clinical trials and the submission of a successful IND or CTA and NDA or NDS is a complicated process. As an organization, ESSA has limited experience in preparing, submitting and prosecuting regulatory filings and has not submitted an NDA or NDS. ESSA's interactions with the FDA to date have been limited to the completed EPI-506 clinical trial and the initiation of the Phase I clinical trial for EPI-7386. Consequently, even if ESSA's initial clinical trials are successful, the Company may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA or NDS submission and approval of ESSA's proposed products or any other future product candidate ESSA may develop. The Company may require more time and incur greater costs than competitors and may not succeed in obtaining regulatory approvals of products that the Company develops. Failure to commence or complete, or delays in, ESSA's planned clinical trials, would prevent ESSA from or delay ESSA in commercializing proposed products or any other future product candidate ESSA develops.

ESSA may not be able to successfully commercialize its Aniten series of compounds.

Even if a candidate from ESSA's Aniten series were to be successfully developed and obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, may be subject to burdensome post-approval study or risk management requirements, or may be limited to a subset of CRPC patients with limited commercial value. If ESSA is unable to obtain regulatory approval in one or more jurisdictions, or any approval contains significant limitations, ESSA may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other future product candidates that ESSA may discover, in-license, develop or acquire in the future. Also, any regulatory approval of any future product candidates, once obtained, may be withdrawn. Furthermore, even if ESSA obtains regulatory approval for a product candidate, the commercial success of such product candidate will depend on a number of factors, including the following:

- development of a commercial organization or establishment of a commercial collaboration with a commercial infrastructure;
- establishment of commercially viable pricing and approval for adequate reimbursement from third-party and government payors;
- the ability of ESSA's third-party manufacturers to manufacture quantities of the compound using commercially efficient processes and at a scale sufficient to meet anticipated demand and enable ESSA to reduce its cost of manufacturing;
- ESSA's success in educating physicians and patients about the benefits, administration and use of the compound;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of ESSA's own or its potential strategic collaborators' marketing, sales and distribution strategy and operations;
- acceptance of the product candidate as safe and effective by patients and the medical community; and
- a continued acceptable safety profile of a product candidate following approval.

Many of these factors are beyond ESSA's control. If ESSA, or its potential commercialization collaborators, are unable to successfully commercialize a product candidate, ESSA may not be able to earn sufficient revenues to continue the Company's business.

The Company's product candidate and potential future product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Although any future product candidates will undergo safety testing, not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from any of ESSA's product candidate and potential future product candidates could arise either during clinical development or, if approved by regulatory authorities, after the approved product has been marketed. The results of any future clinical trials may show that the product candidate(s) cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings, limited patient populations or potential product liability claims.

If any of ESSA's product candidate and potential future product candidates receive marketing approval and it or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take ESSA's approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- it may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- it may be subject to limitations on how it may promote or distribute the product;
- sales of the product may decrease significantly;
- it may be subject to litigation or product liability claims; and
- ESSA's reputation may suffer.

Any of these events could prevent ESSA or its future collaborative partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent ESSA from generating significant revenue from the sale of ESSA's products.

If ESSA is unable to enroll subjects in clinical trials, ESSA will be unable to complete these trials on a timely basis.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the impact of Covid-19, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, ability to obtain and maintain patient consents, risk that enrolled subjects will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications ESSA is investigating. Furthermore, ESSA plans to rely on clinical research organizations ("CROs") and clinical trial sites to ensure the proper and timely conduct of the Company's clinical trials, and while the Company has agreements governing their committed activities, the Company has limited influence over their actual performance.

If ESSA experiences delays in the completion or termination of any clinical trial of any future product candidates, the commercial prospects of product candidates will be harmed, and ESSA's ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing ESSA's clinical trials will increase costs, slow down product candidate development and approval process and could shorten any periods during which ESSA may have the exclusive right to commercialize product candidates or allow competitors to bring products to market before ESSA does, and jeopardize ESSA's ability to commence product sales, which would impair ESSA's ability to generate revenues and may harm ESSA's business, results of operations, financial condition and cash flows and future prospects. In addition, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of ESSA's proposed products or future product candidates.

ESSA may conduct trials for future product candidates at sites outside the United States and the FDA may not accept data from trials conducted in such locations.

ESSA may in the future choose to conduct more clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA chooses to not accept data collected outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt the development of the Company's proposed products or any future product candidates.

Even if the Company obtains marketing approval for any product candidate and potential future products, the Company will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense.

Even if the Company obtains U.S., Canadian or European regulatory approval for a future product candidate, which would not occur until the Company successfully completes multiple clinical trials, including Phase III clinical trials, the FDA, TPD or EMA may still impose significant restrictions on its indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials or clinical outcome studies and post-market surveillance to monitor the safety and efficacy of ESSA's potential products. Even if the Company secures U.S., Canadian or European regulatory approval, the Company would continue to be subject to ongoing regulatory requirements governing manufacturing, labeling, packaging, storage, quality assurance, distribution, import, export, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with GCP obligations, for any clinical trials that the Company conducts post approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

With respect to any product candidates for which ESSA obtains regulatory approval, ESSA will be subject to post-marketing regulatory obligations, including the requirements by the FDA, EMA and similar agencies in other jurisdictions to maintain records regarding product safety and to report to regulatory authorities serious or unexpected adverse events. Compliance with extensive post-marketing record keeping and reporting requirements requires a significant commitment of time and funds, which may limit ESSA's ability to successfully commercialize approved products.

In addition, manufacturing of approved drug products must comply with extensive regulations governing cGMP. Manufacturers and their facilities are subject to continual review and periodic inspections. As ESSA will be dependent on third parties for manufacturing, ESSA will have limited ability to ensure that any entity manufacturing products on its behalf is doing so in compliance with applicable cGMP requirements. Failure or delay by any manufacturer of ESSA's products to comply with cGMP regulations or to satisfy regulatory inspections could have a material adverse effect on ESSA, including potentially preventing ESSA from being able to supply products for clinical trials or commercial sales. In addition, manufacturers may need to obtain approval from regulatory authorities for product, manufacturing, or labeling changes, which requires time and money to obtain and can cause delays in product availability. ESSA is also required to comply with good distribution practices such as maintenance of storage and shipping conditions, as well as security of products, in order to ensure product quality determined by cGMP is maintained throughout the distribution network. In addition, ESSA is subject to regulations governing the import and export of its products.

Sales and marketing of pharmaceutical products are subject to extensive federal and state or other laws governing on-label and off-label advertising, scientific/educational grants, gifts, consulting and pricing and are also subject to consumer protection and unfair competition laws. Compliance with these extensive regulatory requirements will require training and monitoring of any future sales force, which will impose a substantial cost on ESSA and ESSA's collaborators. To the extent any future ESSA products are marketed by collaborators, ESSA's ability to ensure their compliance with applicable regulations will be limited.

Failure to comply with applicable legal and regulatory requirements may result in administrative or judicial sanctions.

If the Company or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, lack of efficacy, problems with the facility where the product is manufactured, or the Company or its manufacturers fail to comply with applicable regulatory requirements, the Company may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by the Company, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements;
- withdrawal of the product from the market and product recalls; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit the Company's ability to commercialize potential products and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase the Company's product liability exposure.

In the future, the regulatory climate might change due to changes in the FDA and other regulatory authorities' staffing, policies or regulations and such changes could impose additional post-marketing obligations or restrictions and related costs. While it is impossible to predict future legislative or administrative action, if the Company is not able to maintain regulatory compliance, the Company will not be able to market its drugs and its business could suffer.

If clinical trials for ESSA's product candidate and potential future product candidates are prolonged, delayed or stopped, ESSA may be unable to obtain regulatory approval and commercialize such product candidates on a timely basis, or at all, which would require ESSA to incur additional costs and delay receipt of any product revenue.

ESSA may experience delays in any future preclinical studies or clinical trials, and ESSA does not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement of these planned clinical trials could be substantially delayed or prevented by several factors, including:

- discussions with the FDA or other regulatory agencies regarding the scope or design of ESSA's clinical trials;
- the limited number of, and competition for, suitable sites to conduct ESSA's clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as ESSA's product candidates;
- any delay or failure to obtain regulatory approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient supplies of the product candidate for ESSA's clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs; and
- delay or failure to obtain institutional review board ("IRB"), approval to conduct a clinical trial at a prospective site.

The completion of ESSA's clinical trials, once started, could also be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- lack of efficacy during clinical trials;
- termination of ESSA's clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow ESSA's clinical trial protocols;
- inability to monitor patients adequately during or after treatment by ESSA and/or ESSA's CROs;
- ESSA's CROs or clinical study sites failing to comply with regulatory requirements or meet their contractual obligations to ESSA in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- the inability to produce or obtain sufficient quantities of the product candidate to complete clinical studies;
- the inability to scale up manufacture of the product candidate into a commercially acceptable formulation at reasonable cost;
- the inability to address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial; and
- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing.

Changes in regulatory requirements, policies and guidelines may also occur and ESSA may need to significantly amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Such changes may require ESSA to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. ESSA's clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of ESSA's clinical trial sites with respect to that site, or ESSA, due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or ESSA's clinical protocols;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; and
- upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of ESSA's product candidates.

Product development costs for any of ESSA's potential products will increase if it has delays in testing or approval or if the Company needs to perform more or larger clinical studies than planned. Any delays in completing the Company's future clinical trials will increase its costs, slow down its development and approval process and jeopardize its ability to generate revenues. Any of these occurrences may have a material adverse effect on the Company's business, financial condition and prospects.

ESSA relies on third parties to conduct its preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, this could substantially harm ESSA's business because it may not be able to obtain regulatory approval for or commercialize product candidates in a timely manner or at all.

ESSA has extensively relied upon and plans to continue to extensively rely upon entities outside of its control, including CROS and academic institutions, to monitor and manage data for its ongoing preclinical and clinical programs. ESSA relies on these parties for execution of its preclinical studies and clinical trials, and it controls only some aspects of their activities. Nevertheless, ESSA is responsible for ensuring that each of its studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and ESSA's reliance on CROS and academic institutions does not relieve it of these responsibilities. ESSA also relies on third parties to assist in conducting its preclinical studies in accordance with GLP and the Animal Welfare Act requirements. ESSA and the third parties that it relies on are required to comply with federal regulations and current GCP, which are international standards meant to protect the rights and health of patients that are enforced by the FDA and comparable foreign regulatory authorities for all of ESSA's products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If ESSA or any of the third parties it relies on fail to comply with applicable GCP, the clinical data generated in ESSA's clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require ESSA to perform additional clinical trials before approving ESSA's marketing applications. ESSA cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of its clinical trials comply with GCP requirements. In addition, ESSA's clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require ESSA to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

The third parties that ESSA relies upon are not its employees, and except for remedies available to the Company under its agreements with such third parties, ESSA cannot control whether or not they devote sufficient time and resources to the Company's ongoing clinical, nonclinical and preclinical programs. Academic institutions may not operate under the same commercial standards as other third-party CROs that undertake such work and may not be able to devote adequate time and resources to preclinical studies. If CROs or academic institutions do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, ESSA's preclinical or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize future product candidates. As a result, ESSA's results of operations and the commercial prospects for its future product candidates would be harmed, its costs could increase and its ability to generate revenues could be delayed.

Because ESSA has relied on third parties, its internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to ESSA's standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires ESSA to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. ESSA currently has a small number of employees, which limits the internal resources we have available to identify and monitor third-party providers. To the extent ESSA is unable to identify and successfully manage the performance of third-party service providers in the future, its business may be adversely affected. Though ESSA carefully manages its relationships with CROs and academic institutions, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on ESSA's business, results of operations, financial condition and cash flows and future prospects.

If ESSA's relationships with CROs or academic institutions terminate, its drug development efforts could be delayed.

ESSA relies on entities outside of its control, including CROs and academic institutions, for preclinical studies and clinical trials related to its drug development efforts. Switching or adding additional CROs or academic institutions would involve additional cost and would require management time and focus. The CROs and academic institutions that ESSA relies on have the right to terminate their agreements with the Company in the event of an uncured material breach. If any of ESSA's relationships with CROs and academic institutions terminate, the Company could experience a significant delay in identifying, qualifying and managing performance of a comparable third-party service provider, which could adversely affect its development programs. In addition, there is a natural transition period when a new CRO or academic institution commences work and the new CRO or academic institution may not provide the same type or level of services as the original provider. ESSA may not be able to enter into arrangements with alternative CROs or academic institutions or be able to do so on commercially reasonable terms.

ESSA has limited experience manufacturing product candidates on a large clinical or commercial scale and has no manufacturing facility. As a result, ESSA may in the future be dependent on third party manufacturers for the manufacture of product candidates as well as on third parties for ESSA's supply chain, and if ESSA experiences problems with any future third parties, the manufacturing of ESSA's product candidates or products could be delayed.

ESSA does not own or operate facilities for the manufacture of future potential product candidates. ESSA currently has no plans to build internal clinical or commercial scale manufacturing capabilities. As a result, ESSA potentially may rely on third-party contract manufacturing organizations, in the future, for the manufacture of active pharmaceutical ingredients for ESSA's potential products. Also, ESSA may potentially rely on another contract manufacturing organization for the production of the final product formulation. To meet ESSA's projected potential needs for clinical supplies to support its activities through regulatory approval and commercial manufacturing, the contract manufacturing organizations with whom ESSA may potentially work will need to increase the scale of production. ESSA may need to identify additional contract manufacturing organizations for continued production of supply for product candidates in the event the current potential contract manufacturing organizations ESSA chooses to utilize are unable to scale production, or if ESSA otherwise experiences any problems with them. Although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers. ESSA may encounter technical difficulties or delays in the transfer of any future potential product manufacturing on a commercial scale to additional third-party manufacturers. ESSA may be unable to enter into agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. If ESSA is unable to arrange for alternative third-party manufacturing sources or to do so on commercially reasonable terms or in a timely manner, ESSA may not be able to complete development of its potential product candidates, market or distribute them.

Reliance on third-party manufacturers entails risks to which ESSA would not be subject if ESSA manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond ESSA's control, including a failure to synthesize and manufacture product candidates or any products ESSA may eventually commercialize in accordance with ESSA's specifications and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to ESSA. In addition, the FDA and other regulatory authorities require that ESSA's product candidates and any products that ESSA may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by ESSA's third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of ESSA's potential product candidates and could cause ESSA to incur higher costs and prevent ESSA from commercializing product candidates successfully. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to ESSA, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Any significant disruption in ESSA's supplier relationships could harm the Company's business. Any significant delay in the supply of a product candidate or its key materials for a potential ongoing clinical study could considerably delay completion of ESSA's potential clinical trials, product testing and regulatory approval of ESSA's potential product candidates. If ESSA's manufacturers or ESSA is unable to purchase these key materials after regulatory approval has been obtained for ESSA's product candidates, the commercial launch of ESSA's product candidates would be delayed or there would be a shortage in supply, which would impair ESSA's ability to generate revenues from the sale of its product candidates. It may take several years to establish an alternative source of supply for ESSA's product candidates and to have any such new source approved by the FDA.

Failure to obtain regulatory approval in international jurisdictions would prevent any product candidates from being marketed outside the United States.

In order to market and sell ESSA's products in the European Union and many other jurisdictions, it must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for ESSA and could delay or prevent the introduction of its potential products in certain countries. ESSA may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. A failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. ESSA may not be able to file for marketing approvals and may not receive necessary approvals to commercialize its potential products in any market. If ESSA is unable to obtain approval of any of its future product candidates by regulatory authorities in the European Union or another jurisdiction, the commercial prospects of that product candidate may be significantly diminished and its business prospects could decline.

Recently enacted and future legislation in the United States may increase the difficulty and cost for the Company to obtain marketing approval of, and commercialize, its products and affect the prices the Company may obtain.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for ESSA's products, restrict or regulate post-approval activities and affect the Company's ability to profitably sell products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. The Company does not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of ESSA's products, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject the Company to more stringent product labeling and post-marketing testing and other requirements.

In recent years, the U.S. Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. CMS also has authority to revise Medicare reimbursement rates and to implement Medicare coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price ESSA can receive for those products, if approved. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act (the "ACA") was signed into law. This law, which was intended to broaden access to health insurance, significantly impacted the pharmaceutical industry. Among other things, the ACA imposed an annual fee on manufacturers of branded prescription drugs, increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; expanded the healthcare fraud and abuse laws, implemented a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer discounts off negotiated prices; expanded the eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program; and imposed a number of substantial new compliance provisions related to pharmaceutical companies' interactions with healthcare practitioners.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act, signed into law by President Trump in 2017, effectively repealed the individual health insurance mandate, which is considered a key component of the ACA. In November 2020, the United States Supreme Court heard oral argument in a case regarding the constitutionality of the ACA and the individual mandate. The ongoing challenges to the ACA and new legislative proposals have resulted in uncertainty regarding the ACA's future viability and destabilization of the health care market. These reforms could have an adverse effect on anticipated revenue from product candidates that ESSA may successfully develop and for which ESSA may obtain marketing approval and may affect ESSA's overall financial condition and ability to develop or commercialize product candidates. For example, it is possible that efforts to repeal the ACA, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. The scope of potential future legislation to repeal and replace the ACA provisions is highly uncertain in many respects, as is the effect of such future legislation on ESSA's business and prospects.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011. Although Medicare sequestration will remain in effect through 2027 unless additional Congressional action is taken, the Coronavirus Aid, Relief, and Economic Security (CARES) Act passed in March 2020 temporarily suspended Medicare sequestration from May 1, 2020 through December 31, 2020. Separately, in January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect future customer demand and affordability for any future our products, if approved and, accordingly, the results of our financial operations.

Further, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. In response to the global COVID-19 pandemic, in March 2020 the FDA announced its intention to postpone most domestic and foreign inspections of manufacturing facilities, and regulatory authorities outside the United States adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. Although the FDA resumed domestic on-site inspections in July 2021, inspections are being scheduled based upon each state's phase of reopening and the current intensity and risk of COVID-19 infections in a geographic region, and foreign inspections have not resumed. This or other decreases in FDA inspection or regulatory activity could delay regulatory approval of our product candidates. Changes to the FDA's policies and regulations may also impact our product candidates. For example, in December 2016, the 21st Century Cures Act ("Cures Act") was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. In addition, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 ("Right to Try Act") was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act. ESSA cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on its product candidates, if any, may be.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action in the United States. For example, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set and advertise prices for their marketed products, which have resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. On July 24, 2020, President Trump announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including eliminating protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; allowing the importation of certain drugs from other countries through individual waivers, permitting the re-importation of insulin products and prioritizing finalization of FDA's December 2019 proposed rule to permit the importation of drugs from Canada; ensuring that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries; and reducing the cost of insulin and epinephrine to patients of Federally Qualified Health Centers. While the scope and details of these executive orders are not clear, this continues to signal that the U.S. executive branch may pursue new measures to constrain drug costs and Medicare payments for drugs. The volume of drug pricing-related bills has dramatically increased under the recent Congresses and, among other recent proposals, Congress has proposed bills to change the Medicare Part D benefit to impose an inflation-based rebate in Medicare Part D and to alter the benefit structure to increase manufacturer contributions in the catastrophic phase. While the U.S. election cycle creates uncertainty about which, if any, measures will ultimately be enacted and their potential impacts, the U.S. Congress and executive branch may continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, individual states in the United States are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries, such as Canada, as well as bulk purchasing. There has also been increased discussion at the federal level, including by the Trump Administration, of proposals intended to encourage re-importation. These and other potential reforms could have a significant impact on the pharmaceutical industry and on the development and potential future pricing of ESSA's product candidates.

ESSA's business may be materially adversely affected by new legislation, new regulatory requirements and the continuing efforts of governmental and third-party payors to contain or reduce the costs of healthcare through various means.

Governments and regulatory authorities in Europe and other markets in which ESSA intends to sell its products may propose and adopt new legislation and regulatory requirements relating to pharmaceutical approval criteria and manufacturing requirements. Such legislation or regulatory requirements, or the failure to comply with such, could adversely impact ESSA's operations and could have a material adverse effect on ESSA's business, financial condition and results of operations.

In recent years, national, federal, provincial, state, and local officials and legislators have proposed, or are reportedly considering proposing, a variety of price-based reforms to the healthcare systems in the European Union, the United States and other countries. Some proposals include measures that would limit or eliminate payments for certain medical procedures and treatments or subject the pricing of pharmaceuticals to government control. Furthermore, in certain foreign markets, the pricing or profitability of healthcare products is subject to government controls and other measures that have been prepared by legislators and government officials. While ESSA cannot predict whether any such legislative or regulatory proposals or reforms will be adopted, the adoption of any such proposals or reforms could adversely affect the commercial viability of the Company's existing and potential products. Significant changes in the healthcare system in the European Union and other countries may have a substantial impact on the manner in which ESSA conducts its business. Such changes could also have a material adverse effect on ESSA's business, financial condition and results of operations.

Risks Related to ESSA's Financial Position and Need for Additional Capital

ESSA will have significant additional future capital needs for future clinical trials and there are uncertainties as to the Company's ability to raise additional funding.

Management has forecasted that ESSA's working capital will be sufficient to execute its planned expenditures for the coming fiscal year. On current plans, ESSA believes it has sufficient capital resources to continue and expand its business, including the development of its preclinical Aniten series of compounds ("Aniten") through the conduct of the initial Phase I trial of its IND candidate EPI-7386, a subsequent initial expansion phase, and at least one initial Phase I combination trial of EPI-7386 with an anti-androgen. Advancing ESSA's novel and proprietary therapies beyond these activities or acquisition and development of any new products or product candidates would require considerable resources and additional access to capital. In addition, ESSA's future cash requirements may vary materially from those now expected. For example, ESSA's future capital requirements may increase if:

- the Company experiences setbacks in its progress with non-clinical studies or if future clinical trials are delayed;
- the Company is required to perform additional non-clinical studies and clinical trials;
- the Company elects to develop, acquire or license new technologies, products or businesses;
- the Company experiences competition from other life sciences companies or in more markets than anticipated;
- the Company experiences delays or unexpected increases in connection with obtaining regulatory approvals in the various markets where ESSA hopes to sell its products;
- the Company experiences unexpected or increased costs relating to preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, or other lawsuits, brought by either ESSA or ESSA's competition; or
- the Company experiences scientific progress sooner than expected in its discovery and R&D projects, if ESSA expands the magnitude and scope of these activities, or if ESSA changes its focus as a result of ESSA's discoveries.

ESSA could potentially seek additional funding through strategic collaborations, alliances and licensing arrangements, through public or private equity or debt financing, or through other transactions. However, if future sales are slow to increase or if capital market conditions in general, or with respect to life sciences companies such as ESSA's, are unfavorable, ESSA's ability to obtain significant additional funding on acceptable terms, if at all, will be negatively affected. There is no certainty that any such financing will be provided or provided on favorable terms.

If sufficient capital is not available, ESSA may be required to delay or abandon its business expansion or R&D projects, either of which could have a material adverse effect on ESSA's business, financial condition, prospects or results of operations.

ESSA may not be able to raise additional capital on favorable terms, which may result in dilution to ESSA's existing shareholders, restrictions on ESSA's operations or the requirement for ESSA to relinquish rights to technologies or any future product candidates.

Until the Company can generate substantial revenue from product sales, if ever, the Company expects to finance future cash needs through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. Additional financing that the Company may pursue may involve the sale of its Common Shares or financial instruments that are exchangeable for, or convertible into, its Common Shares, which could result in significant dilution to ESSA's shareholders and the terms may include liquidation or other preferences that adversely affect the rights of existing shareholders. Additional capital may not be available on reasonable terms, if at all. Furthermore, these securities may have rights senior to those of ESSA's Common Shares and could contain covenants that include restrictive covenants limiting ESSA's ability to take important actions and potentially impair ESSA's competitiveness, such as limitations on ESSA's ability to incur additional debt, make capital expenditures, acquire, sell or license intellectual property rights or declare dividends. If ESSA raises additional funds through strategic collaborations and alliances or licensing arrangements with third parties, ESSA may have to relinquish valuable rights to technologies or future product candidates, or grant licenses on terms that are not favorable to ESSA. If the Company is unable to raise additional funds when needed, the Company may be required to delay, limit, reduce or terminate its product development or commercialization efforts or grant rights to develop and market product candidates that ESSA would otherwise prefer to develop and market ourselves.

The Company remains subject to the restrictions and conditions of the CPRIT Agreement. Failure to comply with the CPRIT Agreement may materially and adversely affect ESSA's financial condition and results of operations.

ESSA relied on the CPRIT Grant to fund a portion of its preclinical and Phase 1 clinical development costs of clinical candidate EPI-506, which ceased development in September 2017. The total of the CPRIT Grant was US$12 million, of which ESSA has received a total of US$11.7 million to date, as follows: US$2.8 million (on grant execution), US$3.7 million (upon the clearance of the IND of EPI-506, ESSA's first-generation agent, by the FDA) and US$5.2 million (upon commencement of the Phase I clinical trial of EPI-506 in November 2015). The CPRIT Grant is subject to various requirements, including ESSA's compliance with the scope of work outlined in the CPRIT Agreement and demonstration of its progress towards achievement of the milestones set forth in the CPRIT Agreement. If ESSA fails to comply with the terms of the CPRIT Agreement, is found to have used any grant proceeds for purposes other than intended, or fails to maintain the required level of operations in the State of Texas for three years following the final payment of grant funds, CPRIT could determine that ESSA is in default of its obligations under the CPRIT Agreement and could, among other things, seek reimbursement of all proceeds of the CPRIT Grant received by ESSA. ESSA received and responded to a request in October 2018 for information from CPRIT regarding the nature and extent of the Company's operations in Texas. Although the Company believes it has at all times acted in compliance with the CPRIT Agreement and believes its response to CPRIT's request for information is satisfactory, there can be no assurance that CPRIT will agree with ESSA's determination. If ESSA is found to be in default under the CPRIT Agreement and such default is not waived by CPRIT, the Company may not receive the remaining funds of the CPRIT Grant or could be required to reimburse a portion or all of the CPRIT Grant. ESSA cannot be certain that its assets or cash flows or ability to raise additional capital will be sufficient to fully repay the CPRIT Grant. Being required to reimburse all or a portion of the CPRIT Grant would impact ESSA's ongoing operations, which could materially and adversely affect its financial condition and results of operations.

The Company has incurred significant losses in every quarter since its inception and anticipates that it will continue to incur significant losses in the future and may never generate profits from operations or maintain profitability.

ESSA is a clinical stage pharmaceutical company with a limited operating history. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. ESSA does not have any products approved by regulatory authorities for marketing or commercial sale and has not generated any revenue from product sales, or otherwise, to date. Furthermore, ESSA continues to incur significant research, development and other expenses related to its ongoing operations. As a result, ESSA is not profitable and has incurred losses in every reporting period since inception in 2009. For the years ended September 30, 2020 and September 30, 2019, ESSA reported net losses of $23,445,370 and $12,756,832, respectively. As of September 30, 2020, ESSA had an accumulated deficit since inception of $80,970,304.

The Company expects to continue to incur significant expenses and operating losses for the foreseeable future. ESSA anticipates these losses will increase as it continues the research and development of, and seeks regulatory approvals for, its product candidate and any of its potential future product candidates and potentially begins to commercialize any products that may achieve regulatory approval. ESSA may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its financial condition. The size of ESSA's future net losses will depend, in part, on the rate of future growth of ESSA's expenses and ESSA's ability to generate revenues. The Company's prior losses and expected future losses have had and will continue to have an adverse effect on the Company's financial condition.

Even if the Company is able to commercialize any product candidate, there can be no assurance that the Company will generate significant revenues or ever achieve profitability.

The Company expects to continue to incur substantial losses for the foreseeable future, and these losses may be increasing. The Company is uncertain about when or if it will be able to achieve or sustain profitability. If the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair the Company's ability to sustain operations and adversely affect the price of the Common Shares and its ability to raise capital.

ESSA has a limited operating history, which may make it difficult for you to evaluate the success of ESSA's business to date and to assess ESSA's future viability.

The Company's operations in 2020 have been primarily limited to organizing and staffing ESSA, establishing relationships with consultants and contract vendors with relevant expertise, acquiring the in-licensing of intellectual property, discovering and developing novel small molecule product candidates, conducting preliminary preclinical research, preparing for the execution of a Phase I clinical study of its next-generation agent EPI-7386 and conducting a Phase I clinical study of its next-generation agent EPI-7386. ESSA is a development stage company with limited operating history and no revenue. ESSA has identified a product candidate, EPI-7386, to advance through clinical development but does not have any products ready for commercialization. Consequently, evaluating ESSA's performance, viability or future success will be more difficult than if ESSA had a longer operating history or approved products on the market.

Risks Related to ESSA's Intellectual Property

ESSA relies on proprietary technology, the protection of which can be unpredictable and costly.

The Company's activities depend, in part, on its ability to (i) obtain and maintain patents, trade secret protection and operate without infringing the intellectual proprietary rights of third parties, (ii) successfully defend these patents (including patents owned by or licensed to the Company) against third-party challenges and (iii) successfully enforce these patents against third-party competitors. There is no assurance that the Company will be granted such patents or proprietary technology or that such granted patents or proprietary technology will not be circumvented through the adoption of a competitive, though non-infringing, process or product. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of the Company's intellectual property. Accordingly, the Company cannot predict the breadth of claims that may be allowable or enforceable in its patents (including patents owned by or licensed to the Company). Failure to protect the Company's existing and future intellectual property rights could seriously harm its business and prospects and may result in the loss of its ability to exclude others from using the Company's technology or its own right to use the technologies. If the Company does not adequately ensure the right to use certain technologies, it may have to pay others for the right to use their intellectual property, pay damages for infringement or misappropriation or be enjoined from using such intellectual property. The Company's patents do not guarantee the right to use the technologies if other parties own intellectual property rights that are necessary in order to use such technologies. The Company's patent position is subject to complex factual and legal issues that may give rise to uncertainty as to the validity, scope and enforceability of a particular patent. The Company's and the Company's licensors' patents and patent applications, if issued, may be challenged, invalidated or circumvented by third parties. U.S. patents and patent applications may also be subject to interference proceedings, re-examination proceedings, derivation proceedings, post-grant review or inter partes review in the United States Patent and Trademark Office ("USPTO"), challenging the Company's or the Company's licensors' patent rights. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office.

In addition, there is a risk that improved versions of ESSA's own product developed by third parties will be granted patent protection and compete with ESSA's products. For example, any patents ESSA obtains may not be sufficiently broad to prevent others from utilizing its technologies or from developing competing products and technologies. Third parties may attempt to circumvent ESSA's patents by means of alternative designs and processes or may independently develop similar products, duplicate any of ESSA's products not under patent protection, or design around the inventions ESSA claims in any of its existing patents, existing patent applications or future patents or patent applications. The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of ESSA's coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents. It is impossible to anticipate the breadth or degree of protection that patents will afford products developed by ESSA or their underlying technology.

In any case, there can be no assurance that:

- any rights under U.S., Canadian, or foreign patents owned by the Company or other patents that third parties license to the Company will not be curtailed;
- the Company was the first inventor of inventions covered by its issued patents or pending applications or that the Company was the first to file patent applications for such inventions;
- the Company's pending or future patent applications will be issued with the breadth of claim coverage sought by the Company, or be issued at all;
- the Company's competitors will not independently develop or patent technologies that are substantially equivalent or superior to the Company's technologies;
- third parties will not attempt to circumvent ESSA's patents by means of alternative designs and processes or that third parties will not also independently develop similar products, duplicate any of ESSA's products not under patent protection, or design around the inventions ESSA claims in any of the Company's existing patents, existing patent applications or future patents or patent applications;
- any of the Company's trade secrets will not be learned independently by its competitors; or
- the steps the Company takes to protect its intellectual property will be adequate.

In addition, effective patent, trademark, copyright and trade secret protection may be unavailable, limited or not sought in certain foreign countries. Further, countries ESSA may sell to may not protect its intellectual property to the same extent as the laws of the United States, Canada or Europe, and may lack rules and procedures required for defending ESSA's patents.

There is a risk that any patents issued relating to ESSA's products or any patents licensed to ESSA may be successfully challenged or that the practice of its products might infringe the patents of third parties. If the practice of ESSA's products infringes the patents of third parties, the Company may be required to design around such patents, potentially causing increased costs and delays in product development and introduction or precluding ESSA from developing, manufacturing or selling its planned products. In addition, disputes may arise as to the rights to know-how and inventions among ESSA's employees and consultants who use intellectual property owned by others for the work performed for the Company. The scope and validity of patents which may be obtained by third parties, the extent to which ESSA may wish or need to obtain patent licenses and the cost and availability of such licenses are currently unknown. If such licenses are obtained, it is likely they would be royalty bearing, which could reduce ESSA's income. If licenses cannot be obtained on an economical basis, delays in market introduction of its planned products could occur or introduction could be prevented, in some cases causing the expenditure of substantial funds.

In certain instances, ESSA may elect not to seek patent protection but instead rely on the protection of the Company's technology through confidentiality agreements or trade secrets. There can be no assurance that these agreements will not be breached, that the Company will have adequate remedies for any breach or that such persons or institutions will not assert rights to intellectual property arising out of these relationships. The value of ESSA's assets could also be reduced to the extent that third parties are able to obtain patent protection with respect to aspects of ESSA's technology or products or that confidential measures ESSA has in place to protect the Company's proprietary technology are breached or become unenforceable. However, third parties may independently develop or obtain similar technology and such third parties may be able to market competing products and obtain regulatory approval through a showing of equivalency to one of ESSA's products which has obtained regulatory approval, without being required to undertake the same lengthy and expensive clinical studies that ESSA would have already completed. The cost of enforcing the Company's patent rights or defending rights against infringement charges by other patent holders may be significant and could limit operations.

Litigation may also be necessary to enforce patents issued or licensed to ESSA or to determine the scope and validity of a third party's proprietary rights. ESSA could incur substantial costs if the Company is required to defend itself in patent suits brought by third parties, if ESSA participates in patent suits brought against or initiated by ESSA's corporate collaborators or if ESSA initiates such suits. The Company may not have the necessary resources to participate in or defend any such activities or litigation. Even if ESSA did have the resources to vigorously pursue its interests in litigation, because of the complexity of the subject matter, it is impossible to predict whether ESSA would prevail in any such action. Any claims of patent infringement asserted by third parties may:

- divert the time and attention of the Company's technical personnel and management;
- cause product development or commercialization delays;
- require the Company to cease or modify its use of the technology and/or develop non-infringing technology; or
- require the Company to enter into royalty or licensing agreements.

An adverse outcome in litigation, or interference or derivation proceeding to determine priority or other proceeding in a court or patent or selling office could subject ESSA to significant liabilities, require disputed rights to be licensed from third parties or require ESSA to cease using certain technology or products, any of which may have a material adverse effect on the Company's business, financial condition and results of operations.

ESSA may not be able to protect its intellectual property rights throughout the world.

Filing, prosecuting and defending patents on ESSA's product candidate and potential future product candidates throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States or federal and provincial laws in Canada. Consequently, ESSA may not be able to prevent third parties from practicing its inventions in all countries outside the United States or Canada, or from selling or importing products made using its inventions in and into the United States, Canada or other jurisdictions. Competitors may use ESSA's technologies in jurisdictions where it has not obtained patent protection to develop their own products and may export otherwise infringing products to territories where ESSA has patent protection, but where enforcement is not as strong as that in the United States or Canada. These products may compete with ESSA's products in jurisdictions where it does not have any issued patents and its patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for ESSA to stop the infringement of its patents or marketing of competing products in violation of its proprietary rights generally. Proceedings to enforce ESSA's patent rights in foreign jurisdictions could result in substantial cost and divert its efforts and attention from other aspects of its business. ESSA may not prevail in any lawsuits that it initiates and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of ESSA's patents, requiring it to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of ESSA's products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, ESSA may have limited remedies if patents are infringed or if it is compelled to grant a license to a third-party, which could materially diminish the value of those patents. This could limit ESSA's potential revenue opportunities. Accordingly, ESSA's efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that it owns or licenses.

ESSA may be subject to claims by third parties asserting that ESSA, or ESSA's employees or consultants have misappropriated their intellectual property, or claiming ownership of what ESSA regards as its own intellectual property.

Certain of ESSA's current or former employees or consultants, including senior management, were previously employed, or continue to be employed, at universities or other public institutions, or at other biotechnology or pharmaceutical companies, including ESSA's competitors or potential competitors. Some of these employees, executed proprietary rights, nondisclosure and noncompetition agreements, in connection with such previous employment. ESSA may be subject to claims that ESSA, or these employees, have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. If ESSA fails in prosecuting or defending any such claims, in addition to paying monetary damages, ESSA may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third-party, and ESSA could be required to obtain a license from such third-party to commercialize ESSA's technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if ESSA is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Obtaining and maintaining ESSA's patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and its patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If ESSA or its future potential licensors fail to maintain the patents and patent applications covering product candidates, ESSA's competitive position would be adversely affected.

Other Risks Related to ESSA's Business

The Company's business and operations would suffer in the event of computer system failures or security breaches.

In the ordinary course of ESSA's business, the Company collects, stores and transmits confidential information, including intellectual property, proprietary business information and personal information. Despite the implementation of security measures, ESSA's internal computer systems, and those of other third parties on which the Company relies, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Significant disruptions of ESSA's information technology systems or security breaches could adversely affect ESSA's business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to the Company. If such disruptions were to occur and cause interruptions in ESSA's operations, it could result in a material disruption of ESSA's drug development program. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned preclinical studies or clinical trials could result in delays in ESSA's efforts to identify and develop product candidates and significantly increase its costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of, or damage to, ESSA's data or applications, or inappropriate disclosure of confidential or proprietary information, the Company could incur liability and the further development of EPI compounds or the Company's product candidates could be delayed.

Business disruptions could seriously harm ESSA's future revenues and financial condition and increase costs and expenses.

ESSA's operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which ESSA is predominantly self-insured. ESSA does not carry insurance for all categories of risk that ESSA's business may encounter. The occurrence of any of these business disruptions could seriously harm ESSA's operations and financial condition and increase costs and expenses. Further, any significant uninsured liability may require ESSA to pay substantial amounts, which would adversely affect ESSA's business, results of operations, financial condition and cash flows from future prospects.

ESSA's business depends heavily on the use of information technologies.

Several key areas of ESSA's business depend on the use of information technologies. Despite ESSA's best efforts to prevent such behavior, third parties may nonetheless attempt to hack into ESSA's systems and obtain data relating to ESSA's preclinical studies or proprietary information on potential products. If ESSA fails to maintain or protect ESSA's information systems and data integrity effectively, ESSA could lose or have difficulty attracting customers, have difficulty preventing, detecting and controlling fraud, have regulatory sanctions or penalties imposed, experience increases in operating expenses, incur expenses or lose revenues, or suffer other adverse consequences as a result of a data privacy breach. While ESSA has invested in the protection of data and information technology, there can be no assurance that ESSA's efforts, or those of ESSA's third-party collaborators, if any, to implement adequate security and quality control measures for data processing would be sufficient to protect against data deterioration or loss in the event of a system malfunction, or to prevent data from being stolen or corrupted in the event of a security breach. Any such loss or breach could have a material adverse effect on ESSA's business, operating results and financial condition.

If the Company is not successful in attracting and retaining highly qualified personnel, the Company may not be able to successfully implement its business strategy.

The Company's ability to compete in the highly competitive pharmaceuticals industry depends in large part upon its ability to attract and retain highly qualified managerial, scientific and medical personnel. Competition affects the Company's ability to hire and retain highly qualified personnel on acceptable terms. The Company is highly dependent on its management, scientific and medical personnel. The Company's management team has substantial knowledge in many different aspects of drug development and commercialization. Despite the Company's efforts to retain valuable employees, members of its management, scientific and medical teams may terminate their employment with the Company on short notice or, potentially, without any notice at all. The loss of the services of any of the Company's executive officers or other key employees could potentially harm its business, operating results or financial condition. The Company's success may also depend on its ability to attract, retain and motivate highly skilled junior, mid-level, and senior managers and scientific personnel. Other pharmaceutical companies with which the Company competes for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than the Company does. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what the Company has to offer. If the Company is unable to continue to attract and retain high-quality personnel, the rate and success at which the Company can develop and commercialize product candidates would be limited.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain the Company's future revenues.

In many of the markets ESSA hopes to sell future products in, successful commercialization of any product candidate will depend, in part, on the extent to which coverage and reimbursement for such product candidates and related treatments will be available from government healthcare programs, private health insurers, managed care plans and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States.

Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require ESSA to provide scientific and clinical support for the use of ESSA's products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

A primary trend in the U.S. healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. ESSA cannot be sure that coverage and reimbursement will be available for any product candidates that it or any future collaborator commercialize and, if reimbursement is available, the level of reimbursement. In addition, coverage and reimbursement may impact the demand for, or the price of, any product candidate for which ESSA or a collaborator obtains marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, ESSA or its collaborators may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the TPD, FDA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers ESSA's costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover ESSA's and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. ESSA's or any collaborator's inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any approved products that ESSA or its collaborators develop could have a material adverse effect on ESSA's operating results, ability to raise capital needed to commercialize product candidates and overall financial condition.

The directors and officers of ESSA may be subject to conflicts of interest.

Some of the directors and officers are engaged and will continue to be engaged in the search for additional business opportunities on behalf of other corporations and situations may arise where these directors and officers will be in direct competition with the Company. Not all of the Company's directors or officers are subject to non-competition agreements. Some of the directors and officers of the Company are or may become directors or officers of the other companies engaged in other business ventures whose operations may, from time to time, be in direct competition with ESSA's operations. Conflicts, if any, will be dealt with in accordance with the relevant provisions of the Business Corporations Act (British Columbia) and under the Company's articles of incorporation.

The Company faces intense competition from other biotechnology and pharmaceutical companies and its operating results will suffer if the Company fails to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. The Company's potential competitors in the United States and globally include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies and specialized cancer treatment companies. Many companies, as well as research organizations, currently engage in, or have in the past engaged in, efforts related to the development of products in the same therapeutic areas as ESSA does. Due to the size of the prostate cancer treatment market and the large unmet medical need for products that treat CRPC, a number of the world's largest pharmaceutical companies are developing, or could potentially develop, products that could compete with the Company's future product candidates.

Many of the companies developing competing technologies and products in ESSA's field have significantly greater financial resources and expertise in discovery, R&D, manufacturing, preclinical studies and clinical testing, obtaining regulatory approvals and marketing than ESSA does. Other smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for discovery, research, clinical development and marketing of products similar to ESSA's. There is a risk that one or more of ESSA's competitors may develop more effective or more affordable products and that such competitors will commercialize products that will render its product candidates obsolete. ESSA faces competition with respect to product efficacy and safety, ease of use and adaptability to various modes of administration, acceptance by physicians, the timing and scope of regulatory approvals, availability of resources, reimbursement coverage, price and patent positions of others. In addition, these companies and institutions also compete with ESSA in recruiting and retaining qualified personnel. If the Company is not able to compete effectively against its current and future competitors, its business will not grow and its financial condition and operations will suffer materially adverse effects.

The Company may face exposure to adverse movements in foreign currency exchange rates.

ESSA's business may expand internationally and as a result, a significant portion of its revenues, expenses, current assets and current liabilities may be preliminary denominated in foreign currencies, while its financial statements are expressed in U.S. dollars. A decrease in the value of such foreign currencies relative to the U.S. dollar could result in losses in revenues from currency exchange rate fluctuations. To date, ESSA has not hedged against risks associated with foreign exchange rate exposure. ESSA cannot be sure that any hedging techniques it may implement in the future will be successful or that its business, financial condition, and results of operations will not be materially adversely affected by exchange rate fluctuations.

If ESSA is not able to convince public payors and hospitals to include ESSA's products on their approved formulary lists, revenues may not meet expectations and ESSA's business, results of operations and financial condition may be adversely affected.

Hospitals establish formularies, which are lists of drugs approved for use in the hospital. If a drug is not included on the hospital's formulary, the ability to promote and sell ESSA's products may be limited or denied. If ESSA fails to secure and maintain formulary inclusion for products on favorable terms or are significantly delayed in doing so, ESSA may have difficulty achieving market acceptance of products and ESSA's business, results of operations and financial condition could be materially adversely affected.

The Company has never marketed a drug before, and if the Company is unable to establish an effective sales force and marketing infrastructure, or enter into acceptable third-party sales and marketing or licensing arrangements, the Company may be unable to generate any revenue.

ESSA does not currently have an infrastructure for the sales, marketing and distribution of pharmaceutical drug products and the cost of establishing and maintaining such an infrastructure may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, ESSA must build its sales, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services. If ESSA is unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, ESSA may not be able to generate product revenue and may not become profitable. ESSA will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, ESSA may be unable to compete successfully against these more established companies.

In order to establish the Company's sales and marketing infrastructure, the Company will need to expand the size of its organization and the Company may experience difficulties in managing this growth.

As the Company's development and commercialization plans and strategies develop, the Company expects that it will need to expand the size of its employee base for managerial, operational, sales, marketing, financial and other resources.

Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, the Company's management may have to divert a disproportionate amount of its attention away from the Company's day-to-day activities and devote a substantial amount of time to managing these growth activities. The Company's future financial performance and its ability to commercialize its potential products and any other future product candidates and its ability to compete effectively will depend, in part, on the Company's ability to effectively manage any future growth.

ESSA's product candidate and potential future products may, if approved for sale, not achieve or maintain expected levels of market acceptance, which could have a material adverse effect on its business, financial condition and results of operations and could cause the market value of its securities to decline.

Even if ESSA is able to obtain regulatory approvals for its product candidates, the success of those products is dependent upon achieving and maintaining market acceptance. New product candidates that appear promising in development may fail to reach the market or may have only limited or no commercial success. Levels of market acceptance for ESSA's products could be impacted by several factors, many of which are not within ESSA's control, including but not limited to:

- demonstration of clinical safety and efficacy of ESSA's potential products and other possible AR-NTD inhibitors generally;
- safety, efficacy, convenience and cost-effectiveness of ESSA's products compared to products of its competitors;
- the prevalence and severity of any adverse side effects;
- scope of approved uses and marketing approval;
- limitations or warnings contained in FDA-approved labeling;
- timing of market approvals and market entry;
- the willingness of physicians to prescribe ESSA's potential products and of the target patient population to try new therapies;
- the inclusion of AR-NTD inhibitor products in applicable treatment guidelines;
- new procedures or methods of treatment that may reduce the incidences of any of the indications for which ESSA's potential products shows utility;
- difficulty in, or excessive costs to, manufacture;
- infringement or alleged infringement of the patents or intellectual property rights of others;
- the introduction of any new products, including generic AR-NTD inhibitor products, that may in the future become available to treat indications for which ESSA's potential product may be approved;
- availability of alternative products from ESSA's competitors;
- acceptance of the price of ESSA's products; and
- ability to market ESSA's products effectively at the retail level.

In addition, the success of any new product will depend on ESSA's ability to either successfully build its in-house sales capabilities or to secure new, or to realize the benefits of existing arrangements with third-party marketing or distribution partners. Seeking out, evaluating and negotiating marketing or distribution agreements may involve the commitment of substantial time and effort and may not ultimately result in an agreement. In addition, the third-party marketing or distribution partners may not be as successful in promoting ESSA's products as it had anticipated. If ESSA is unable to commercialize new products successfully, whether through a failure to achieve market acceptance, a failure to build its own in-house sales capabilities, a failure to secure new marketing partners or to realize the benefits of ESSA's arrangements with existing marketing partners, there may be a material adverse effect on ESSA's business, financial condition and results of operations and it could cause the market value of ESSA's securities to decline.

In addition, by the time any products are ready to be commercialized, what ESSA believes to be the market for these products may have changed. The Company's estimates of the number of patients who have received or might have been candidates to use a specific product may not accurately reflect the true market or market prices for such products or the extent to which such products, if successfully developed, will actually be used by patients. ESSA's failure to successfully introduce and market its products that are under development would have a material adverse effect on its business, financial condition and results of operations.

The Company may acquire businesses or products or form strategic alliances in the future and the Company may not realize the benefits of such acquisitions.

The Company may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that the Company believes will complement or augment its existing business.

If the Company acquires businesses in the future, it may not be able to realize the benefit of acquiring such businesses if the Company is unable to successfully integrate them with its existing operations and company culture. The Company may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent the Company from realizing their expected benefits. The potential failure of the due diligence processes to identify significant problems, liabilities or other shortcomings or challenges with respect to intellectual property, product quality, revenue recognition or other accounting practices, taxes, corporate governance and internal controls, regulatory compliance, employee, customer or partner disputes or issues and other legal and financial contingencies could decrease or eliminate the anticipated benefits and synergies of any acquisition and could negatively affect ESSA's future business and financial results.

As part of ESSA's business strategy, it may also continue to acquire additional companies, products or technologies principally related to, or complementary to, ESSA's current operations. Any such acquisitions will be accompanied by certain risks including but not limited to:

- exposure to unknown liabilities of acquired companies and the unknown issues with any associated technologies or research;
- higher than anticipated acquisition costs and expenses;
- the difficulty and expense of integrating operations, systems and personnel of acquired companies;
- disruption of ESSA's ongoing business;
- inability to retain key customers, distributors, vendors and other business partners of the acquired company;
- diversion of management's time and attention; and
- possible dilution to shareholders.

Also, the anticipated benefit of any joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of ESSA's equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm ESSA's financial condition. ESSA cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on its operating results.

ESSA may not be able to successfully overcome these risks and other problems associated with acquisitions and this may adversely affect ESSA's business, financial condition or results of operations.

ESSA may seek to enter into collaborations with third parties for the development and commercialization of its product candidate and potential future product candidates. If ESSA fails to enter into such collaborations, or such collaborations are not successful, it may not be able to capitalize on the market potential of its product candidate and potential future product candidates.

The Company may seek third-party collaborators for development and commercialization of its product candidate and potential future product candidates. ESSA is not currently party to any such arrangement. However, if ESSA does enter into any such arrangements with any third parties in the future, it will likely have limited control over the amount and timing of resources that its collaborators dedicate to the development or commercialization of ESSA's product candidates. The Company's ability to generate revenues from these arrangements will depend on its collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving ESSA's product candidates would pose the following risks:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of ESSA's product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with ESSA's products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ESSA's;
- collaborators with marketing and distribution rights to one or more of ESSA's products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend ESSA's intellectual property rights or may use ESSA's proprietary information in such a way as to invite litigation that could jeopardize or invalidate ESSA's intellectual property or proprietary information or expose ESSA to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose ESSA to litigation and potential liability;
- disputes may arise between the collaborators and ESSA that result in the delay or termination of the research, development or commercialization of ESSA's products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a collaborator of ESSA's were to be involved in a business combination, the continued pursuit and emphasis on ESSA's product development or commercialization program could be delayed, diminished or terminated.

ESSA's 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 ESSA's reputation.

ESSA is exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards ESSA has established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to ESSA. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to ESSA's reputation. If any such actions are instituted against ESSA and ESSA is not successful in defending itself or asserting ESSA's rights, those actions could have a significant impact on ESSA's business, results of operations, financial condition and cash flows from future prospects, including the imposition of significant fines or other sanctions.

If product liability lawsuits are brought against the Company, it may incur substantial liabilities and may be required to cease the sale, marketing and distribution of its product candidate and potential future products.

The Company could face a potential risk of product liability as a result of its potential sales, marketing and distribution activities relating to any future commercialization of any future product. For example, the Company may be sued if any product it develops allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under U.S. state or Canadian provincial or other foreign consumer protection legislation. If the Company cannot successfully defend itself against product liability claims, it may incur substantial liabilities or be required to cease the sale, marketing and distribution of its products. Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any future products that the Company may develop;
- injury to the Company's reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and the Company's resources;
- substantial monetary awards to consumers, trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize;
- the inability to continue the sale, marketing and distribution of ESSA's product candidate and potential future products; and
- a decline in the price of the Common Shares or other outstanding securities.

The Company currently maintains insurance that it believes has sufficient coverage to protect against the liability risks discussed above and the Company believes this coverage is consistent with industry norms for companies at a similar stage of development. However, if the Company is unable to obtain and retain sufficient product liability insurance in the future at an acceptable cost to protect against potential product liability claims, the commercialization of products it develops could be hindered or prevented.

Compulsory licensing or generic competition may affect the Company's business in certain countries.

In a number of countries, governmental authorities and other groups have suggested that companies which manufacture medical products (e.g., pharmaceuticals) should make products available at a low cost. In some cases, governmental authorities have held that where a pharmaceutical company does not do so, its patents might not be enforceable to prevent generic competition. Alternatively, some governmental authorities could require that ESSA grant compulsory licenses to allow competitors to manufacture and sell their own versions of ESSA's products, thereby reducing ESSA's sales or the sales of ESSA's licensee(s). In all of these situations, the results of future operations in these countries if any, could be adversely affected.

ESSA incurs significantly increased costs and devotes substantial management time as a result of operating as a public company.

As a public company, ESSA incurs significant legal, accounting and other expenses. For example, ESSA is subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and may be required to comply with the applicable requirements of Sarbanes-Oxley and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. ESSA's continued compliance with these requirements increase its legal and financial compliance costs and make some activities more time consuming and costly. In addition, ESSA's management and other personnel need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, ESSA may or in the future incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of Sarbanes-Oxley, which involves annual assessments of a company's internal controls over financial reporting. ESSA may in the future need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and may need to establish an internal audit function. ESSA cannot always predict or estimate the amount of additional costs incurred as a result of being a public company or the timing of such costs.

Risks Related to Additional Legal Compliance and Regulatory Matters

ESSA is subject to risks inherent in foreign operations.

ESSA intends to pursue international market growth opportunities, such that international sales may account for a significant portion of its revenue. ESSA is subject to a number of risks associated with its potential international business operations, sales and marketing activities that may increase liability, costs, lengthen sales cycles and require significant management attention. These risks include:

- compliance with the laws of the United States, Canada, the European Union and other jurisdictions where ESSA may conduct business, including import and export legislation;
- increased reliance on third parties to establish and maintain foreign operations;
- the complexities and expenses of administering a business abroad;
- complications in compliance with, and unexpected changes in, foreign regulatory requirements;
- instability in economic or political conditions, including inflation, recession and actual or anticipated military conflicts, social upheaval or political uncertainty;
- foreign currency fluctuations;
- foreign exchange controls and cash repatriation restrictions;
- tariffs and other trade barriers;
- difficulties in collecting accounts receivable;
- differing tax structures and related potential adverse tax consequences;
- uncertainties of laws and enforcement relating to the protection of intellectual property or secured technology;
- litigation in foreign court systems;
- unauthorized copying or use of ESSA's intellectual property;

- cultural and language differences;
- difficulty in managing a geographically dispersed workforce in compliance with local laws and customs that vary from country to country; and
- other factors, depending upon the country involved.

There can be no assurance that the policies and procedures ESSA implements to address or mitigate these risks will be successful, that ESSA's personnel will comply with them or that ESSA will not experience these factors in the future or that they will not have a material adverse effect on ESSA's business, results of operations and financial condition.

Laws and regulations governing international operations may preclude ESSA 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.

ESSA must comply with numerous laws and regulations in each jurisdiction in which ESSA plans to operate. ESSA must also comply with U.S. laws applicable to the foreign operations of U.S. individuals, such as the FCPA, and Canadian laws applicable to the foreign operations of Canadian businesses and individuals, such as the CFPOA. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The CFPOA prohibits Canadian businesses and individuals from giving or offering to give a benefit of any kind to a foreign public official, or any other person for the benefit of the foreign public official, where the ultimate purpose is to obtain or retain a business advantage. Furthermore, a company may be found liable for violations by not only its employees, but also by its third-party agents. Any failure to comply with the CFPOA, as well as applicable laws and regulations in foreign jurisdictions, could result in substantial penalties or restrictions on ESSA's ability to conduct business in certain foreign jurisdictions, which may have a material adverse impact on ESSA and its share price.

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring ESSA to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical studies and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of ESSA's failure to satisfy any of its obligations under laws governing international business practices would have a negative impact on its operations and harm its reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

ESSA's employees or other agents may, without the Company's knowledge and despite the Company's efforts, engage in prohibited conduct under its policies and procedures and the CFPOA, FCPA or other anti-bribery laws that ESSA may be subject to for which it may be held responsible. If ESSA's employees or other agents are found to have engaged in such practices, it could suffer severe penalties and other consequences that may have a material adverse effect on its business, financial condition and results of operations.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If ESSA expands its presence outside of the United States in the future, it will be required to dedicate additional resources to comply with these laws, and these laws may preclude ESSA from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit ESSA's growth potential and increase development costs.

ESSA is subject to U.S. laws relating to fraud and abuse and patients' rights.

As a pharmaceutical company, even though ESSA does not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to ESSA's future arrangements with third-party payors and customers who are in a position to purchase, recommend and/or prescribe ESSA's product candidates for which the Company obtains marketing approval. These broadly applicable fraud and abuse and other healthcare laws and regulations may constrain ESSA's future business or financial arrangements and relationships with healthcare professionals, principal investigators, consultants, customers, and third-party payors and other entities, including ESSA's marketing practices, educational programs and pricing policies. Restrictions under applicable federal and state healthcare laws and regulations that may affect ESSA's ability to operate include, but are not limited to, the following:

- the U.S. Anti-Kickback Statute, among other things, prohibits persons from knowingly and willfully soliciting, offering, receiving or providing paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, among other things, prohibits individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

Efforts to ensure that ESSA's business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that ESSA's business practices do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If ESSA's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to ESSA, the Company may be subject to penalties, including without limitation, significant civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings, and the curtailment or restructuring of ESSA's operations. If any physicians or other healthcare providers or entities with whom ESSA expects to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Moreover, ESSA expects there will continue to be federal and state laws and regulations, proposed and implemented, that could impact ESSA's operations and business. The extent to which future legislation or regulations, if any, relating to healthcare fraud abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on ESSA's business remains uncertain.

If ESSA fails to comply with environmental, health and safety laws and regulations, ESSA could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of ESSA's business.

ESSA is subject to numerous environmental, health and safety laws and regulations in the United States and in Canada, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. ESSA's operations could involve the use of hazardous and flammable materials, including chemicals and biological materials. ESSA's operations could also produce hazardous waste products. The Company's general practice would be to contract with third parties for the disposal of such materials and wastes. ESSA cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from ESSA's use of hazardous materials, it could be held liable for any resulting damages, and any liability could exceed its resources. ESSA also could incur significant costs associated with civil or criminal fines and penalties.

Although ESSA maintains workers' compensation insurance to cover for costs and expenses ESSA may incur due to injuries to employees resulting from the use of any hazardous materials, this insurance may not provide adequate coverage against potential liabilities. ESSA does not maintain insurance for environmental liability or toxic tort claims that may be asserted against it in connection with its storage or disposal of biological or hazardous materials.

In addition, ESSA may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair ESSA's research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

The change from foreign private issuer to U.S. domestic issuer status may result in additional costs and expenses to us.

As of March 31, 2020, we determined that we no longer qualify as a "foreign private issuer," as such term is defined in Rule 405 under the U.S. Securities Act of 1933, as amended (the "Securities Act"). As a result, as of October 1, 2020, we are no longer eligible to use the rules and forms designated for foreign private issuers and we are considered a U.S. domestic issuer. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than the costs incurred as a foreign private issuer. As a result, we are now required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are generally more detailed and extensive than the forms available to a foreign private issuer. In addition, we are required to comply with U.S. proxy requirements and Regulation FD (Fair Disclosure) and our officers, directors and principal shareholders are subject to the beneficial ownership reporting and short-swing profit recovery requirements in Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We are also no longer eligible to rely upon exemptions from corporate governance requirements that are available to foreign private issuers or to benefit from other accommodations for foreign private issuers under the rules of the SEC or Nasdaq, which may involve additional costs.

ESSA is and there is a risk that ESSA may continue to be a "passive foreign investment company" which would likely result in materially adverse U.S. federal income tax consequences for U.S. investors.

ESSA believes it was classified as a PFIC for the taxable year ending September 30, 2020, and believes it may be classified as a PFIC for the current taxable year and in future taxable years. However, the determination as to whether ESSA is a PFIC for any taxable year is based on the application of complex U.S. federal income tax rules that are subject to differing interpretations. If ESSA is a PFIC for any taxable year during which a U.S. Holder (as defined under "United States Federal Income Tax Considerations") holds the Common Shares, it would likely result in adverse U.S. federal income tax consequences for such U.S. Holder. U.S. Holders should carefully read "United States Federal Income Tax Considerations—Passive Foreign Investment Company Rules" for more information and consult their own tax advisors regarding the consequences of ESSA being treated as a PFIC for U.S. federal income tax purposes, including the advisability of making a qualified electing fund ("QEF") election (including a protective election), which may mitigate certain possible adverse U.S. federal income tax consequences but may result in an inclusion in gross income without receipt of such income.

The Company's status as an Emerging Growth Company and the reduced disclosure requirements applicable to Emerging Growth Companies may make the Common Shares less attractive to investors.

ESSA is an "emerging growth company," as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As such, the Company is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of Sarbanes-Oxley.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards, and delay compliance with new or revised accounting standards until those standards are applicable to private companies. ESSA will not take advantage of the extended transition period for complying with new or revised accounting standards. This election is irrevocable.

ESSA may take advantage of some or all of the reduced regulatory and reporting requirements that will be available to it so long as it qualifies as an "emerging growth company" and thus the level of information provided may be different than that of other U.S. public companies. If ESSA does take advantage of any of these exemptions, some investors may find its securities less attractive, which could result in a less active trading market for ESSA's Common Shares, and its share price may be more volatile as a result.

ESSA could be an emerging growth company until the last day of the first fiscal year following the fifth anniversary of its U.S. initial public offering, although circumstances could cause ESSA to lose that status earlier if annual revenues exceed US$1.07 billion, if ESSA issues more than US$1.0 billion in non-convertible debt in any three-year period or if ESSA becomes a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act.

It may be difficult for United States investors to effect services of process or enforcement of actions against the Company or certain of its directors and officers under U.S. federal securities laws.

The Company is incorporated under the laws of the Province of British Columbia, Canada. Its directors and officers reside in Canada or the United States. Because a number of these persons and a substantial portion of the assets of the Company are located outside the United States, it will be difficult for United States investors to effect service of process in the United States upon the Company or the directors or officers of the Company, or to realize in the United States upon judgments of United States courts predicated upon civil liabilities under the Exchange Act or other United States laws. There is substantial doubt as to whether an original action could be brought successfully in Canada against any of such persons or the Company predicated solely upon such civil liabilities and whether a judgment of a United States court predicated solely upon such civil liabilities would be enforceable in Canada by a Canadian court.

Risks Relating to ESSA's Common Shares

ESSA's Common Shares could be delisted from the Nasdaq, which could affect ESSA's Common Shares' market price and liquidity.

The Company's listing on the Nasdaq is contingent upon meeting all the continued listing requirements of the Nasdaq, which include maintaining (i) a minimum bid price of not less than $1.00 per share and (ii) either a minimum stockholders' equity of $2,500,000, a minimum market value of $35 million or a minimum $500,000 of net income from continuing operations. Nasdaq listing rules provide that noncompliance with such requirements exists if the deficiency continues for a period of 30 consecutive business days.

If the Company's Common Shares are delisted from the Nasdaq, its ability to raise capital in the future may be limited. Delisting could also result in less liquidity for the Company's shareholders and a lower share price. Such a delisting would likely have a negative effect on the price of the Company's Common Shares and could impair the Company shareholders' ability to sell or purchase the Company's Common Shares. In the event of a delisting, the Company would expect to take actions to restore its compliance with the Nasdaq's listing requirements, but it can provide no assurance that any action taken by the Company would result in its Common Shares becoming listed again, or that any such action would stabilize the market price or improve the liquidity of its Common Shares.

The market price and trading volume of ESSA's Common Shares may be volatile, which could result in rapid and substantial losses for its shareholders or securities litigation.

The market price of ESSA's Common Shares may be highly volatile and could be subject to wide fluctuations. In addition, the trading volume in the Common Shares may fluctuate and cause significant price variations to occur as demonstrated by ESSA's share price's low on the Nasdaq was $3.00 and high was $8.31 during the fiscal year. The market price of the Common Shares may fluctuate or decline significantly in the future. Some of the factors that could negatively affect ESSA's share price or result in fluctuations in the price or trading volume of the Common Shares include:

- quarterly variations in operating results;
- operating results that vary from the expectations of securities analysts and investors;
- change in valuations;
- changes in ESSA's operations;
- expenses ESSA incurs related to future research;
- regulatory approvals;
- fluctuations in the demand for ESSA's product candidates;
- changes in the industry in which ESSA operates;
- announcements by ESSA or other companies of significant contracts, acquisitions, dispositions, strategic partnerships, joint ventures, capital commitments, plans, prospects, service offerings or operating results;
- additions or departures of key personnel;
- future sales of ESSA's securities;
- trading of ESSA's securities by a large shareholder;
- other risk factors discussed herein; and
- other unforeseen events.

Stock markets in the United States and Canada have experienced extreme price and volume fluctuations. Market fluctuations, as well as general political and economic conditions such as acts of terrorism, prolonged economic uncertainty, a recession or interest rate or currency rate fluctuations, could adversely affect the market price of ESSA's Common Shares resulting in substantial losses for shareholders. Also, in the past, companies that have experienced volatility in the market price of their common shares have been subject to securities litigation. ESSA may be the target of this type of litigation in the future. Securities litigation against ESSA could result in substantial costs and divert management's attention from other business concerns, which could materially harm ESSA's business.

The Company has never declared dividends and may not do so in the future.

ESSA has not declared or paid any cash dividends on Common Shares to date. The payment of dividends in the future will be dependent on ESSA's earnings and financial condition and on such other factors as ESSA's Board considers appropriate. Unless and until ESSA pays dividends, shareholders may not receive a return on their shares. There is no present intention by the Board to pay dividends on the Common Shares.

The Company may experience future sales or issue additional securities.

The market price of the Company's equity securities could decline as a result of issuances of securities by the Company or sales by the Company's existing shareholders of Common Shares in the market, or the perception that such sales could occur. Sales of Common Shares by shareholders might also make it more difficulty for the Company to sell equity securities at a time and price that the Company deems appropriate. Sales or issuances of substantial numbers of Common Shares, or the perception that such sales could occur, may adversely affect the prevailing market prices of the Common Shares. With any additional sale or issuance of Common Shares, investors will suffer dilution to their voting power and the Company may experience dilution in its earnings per share.

Additionally, as of September 30, 2020, there are 8,863,504 pre-funded warrants outstanding, which are exercisable into Common Shares at a nominal exercise price. If holders of these pre-funded warrants exercise these securities, existing shareholders will suffer dilution to their voting power and the Company may experience dilution in its earnings per share, as well as a negative impact on its share price.

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

Maintaining effective internal control over financial reporting is necessary for ESSA to produce reliable financial reports and is important in helping to prevent financial fraud. If ESSA is unable to maintain adequate internal controls, ESSA's business and operating results could be harmed.

Pursuant to Section 404(a) of the Sarbanes-Oxley Act and the related rules of the SEC, ESSA's management is required to, among other things, assess annually the effectiveness of its internal control over financial reporting and certify that it has established effective disclosure controls and procedures and internal controls over financial reporting for the period ended September 30, 2020. As a non-accelerated public company, ESSA is not currently required to comply with Section 404(b) of the Sarbanes-Oxley Act.

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

The process of designing and implementing effective internal controls and procedures, and expanding ESSA's internal accounting capabilities, is a continuous effort that requires ESSA to anticipate and react to changes in ESSA's business and the economic and regulatory environments and expend significant resources to establish and maintain a system of internal controls that is adequate to satisfy ESSA's reporting obligations as a public company. The standards that must be met for management to assess the internal control over financial reporting as effective are complex, and require significant documentation, testing and possible remediation to meet the detailed standards. ESSA cannot be certain at this time whether the Company will be able to successfully complete the continuing implementation of controls and procedures or the certification and attestation requirements of Section 404(a) of Sarbanes-Oxley on a continuous basis.

If a material misstatement occurs in the future, ESSA may fail to meet its future reporting obligations, it may need to restate its financial results and the price of its Common Shares may decline. Any failure of ESSA's internal controls could also adversely affect the results of the periodic management evaluations and any future annual independent registered public accounting firm attestation reports regarding the effectiveness of ESSA's internal control over financial reporting that may be required when Section 404 of Sarbanes-Oxley becomes fully applicable to ESSA. Effective internal controls are necessary for ESSA to produce reliable financial reports and are important to helping prevent financial fraud. If ESSA cannot provide reliable financial reports or prevent fraud, ESSA's business and results of operations could be harmed, investors could lose confidence in ESSA's reported financial information, and the trading price of ESSA's Common Shares could drop significantly.

An active trading market for the Common Shares may not be sustained.

Although ESSA has listed the Common Shares on the Nasdaq, an active trading market for the Common Shares may not be sustained. If an active trading market for the Common Shares is not maintained, the liquidity of the Common Shares and the prices that may be obtained for the Common Shares will be adversely affected.

ESSA's Common Shares may be thinly traded, the prices at which Common Shares trade are volatile and the buying or selling actions of a few shareholders may adversely affect ESSA's share price.

As of September 30, 2020, ESSA's public float, which is defined as Common Shares outstanding minus Common Shares held by officers, directors, or beneficial holders of greater than 10% of ESSA's outstanding Common Shares, represented approximately 11.14% of ESSA's outstanding Common Shares. In addition, the Company is aware of a number of significant shareholders, defined as a holding greater than 5%, who have participated in recent financings. The average number of shares traded in any given day over the past year has been relatively small compared to the public float. Thus, the actions of a few shareholders either buying or selling ESSA's Common Shares may adversely affect the price of the Common Shares. Historically, securities similar to ESSA's Common Shares have experienced extreme price and volume fluctuations that do not necessarily relate to operating performance and could result in rapid and substantial losses for shareholders.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about ESSA's business, its stock price and trading volume could decline.

The trading market for ESSA's Common Shares depends in part on the research and reports that securities or industry analysts publish about it, or its business. If one or more of the securities or industry analysts who cover ESSA downgrade its Common Shares or publish inaccurate or unfavorable research about its business, its stock price would likely decline. If one or more of these analysts cease coverage of ESSA or fail to publish reports on it regularly, demand for ESSA's stock could decrease, which might cause its stock price and trading volume to decline.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our headquarters are located in Vancouver, British Columbia, where we rent office space on a short-term lease. Our U.S. offices are located in Houston, Texas and South San Francisco, California. The Houston office is rented on a short-term basis. In March 2018, we entered into a lease for the South San Francisco office that expires March 31, 2021.

We believe that our existing facilities are adequate for our immediate needs and can accommodate our anticipated growth. We believe that, should it be needed, additional space can be leased to accommodate any future growth.

Item 3. Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. As of September 30, 2020, we are not a party to any legal proceedings that, in the opinion of our management, would reasonably be expected to have a material adverse effect on our business, financial condition, operating results or cash flows if determined adversely to us. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities Market Information

Our Common Shares began trading on the Nasdaq under the symbol "EPIX" on July 9, 2015. Our Common Shares traded under the symbol "EPI" on the TSX from July 28, 2015 until November 24, 2017. On November 27, 2017, we delisted our Common Shares from the TSX and began trading on the TSX-V under the same symbol, "EPI." On October 30, 2020, we delisted our Common Shares from the TSX-V. The following table sets forth the high and low sales prices per Common Share as reported on the Nasdaq and TSX-V for the periods indicated.

	Nasdaq		TSX-V	
	High	Low	High	Low
	US$		C$	
Quarter Ended				
September 30, 2020	8.31	7.48	11.34	7.52
June 30, 2020	6.29	3.60	8.50	5.36
March 31, 2020	5.94	5.70	7.60	4.00
December 31, 2019	6.14	3.00	8.45	4.04
September 30, 2019	3.39	1.41	4.26	1.90
June 30, 2019	3.74	3.34	4.75	2.21
March 31, 2019	4.50	4.00	5.50	2.81
December 31, 2018	4.15	1.87	5.00	2.50

On December 15, 2020, the last reported sale price of our Common Shares on the Nasdaq was $7.58 per share.

Holders

As at December 15, 2020, we had 356 shareholders of record holding our Common Shares, of which 34 were U.S. shareholders. A substantially greater number of holders of ESSA's Common Shares are "street name" or beneficial holders whose shares of record are held by banks, brokers, and other financial institutions.

Dividends

We have never paid any dividends on our Common Shares or any of our other securities. We currently intend to retain any future earnings to finance the growth and development of our business, and we do not anticipate that we will declare or pay any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements, restrictions under any future indebtedness and other factors the board of directors deems relevant.

Canadian Federal Income Tax Considerations for United States Holders

The following is a summary, as of today's date, of the principal Canadian federal income tax considerations under the *Income Tax Act* (Canada) ("Tax Act") that generally apply to an investor who acquires Common Shares, who, for the purposes of the Tax Act and at all relevant times, deals at arm's length, and is not affiliated with ESSA and who acquires and holds Common Shares, as capital property (a "Holder"). Generally, Common Shares will be considered to be capital property to a Holder provided that the Holder does not use Common Shares in the course of carrying on a business of trading or dealing in securities and such Holder has not acquired them or been deemed to have acquired them in one or more transactions considered to be an adventure or concern in the nature of trade.

This summary is based upon the current provisions of the *Canada-United States Income Tax Convention (1980)* ("Treaty"), the Tax Act and its regulations and the current published administrative policies and assessing practices of the Canada Revenue Agency ("CRA"). This summary takes into account all specific proposals to amend the Tax Act and its regulations publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof (the "Tax Proposals") and assumes that the Tax Proposals will be enacted in the form proposed, although no assurance can be given that the Tax Proposals will be enacted in their current form or at all. This summary does not otherwise take into account any changes in law or in the administrative policies or assessing practices of the CRA, whether by legislative, governmental or judicial decision or action, nor does it take into account or consider any provincial, territorial or foreign income tax considerations, which considerations may differ significantly from the Canadian federal income tax considerations discussed in this summary.

This summary only applies to Holders who (i) for the purposes of the Tax Act, have not and will not be resident in Canada at any time, (ii) do not use or hold the Common Shares in carrying on a business in Canada, and (iii) are resident in the United States for income tax purposes and entitled to benefits under the Treaty. Special rules, which are not discussed in this summary, may apply to such a Holder that is an insurer that carries on business in Canada and elsewhere.

This summary is of a general nature only, is not exhaustive of all possible Canadian federal income tax considerations and is not intended to be, nor should it be construed to be, legal or tax advice to any particular Holder. Holders should consult their own tax advisors with respect to their particular circumstances.

Currency

For purposes of the Tax Act, all amounts relating to the acquisition, holding or disposition of Common Shares must be expressed in Canadian dollars. Amounts denominated in any other currency must be converted into Canadian dollars using the rate of exchange quoted by the Bank of Canada on the day the amount first arose, or such other rate of exchange as is acceptable to the CRA.

Dividends

Dividends paid or credited or deemed to be paid or credited to a Holder by ESSA are subject to Canadian withholding tax at the rate of 25% on the gross amount of the dividend unless such rate is reduced by the terms of the Treaty. The rate of withholding tax on dividends paid or credited to a Holder who is resident in the U.S. for purposes of the Treaty, entitled to benefits under the Treaty, and is the beneficial owner of the dividend is generally limited to 15% of the gross amount of the dividend (or 5% in the case of such a Holder that is a company beneficially owning at least 10% of ESSA's voting shares). Holders should consult their own tax advisors regarding the application of the Treaty to dividends based on their particular circumstances.

Dispositions of Common Shares

A Holder generally will not be subject to tax under the Tax Act in respect of a capital gain realized on the disposition or deemed disposition of Common Shares, nor will capital losses arising therefrom be recognized under the Tax Act, unless Common Shares constitute "taxable Canadian property" to the Holder for purposes of the Tax Act, and the gain is not exempt from tax pursuant to the terms of the Treaty.

Provided Common Shares are listed on a "designated stock exchange", as defined in the Tax Act (which currently includes the Nasdaq), at the time of disposition, the Common Shares generally will not constitute taxable Canadian property of a Holder at that time, unless at any time during the 60 month period immediately preceding the disposition the following two conditions are met concurrently:

> (i) the Holder, persons with whom the Holder did not deal at arm's length, and partnerships in which the Holder or such non-arm's length person holds a membership interest (either directly or indirectly through one or more partnerships), or the Holder together with all such persons, owned 25% or more of the issued shares of any class or series of ESSA's shares; and
>
> (ii) more than 50% of the fair market value of the Common Shares was derived directly or indirectly from one or any combination of real or immovable property situated in Canada, "Canadian resource properties" (as defined in the Tax Act), "timber resource properties" (as defined in the Tax Act) or an option, an interest or right in such property, whether or not such property exists.

Notwithstanding the foregoing, a Common Share may otherwise be deemed to be taxable Canadian property to a Holder for purposes of the Tax Act in particular circumstances.

Holders whose Common Shares are taxable Canadian property should consult their own tax advisors.

United States Income Tax Considerations

The following is a summary of the anticipated U.S. federal income tax consequences generally applicable to U.S. Holders (as defined below) of the ownership and disposition of the Company's Common Shares. This summary addresses only holders who acquire and hold the Common Shares as "capital assets" (generally, assets held for investment purposes).

The following summary does not purport to address all U.S. federal income tax consequences that may be relevant to a U.S. Holder (as defined below) as a result of the ownership and disposition of the Common Shares, nor does it take into account the specific circumstances of any particular holder, some of which may be subject to special tax rules (including, but not limited to, brokers, dealers in securities or currencies, traders in securities that elect to use a mark-to-market method of accounting for securities holdings, tax-exempt organizations, insurance companies, banks, thrifts and other financial institutions, persons liable for alternative minimum tax, persons that hold an interest in an entity that holds the Common Shares, persons that will own, or will have owned, directly, indirectly or constructively 10% or more (by vote or value) of our stock, persons that hold the Common Shares as part of a hedging, integration, conversion or constructive sale transaction or a straddle, former citizens or permanent residents of the United States, or persons whose functional currency is not the U.S. dollar).

This summary is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), U.S. Treasury regulations, administrative pronouncements and rulings of the United States Internal Revenue Service (the "IRS"), judicial decisions and the Canada-United States Income Tax Convention (1980), as amended, all as in effect on the date hereof, and all of which are subject to change (possibly with retroactive effect) and to differing interpretations. Except as specifically set forth below, this summary does not discuss applicable income tax reporting requirements. This summary does not describe any state, local or foreign tax law considerations, or any aspect of U.S. federal tax law other than income taxation (e.g., estate or gift tax or the Medicare contribution tax). U.S. Holders (as defined below) should consult their own tax advisers regarding such matters.

No legal opinion from U.S. legal counsel or ruling from the IRS has been requested, or will be obtained, regarding the U.S. federal income tax consequences of the ownership or disposition of the Common Shares. This summary is not binding on the IRS, and the IRS is not precluded from taking a position that is different from, and contrary to, the positions taken in this summary. In addition, because the authorities on which this summary is based are subject to different interpretations, the IRS and U.S. courts could disagree with one or more of the positions taken in this summary.

As used in this summary, a "U.S. Holder" is a beneficial owner of the Common Shares who, for U.S. federal income tax purposes, is (i) a citizen or individual resident of the United States, (ii) a corporation (or other entity that is classified as a corporation for U.S. federal income tax purposes) that is created or organized in or under the laws of the United States, any State thereof or the District of Columbia, (iii) an estate whose income is subject to U.S. federal income tax regardless of its source, or (iv) a trust if (A) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons are authorized to control all substantial decisions of the trust, or (B) the trust has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

The tax treatment of a partner in a partnership (or other entity or arrangement classified as a partnership for U.S. federal income tax purposes) that holds the Common Shares may depend on both the partnership's and the partner's status and the activities of the partnership. Partnerships (or other entities or arrangements classified as a partnership for U.S. federal income tax purposes) that are beneficial owners of the common shares, and their partners and other owners, should consult their own tax advisers regarding the tax consequences of the ownership and disposition of the Common Shares.

Passive Foreign Investment Company Rules

A foreign corporation will be considered a passive foreign investment company ("PFIC") for any taxable year in which (1) 75% or more of its gross income is "passive income" under the PFIC rules or (2) 50% or more of the average quarterly value of its assets produce (or are held for the production of) "passive income." For this purpose, "passive income" generally includes interest, dividends, certain rents and royalties, and certain gains. Moreover, for purposes of determining if the foreign corporation is a PFIC, if the foreign corporation owns, directly or indirectly, at least 25%, by value, of the shares of another corporation, it will be treated as if it holds directly its proportionate share of the assets and receives directly its proportionate share of the income of such other corporation. If a corporation is treated as a PFIC with respect to a U.S. Holder for any taxable year, the corporation will continue to be treated as a PFIC with respect to that U.S. Holder in all succeeding taxable years, regardless of whether the corporation continues to meet the PFIC requirements in such years, unless certain elections are made.

The determination as to whether a foreign corporation is a PFIC is based on the application of complex U.S. federal income tax rules, which are subject to differing interpretations, and the determination will depend on the composition of the income, expenses and assets of the foreign corporation from time to time and the nature of the activities performed by its officers and employees. ESSA believes that it was classified as a PFIC for the taxable year ending September 30, 2020, and ESSA believes that it may be classified as a PFIC for the current taxable year and in future taxable years. However, our actual PFIC status for the current or any future taxable year is uncertain and cannot be determined until after the end of such taxable year.

If we are classified as a PFIC, a U.S. Holder that does not make any of the elections described below would be required to report any gain on the disposition of Common Shares as ordinary income, rather than as capital gain, and to compute the tax liability on the gain and any "Excess Distribution" (as defined below) received in respect of Common Shares as if such items had been earned ratably over each day in the U.S. Holder's holding period (or a portion thereof) for the common shares. The amounts allocated to the taxable year during which the gain is realized or distribution is made, and to any taxable years in such U.S. Holder's holding period that are before the first taxable year in which we are treated as a PFIC with respect to the U.S. Holder, would be included in the U.S. Holder's gross income as ordinary income for the taxable year of the gain or distribution. The amount allocated to each other taxable year would be taxed as ordinary income in the taxable year during which the gain is realized or distribution is made at the highest tax rate in effect for the U.S. Holder in that other taxable year and would be subject to an interest charge as if the income tax liabilities had been due with respect to each such prior year. For purposes of these rules, gifts, exchanges pursuant to corporate reorganizations and use of Common Shares as security for a loan may be treated as a taxable disposition of the Common Shares. An "Excess Distribution" is the amount by which distributions during a taxable year in respect of a Common Share exceed 125% of the average amount of distributions in respect thereof during the three preceding taxable years (or, if shorter, the U.S. Holder's holding period for the Common Shares).

Certain additional adverse tax rules will apply to a U.S. Holder for any taxable year in which we are treated as a PFIC with respect to such U.S. Holder and any of our subsidiaries is also treated as a PFIC (a "Subsidiary PFIC"). In such a case, the U.S. Holder will generally be deemed to own its proportionate interest (by value) in any Subsidiary PFIC and be subject to the PFIC rules described above with respect to the Subsidiary PFIC regardless of such U.S. Holder's percentage ownership in us.

The adverse tax consequences described above may be mitigated if a U.S. Holder makes a timely "qualified electing fund" election (a "QEF election") with respect to its interest in the PFIC. Consequently, if we are classified as a PFIC, it may be advantageous for a U.S. Holder to elect to treat us as a "qualified electing fund" with respect to such U.S. Holder in the first year in which it holds Common Shares. If a U.S. Holder makes a timely QEF election with respect to ESSA, the electing U.S. Holder would be required in each taxable year that we are considered a PFIC to include in gross income (i) as ordinary income, the U.S. Holder's pro rata share of the ordinary earnings of ESSA and (ii) as capital gain, the U.S. Holder's pro rata share of the net capital gain (if any) of ESSA, whether or not the ordinary earnings or net capital gain are distributed. An electing U.S. Holder's basis in Common Shares will be increased to reflect the amount of any taxed but undistributed income. Distributions of income that had previously been taxed will result in a corresponding reduction of basis in the Common Shares and will not be taxed again as distributions to the U.S. Holder.

A QEF election made with respect to ESSA will not apply to any Subsidiary PFIC; a QEF election must be made separately for each Subsidiary PFIC (in which case the treatment described above would apply to such Subsidiary PFIC). If a U.S. Holder makes a timely QEF election with respect to a Subsidiary PFIC, it would be required in each taxable year to include in gross income its pro rata share of the ordinary earnings and net capital gain of such Subsidiary PFIC, but may not receive a distribution of such income. Such a U.S. Holder may, subject to certain limitations, elect to defer payment of current U.S. federal income tax on such amounts, subject to an interest charge (which would not be deductible for U.S. federal income tax purposes if the U.S. Holder were an individual).

If we determine that we, and any subsidiary in which we own, directly or indirectly, more than 50% of such subsidiary's total aggregate voting power, is likely a PFIC in any taxable year, we intend to make available to U.S. Holders, upon request and in accordance with applicable procedures, a "PFIC Annual Information Statement" with respect to ESSA and any such subsidiary for such taxable year. The "PFIC Annual Information Statement" may be used by U.S. Holders for purposes of complying with the reporting requirements applicable to a QEF election with respect to ESSA and any Subsidiary PFIC. The U.S. federal income tax on any gain from the disposition of Common Shares or from the receipt of Excess Distributions may be greater than the tax if a timely QEF election is made.

Alternatively, if we were to be classified as a PFIC, a U.S. Holder could also avoid certain of the rules described above by making a mark-to-market election (instead of a QEF election), provided the Common Shares are treated as regularly traded on a qualified exchange or other market within the meaning of the applicable U.S. Treasury Regulations. However, a U.S. Holder will not be permitted to make a mark-to-market election with respect to a Subsidiary PFIC. U.S. Holders should consult their own tax advisers regarding the potential availability and consequences of a mark-to-market election, as well as the advisability of making a protective QEF election in case we are classified as a PFIC in any taxable year.

During any taxable year in which we or any Subsidiary PFIC is treated as a PFIC with respect to a U.S. Holder, that U.S. Holder generally must file IRS Form 8621. U.S. Holders should consult their own tax advisers concerning annual filing requirements.

The Common Shares

Distributions on the Common Shares

In general, subject to the passive foreign investment company rules discussed above, the gross amount of any distribution received by a U.S. Holder with respect to the Common Shares (including amounts withheld to pay Canadian withholding taxes) will be included in the gross income of the U.S. Holder as a dividend to the extent attributable to our current and accumulated earnings and profits, as determined under U.S. federal income tax principles. We may not calculate our earnings and profits for each year under U.S. federal income tax rules. Accordingly, U.S. Holders should expect that a distribution generally will be treated as a dividend for U.S. federal income tax purposes. Subject to the passive foreign investment company rules discussed above, distributions on the Common Shares to certain non-corporate U.S. Holders that are treated as dividends may be taxed at preferential rates provided we are not treated as a PFIC for the taxable year of the distribution or the preceding taxable year. Such dividends will not be eligible for the "dividends received" deduction ordinarily allowed to corporate shareholders with respect to dividends received from U.S. corporations.

The amount of any dividend paid in Canadian dollars (including amounts withheld to pay Canadian withholding taxes) will equal the U.S. dollar value of the Canadian dollars calculated by reference to the exchange rate in effect on the date the dividend is received by the U.S. Holder, regardless of whether the Canadian dollars are converted into U.S. dollars. A U.S. Holder will have a tax basis in the Canadian dollars equal to their U.S. dollar value on the date of receipt. If the Canadian dollars received are converted into U.S. dollars on the date of receipt, the U.S. Holder should generally not be required to recognize foreign currency gain or loss in respect of the distribution. If the Canadian dollars received are not converted into U.S. dollars on the date of receipt, a U.S. Holder may recognize foreign currency gain or loss on a subsequent conversion or other disposition of the Canadian dollars. Such gain or loss will be treated as U.S. source ordinary income or loss.

Distributions on the Common Shares that are treated as dividends generally will constitute income from sources outside the United States and generally will be categorized for U.S. foreign tax credit purposes as "passive category income." A U.S. Holder may be eligible to elect to claim a U.S. foreign tax credit against its U.S. federal income tax liability, subject to applicable limitations and holding period requirements, for Canadian tax withheld, if any, from distributions received in respect of the Common Shares. A U.S. Holder that does not elect to claim a U.S. foreign tax credit may instead claim a deduction for Canadian tax withheld, but only for a taxable year in which the U.S. Holder elects to do so with respect to all foreign income taxes paid or accrued in such taxable year. The rules relating to U.S. foreign tax credits are complex, and each U.S. Holder should consult its own tax adviser regarding the application of such rules.

Sale, Exchange or Other Taxable Disposition of the Common Shares

A U.S. Holder generally will recognize gain or loss on the sale, exchange or other taxable disposition of Common Shares in an amount equal to the difference, if any, between the amount realized on the sale, exchange or other taxable disposition and the U.S. Holder's adjusted tax basis in the Common Shares exchanged therefor. Subject to the passive foreign investment company rules discussed above, such gain or loss will be capital gain or loss and will be long-term capital gain (currently taxable at a reduced rate for non-corporate U.S. Holders) or loss if, on the date of the sale, exchange or other taxable disposition, the Common Shares have been held by such U.S. Holder for more than one year. The deductibility of capital losses is subject to limitations. Such gain or loss generally will be sourced within the United States for U.S. foreign tax credit purposes.

Required Disclosure with Respect to Foreign Financial Assets

Certain U.S. Holders are required to report information relating to an interest in the Common Shares, subject to certain exceptions (including an exception for common shares held in accounts maintained by certain financial institutions), by attaching a completed IRS Form 8938, Statement of Specified Foreign Financial Assets, with their tax return for each year in which they hold an interest in Common Shares. U.S. Holders should consult their own tax advisers regarding information reporting requirements relating to their ownership of the Common Shares.

Performance Graph

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Recent Sales of Unregistered Securities

None.

Issuer Repurchases of Equity Securities

None.

Item 6. Selected Financial Data

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation

The following discussion should be read in conjunction with the attached financial statements and notes thereto. This Annual Report on Form 10-K, including the following sections, contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see Item 1A, "Risk Factors" of this Annual Report on Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report on Form 10-K. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report on Form 10-K. Throughout this discussion, unless the context specifies or implies otherwise, the terms "ESSA," "the Company," "we," "us," and "our" refer to ESSA Pharma Inc. and its subsidiaries. For a discussion regarding our financial condition and results of operations for fiscal 2019 as compared to fiscal 2018 see Item 5 of our Annual Report on Form 20-F for the fiscal year ended September 30, 2019, filed with the SEC on December 20, 2019.

Overview

ESSA is a clinical stage pharmaceutical company, focused on developing novel and proprietary therapies for the treatment of prostate cancer in patients whose disease is progressing despite treatment with current standard of care therapies, including second-generation anti-androgen drugs such as abiraterone, enzalutamide, apalutamide, and darolutamide. The Company believes its latest series of investigational compounds, including its product candidate EPI-7386, have the potential to significantly expand the interval of time in which patients with castration-resistant prostate cancer ("CRPC") can benefit from anti-hormone-based therapies. The Phase I clinical trial of EPI-7386 "Oral EPI-7386 in Patients With Metastatic Castration-Resistant Prostate Cancer (EPI-7386)" was started in June 2020 with the first patient dosed in July 2020 and is currently actively enrolling patients.

Developments

Significant Business Developments for the Year Ended September 30, 2020

In March 2020, the Company filed an IND application to the FDA to evaluate its lead product candidate, EPI-7386, in a Phase 1 clinical study for the treatment of patients with metastatic castration-resistant prostate cancer. In April 2020, the FDA notified the Company that it may proceed with its proposed clinical investigation of EPI-7386. A CTA was filed and subsequently cleared with Health Canada. The clinical trial is expected to enroll approximately 18 patients at multiple medical institutions in a standard 3+3 trial design with an approximate 10 additional patients enrolled in the dose expansion cohort.

On July 15, 2020, the Company dosed the first patient in a Phase 1 clinical trial designed to evaluate the safety and tolerability of EPI-7386 in mCRPC patients who failed standard of care treatments, including second generation anti-androgens. On September 14, 2020, the Company announced that the FDA granted Fast Track Designation to EPI-7386 for the treatment of adult male patients with mCRPC resistant to standard-of-care treatment.

Financing and Capital

On July 31, 2020, the Company closed the July 2020 Offering. The proceeds to ESSA from the July 2020 Offering, including the exercise of the Option, were approximately US$45.0 million after deducting underwriting discounts and commissions (such commission being equal to 6% of the aggregate gross proceeds of the July 2020 Offering) and other estimated offering expenses. Existing investors participated in the financing along with new investors Pfizer Inc. (NYSE: PFE), Avidity Partners, CAM Capital, Point72, Ridgeback Capital, Sphera Healthcare and Vivo Capital.

Recent Developments

On October 14, 2020, the Company issued 1,493,504 Common Shares upon the cashless exercise of 1,493,504 pre-funded warrants.

On October 26, 2020, ESSA Pharma Inc. announced its strategic decision to voluntarily delist its Common Shares from the TSX-V.

On November 25, 2020, the Company filed a Registration Statement on Form S-3 with the SEC to replace the existing Registration Statement on Form F-3, which, once effective, will allow the Company to raise up to $200 million worth of the securities listed therein.

On December 3, 2020, the Company issued 42,207 Common Shares for stock options exercised for gross proceeds of $153,701.

ESSA has never been profitable and has incurred net losses since inception. ESSA’s net losses were $23,445,370 and $12,756,832 for the years ended September 30, 2020, and 2019, respectively. ESSA expects to incur losses for the foreseeable future, and it expects these losses to increase as it continues the development of, and seek regulatory approvals for, its product candidate. Because of the numerous risks and uncertainties associated with product development, ESSA is unable to predict the timing or amount of increased expenses or when, or if, it will be able to achieve or maintain profitability.

Results of Operations

The following table sets forth ESSA's consolidated statements of financial position and consolidated statements of loss and comprehensive loss as at and for the fiscal years ended September 30, 2020 and 2019:

(US$) Income Statement Data	Year Ended September 30, 2020	Year Ended September 30, 2019
Revenue	—	—
Research and development, net of recoveries	12,145,968	6,696,234
Financing costs	618,109	602,744
General and administration, net of recoveries	11,373,952	5,455,189
Total operating expenses	(24,138,029)	(12,754,167)
Loss before income taxes	(23,734,017)	(12,718,912)
Net loss, net of income tax	(23,445,370)	(12,756,832)
Balance Sheet Data		
Cash	56,320,763	53,322,723
Other current assets	23,921,003	976,285
Deposits	277,637	274,085
Right of use asset	55,162	—
Total assets	80,574,565	54,573,093
Accounts payable and accrued liabilities	1,144,230	1,565,789
Income tax payable	—	300,000
Lease liability	59,094	—
Long-term debt	—	3,708,955
Derivative liability	127,376	16,520
Shareholders' equity	79,243,865	48,981,829
Total liabilities and shareholders' equity	80,574,565	54,573,093

Results of Operations for the Fiscal Years Ended September 30, 2020 and 2019

There was no revenue in any of the fiscal years as reported. The Company incurred a comprehensive loss of $23,445,370 for the year ended September 30, 2020 compared to a comprehensive loss of $12,756,832 for the year ended September 30, 2019. Variations in ESSA's expenses and net loss for the periods resulted primarily from the following factors:

Research and Development Expenditures

R&D expense included the following major expenses by nature:

	Year ended September 30, 2020	Year ended September 30, 2019
Clinical	$ 1,689,143	$ 80,021
Consulting	512,790	301,817
Legal patents and license fees	755,867	781,133
CMC	2,898,911	946,705
Other	72,275	111,750
Preclinical	2,823,117	2,789,753
Research grants and administration	153,379	254,970
Royalties	65,186	65,405
Salaries and benefits	1,264,855	1,012,344
Share-based payments	1,878,372	304,786
Travel and other	32,073	47,550
Total	$ 12,145,968	$ 6,696,234

The overall R&D expense for the year ended September 30, 2020 was $12,145,968 compared to $6,696,234 for the year ended September 30, 2019 and includes non-cash expense related to share-based payments expense of $1,878,372 (2019 - $304,786). R&D expense in 2020 and 2019 was incurred primarily in preclinical research and IND-enabling work on the Company's next-generation Aniten compounds, with expenditures in 2020 reflecting ongoing preclinical work on IND candidate EPI-7386, but also the increased expenditure on chemistry and manufacturing of drug product at third party vendors, in anticipation of the Phase 1 clinical trial which commenced with the dosing of the first patient in July 2020.

The share-based payments expense of $1,878,372 (2019 - $304,786), which is a non-cash expense, relates to the value assigned to stock options and employee share purchase rights granted to key management and consultants of the Company. The expense is recognized in relation to the grant and vesting of these equity instruments, net of expiries and forfeitures, and allocated to research and development, general and administration and financing expenditures relative to the activity of the underlying optionee.

Clinical costs of $1,689,143 (2019 - $80,021) relate to clinical consulting work in preparation for the IND filing in March 2020, clinical site activation costs, and commencement of the Phase I clinical trial of EPI-7386 in July 2020. Only minor preparatory clinical costs were incurred in late 2019 following selection of EPI-7386 as a clinical candidate in March 2019.

Preclinical costs of $2,823,117 (2019 - $2,789,753) were incurred in the identification of the lead compound EPI-7386 in 2019 and the subsequent filing of the IND in 2020.

CMC costs of $2,898,911 (2019 - $946,705) for the year ended September 30, 2020 were incurred in formulation and chemistry work around the Company's next-generation Aniten compounds, and specifically the pharmaceutical characteristics of EPI-7386. In 2020 costs included additional formulation work and cGMP manufacturing of EPI-7386 drug supply in preparation for the clinical trial.

Consulting costs increased to $512,790 for the year ended September 30, 2020 (2019 - $301,817) relating to consulting fees for scientific advisors in connection with candidate selection and preparation of the IND filing, including contract project management services.

Salaries and benefits, related to preclinical and clinical staff, have increased to $1,264,855 (2019 - $1,012,344) 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.

Legal patents and license fees are comparable at $755,867 (2019 - $781,133). In the prior period, the Company submitted a number of patent applications on its next-generation compounds 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 costs in the current period reflect that ongoing investment and the Company anticipates that there will be continued investment into patent applications.

Research grants and administration costs were $153,379 (2019 - $254,970) 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.

General and Administration Expenditures

General and administrative expenses include the following major expenses by nature:

	Year ended September 30, 2020	Year ended September 30, 2019
Amortization	$ 110,324	$ -
Consulting and subcontractor fees	135,181	142,780
Director fees	377,000	252,000
Insurance	594,170	471,852
Investor relations	344,233	319,373
Legal patents and license fees	50,323	-
Office, insurance, IT and communications	313,922	155,208
Professional fees	869,012	675,412
Regulatory fees and transfer agent	159,744	91,764
Rent	59,747	192,479
Salaries and benefits	2,619,120	2,072,746
Share-based payments	5,644,235	841,921
Travel and other	96,941	239,654
Total	$ 11,373,952	$ 5,455,189

General and administration expenses increased to $11,373,952 for the year ended September 30, 2020 from $5,455,189 in the year ended September 30, 2019 and includes non-cash expense related to share-based payments of $5,644,235 (2019 - $841,921). This non-cash expense relates to the value assigned to stock options and employees share purchase rights granted to key management and consultants of the Company. The expense is recognized in relation to the grant and vesting of these equity instruments, net of expiries and forfeitures, and allocated to research and development, general and administration and financing expenditures relative to the activity of the underlying optionee.

Director fees of $377,000 (2019 - $252,000) were incurred for remuneration paid to directors for attendance at meetings and participation in various committees during the period. On July 31, 2019, in connection with the Realm Acquisition, the Company appointed three additional members to the board of directors who receive compensation as directors and members of board committees, which is reflected in increased fees in 2020.

Salaries and benefits expense of $2,619,120 (2019 - $2,072,746) in 2020 reflects merit related salary adjustment and bonuses paid to employees and additional support staff costs.

Insurance expense of $594,170 (2019 - $471,852) relates to increased cost of 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. The Company has realized an increase in premiums which is in line with market trends.

Professional fees of $869,012 (2019 - $675,412) were incurred for legal and accounting services in conjunction with increased corporate activities compared to activities in 2019. Specifically, in the current year, the Company incurred costs to implement an At-The-Market Equity Offering facility. The Company also prepared for, and implemented changes with respect to its transition to a domestic issuer from foreign private issuer, including transition of financial statements to US GAAP.

Rent expense of $59,747 (2019 - $192,479) has decreased relative to the previous period as a consequence of adopting new lease standards for account. Rent expense previously incurred on the South San Francisco office is now classified as a lease payment. Concurrently, the Company recognized amortization of $100,324 (2019 - $Nil) for the related operating lease right-of-use asset.

Liquidity and Capital Resources

ESSA is a clinical stage company and does not currently generate revenue. In July 2020, the Company closed the July 2020 Offering for gross proceeds of approximately US$45.0 million after deducting underwriting discounts and commissions. In October 2019, the Company paid off the SVB Term Loan in full, totaling $3,652,471, comprising $2,953,968 in principal, $10,503 in accrued interest, and the final payment of $688,000. In July 2019, the Company completed the Realm Acquisition, issuing 6,718,150 Common Shares in exchange for net assets of $20,247,296, including $22,244,248 in cash. In August 2019, the Company completed the August 2019 Financing of 6,080,596 Common Shares and 11,919,404 pre-funded warrants at a price of US$2.00 for gross proceeds of US$36,000,000.

On July 31, 2020 the Company completed the July Offering. The net proceeds to the Company from the July Offering were US$45.8 million after deducting underwriting discounts and commissions (such commission being equal to 6% of the aggregate gross proceeds of the July Offering) and associated transaction costs. Certain existing investors participated in the financing along with new investors Pfizer Inc. (NYSE: PFE), Avidity Partners, CAM Capital, Point72, Ridgeback Capital, Sphera Healthcare and Vivo Capital, and others.

As at September 30, 2020, the Company has working capital of $78,949,442 (2019 - $48,724,264). Operational activities during the year ended September 30, 2020 were financed mainly by proceeds from the Realm Acquisition, August 2019 Financing and July 2020 Financing. At September 30, 2020, the Company had available cash reserves and short-term investments of $78,332,100 (2019 - $53,322,723) to settle current liabilities of $1,322,324 (2019 - $5,574,744). At September 30, 2020, the Company believed that it had sufficient capital to satisfy its obligations as they became due and execute its planned expenditures for more than twelve months.

ESSA's future cash requirements may vary materially from those now expected due to a number of factors, including the costs associated with future preclinical work and to take advantage of strategic opportunities, such as partnering collaborations or mergers and acquisitions activities. In the future, it may be necessary to raise additional funds. These funds may come from sources such as entering into strategic collaboration arrangements, the issuance of shares from treasury, or alternative sources of financing. However, there can be no assurance that ESSA will successfully raise funds to continue its operational activities. See "Risk Factors" in Item 1A. elsewhere in this Annual Report.

Critical Accounting Policies and 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 that relate to the following key estimates:

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 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 ASU 2017-01. 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 consolidated financial statements).

Derivative financial instruments

Certain warrants are treated as derivative financial liabilities. The estimated fair value, based on the Black-Scholes model, is adjusted on a quarterly basis with gains or losses recognized in the statement of 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 10 of the 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 of grant and the cost is recorded when 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 them. The fair value of the underlying Common Shares is assessed as the most recent issuance price per common share for cash proceeds.

Trend Information

ESSA is a clinical development stage company and does not currently generate revenue. The Company is focused on the development of small molecule drugs for the treatment of prostate cancer. The Company has acquired a license to certain Licensed IP. As at the date of this Annual Report, no products are in commercial production or use. The Company's financial success will be dependent upon its ability to continue development of its compounds through preclinical and clinical stages to commercialization.

Off-Balance Sheet Arrangement

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

JOBS Act

As a company with less than US$1.07 billion in revenue during the last fiscal year, ESSA qualifies as an "emerging growth company" pursuant to the JOBS Act. An emerging growth company may take advantage of specified exemptions from various requirements that are otherwise applicable generally to public companies in the United States.

The JOBS Act also permits an emerging growth company such as ESSA to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. ESSA will not take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This election is irrevocable. ESSA will remain an emerging growth company until the earliest of:

- the last day of the Company's fiscal year during which it has total annual gross revenues of at least US$1.07 billion;
- the last day of the Company's fiscal year following the fifth anniversary of the completion of an initial public offering;
- the date on which Company has, during the previous three-year period, issued more than US$1 billion in non-convertible debt securities; or
- the date on which the Company is deemed to be a "large accelerated filer" under the Exchange Act, which would occur if the market value of ESSA's Common Shares that are held by non-affiliates exceeds US$700 million as of the last business day of its most recently completed second fiscal quarter.

As a result of ESSA's status as an emerging growth company, the information that the Company provides shareholders may be less comprehensive than what you might receive from other public companies that are not emerging growth companies. When ESSA is no longer deemed to be an emerging growth company, ESSA will not be entitled to the exemptions provided in the JOBS Act.

Safe Harbor

See "*Cautionary Note Regarding Forward-Looking Statements*" in the introduction to this Annual Report.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

ESSA Pharma Inc.

CONSOLIDATED FINANCIAL STATEMENTS
(Expressed in United States dollars)

FOR THE YEARS ENDED SEPTEMBER 30, 2020 and 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Directors of
ESSA Pharma Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of ESSA Pharma Inc. (the "Company"), as of September 30, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, cash flows and changes in shareholders' equity for the years ended September 30, 2020 and 2019, and the related notes and schedules (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of ESSA Pharma Inc. as of September 30, 2020 and 2019, and the results of its operations and its cash flows for the years ended September 30, 2020 and 2019 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatements of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2011.

"DAVIDSON & COMPANY LLP"

Vancouver, Canada Chartered Professional Accountants

December 10, 2020

ESSA PHARMA INC.
CONSOLIDATED BALANCE SHEETS
(Expressed in United States dollars)
AS AT SEPTEMBER 30

	2020	2019 (Note 2)
ASSETS		
Current		
Cash and cash equivalents	$ 56,320,763	$ 53,322,723
Short-term investments (Note 5)	22,011,337	—
Receivables (Note 17)	309,538	360,800
Prepaids (Note 6)	1,600,128	615,485
Operating lease right-of-use assets (Note 8)	55,162	—
	80,296,928	54,299,008
Deposits	277,637	274,085
Total assets	$ 80,574,565	$ 54,573,093
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current		
Accounts payable and accrued liabilities (Note 7)	$ 1,144,230	$ 1,565,789
Current portion of operating lease liability (Note 8)	59,094	—
Current portion of long-term debt (Note 9)	—	3,708,955
Income tax payable	—	300,000
	1,203,324	5,574,744
Derivative liabilities (Note 10)	127,376	16,520
Total liabilities	1,330,700	5,591,264
Shareholders' equity		
Authorized		
Unlimited common shares, without par value		
Unlimited preferred shares, without par value		
Common shares 32,064,411 issued and outstanding (2019 – 20,762,374) (Note 11)	131,086,364	78,545,108
Additional paid-in capital (Note 11)	31,204,284	30,038,134
Accumulated other comprehensive loss	(2,076,479)	(2,076,479)
Accumulated deficit	(80,970,304)	(57,524,934)
	79,243,865	48,981,829
Total liabilities and shareholders' equity	$ 80,574,565	$ 54,573,093

Nature of operations (Note 1)
Commitments (Note 17)

The accompanying notes are an integral part of these consolidated financial statements.

ESSA PHARMA INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Expressed in United States dollars)
FOR THE YEARS ENDED SEPTEMBER 30

	2020	2019 (Note 2)
OPERATING EXPENSES		
Research and development	$ 12,145,968	$ 6,696,234
Financing costs (Notes 8 and 9)	618,109	602,744
General and administration	11,373,952	5,455,189
Total operating expenses	(24,138,029)	(12,754,167)
Foreign exchange	(44,851)	7,845
Interest income	559,719	26,251
Derivative liability (loss) gain (Note 10)	(110,856)	1,159
Loss for the year before taxes	(23,734,017)	(12,718,912)
Income tax recovery (expense) (Note 14)	288,647	(37,920)
Loss and comprehensive loss for the year	$ (23,445,370)	$ (12,756,832)
Basic and diluted loss per common share	$ (1.04)	$ (1.51)
Weighted average number of common shares outstanding – basic and diluted	22,443,893	8,433,441

The accompanying notes are an integral part of these consolidated financial statements.

ESSA PHARMA INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Expressed in United States dollars)
FOR THE YEARS ENDED SEPTEMBER 30

	2020	2019 (Note 2)
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss for the year	$ (23,445,370)	$ (12,756,832)
Items not affecting cash and cash equivalents:		
Amortization of right-of-use asset	110,324	—
Accretion of lease liability	12,992	—
Derivative liability (gain) loss	110,856	(1,159)
Income tax expense	(280,000)	—
Finance expense	211,079	602,744
Unrealized foreign exchange	13,059	16,457
Share-based payments	7,522,608	1,146,707
Changes in non-cash working capital items:		
Receivables	89,938	(59,665)
Prepaids	(1,262,280)	(179,416)
Accounts payable and accrued liabilities	(46,358)	(1,014,049)
Income tax payable	(20,000)	(4,722)
Net cash used in operating activities	(16,983,152)	(12,249,935)
CASH FLOWS FROM INVESTING ACTIVITIES		
Deposits	274,085	201,399
Purchase of short-term investments	(22,011,337)	—
Net cash used in investing activities	(21,737,252)	201,399
CASH FLOWS FROM FINANCING ACTIVITIES		
Cash acquired on acquisition of Realm	—	22,244,248
Transaction costs on acquisition of Realm	(64,804)	(1,860,341)
Termination costs on Realm sublease (Note 4)	—	(246,906)
Lease payments	(119,384)	—
Proceeds on issuance of common shares	48,990,000	36,000,000
Share issuance costs	(3,447,954)	(2,362,329)
Options exercised	915	—
Warrants exercised	257,172	—
Shares purchased through employee share purchase plan	80,714	—
Loan principal repaid	(3,199,799)	(2,808,823)
Loan final payment paid	(688,000)	—
Interest and financing costs paid	(32,235)	(401,929)
Net cash provided by financing activities	41,776,625	50,563,920
Effect of foreign exchange on cash and cash equivalents	(58,181)	(21,805)
Change in cash and cash equivalents for the year	2,998,040	38,493,579
Cash and cash equivalents, beginning of year	53,322,723	14,829,144
Cash and cash equivalents, end of year	$ 56,320,763	$ 53,322,723

Supplemental Disclosure with respect to Cash Flows (Note 12)

The accompanying notes are an integral part of these consolidated financial statements.

ESSA PHARMA INC.
CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
(Expressed in United States dollars)

	Number of shares	Common shares	Additional paid-in capital	Accumulated other comprehensive loss	Deficit	Total
Balance, September 30, 2018 (Note 2)	5,776,098	$ 40,205,997	$ 15,573,597	$ (2,076,479)	$ (44,768,102)	$ 8,935,013
Acquisition of Realm	6,718,150	20,247,296	—	—	—	20,247,296
Financing	6,080,596	12,161,192	23,838,808	—	—	36,000,000
Share issuance costs	—	(2,826,443)	(1,764,982)	—	—	(4,591,425)
Pre-funded warrants exercised	2,187,530	8,757,066	(8,755,996)	—	—	1,070
Share-based payments	—	—	1,146,707	—	—	1,146,707
Loss for the year	—	—	—	—	(12,756,832)	(12,756,832)
Balance, September 30, 2019 (Note 2)	20,762,374	$ 78,545,108	$ 30,038,134	$ (2,076,479)	$ (57,524,934)	$ 48,981,829
Financing	8,165,000	48,990,000	—	—	—	48,990,000
Share issuance costs	—	(3,136,949)	(7,054)	—	—	(3,144,003)
Warrants exercised	3,120,115	6,549,631	(6,292,459)	—	—	257,172
Options exercised	416	1,648	(733)	—	—	915
Shares issued through employee share purchase plan	16,506	136,926	(56,212)	—	—	80,714
Share-based payments	—	—	7,522,608	—	—	7,522,608
Loss for the year	—	—	—	—	(23,445,370)	(23,445,370)
Balance, September 30, 2020	32,064,411	$ 131,086,364	$ 31,204,284	$ (2,076,479)	$ (80,970,304)	$ 79,243,865

The accompanying notes are an integral part of these consolidated financial statements.

1. NATURE OF OPERATIONS

Nature of Operations

ESSA Pharma Inc. (the "Company") was incorporated under the laws of the Province of British Columbia on January 6, 2009. The Company's head office address is Suite 720 – 999 West Broadway, Vancouver, BC, V5Z 1K5. The registered and records office address is the 26th Floor at 595 Burrard Street, Three Bentall Centre, Vancouver, BC, V7X 1L3. The Company is listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "EPIX". On October 30, 2020 the Company's common shares delisted in Canada from the TSX Venture Exchange.

The Company is focused on the development of small molecule drugs for the treatment of prostate cancer. The Company has acquired a license to certain patents (the "NTD Technology") which were the joint property of the British Columbia Cancer Agency and the University of British Columbia. As at September 30, 2020, no products are in commercial production or use.

Acquisition of Realm Therapeutics plc

On July 31, 2019, the Company acquired all of the issued and outstanding shares of Realm Therapeutics plc ("Realm") pursuant to a Scheme of Arrangement as sanctioned on July 29, 2019 by the High Court of Justice in England and Wales (the "Realm Acquisition") (Note 4).

2. BASIS OF PRESENTATION

Basis of Presentation

These accompanying consolidated financial statements, including comparatives, have been prepared in accordance with U.S. GAAP and the accounting policies in Note 3 have been consistently applied in the preparation of the consolidated financial statements. Previously, the Company prepared its consolidated financial statements under International Financial Reporting Standards ("IFRS") as permitted by securities regulators in Canada, as well as in the United States under the status of a Foreign Private Issuer as defined by the United States Securities and Exchange Commission ("SEC"). At the end of the second quarter of 2020, the Company determined that it no longer qualified as a Foreign Private Issuer under the SEC rules. As a result, beginning October 1, 2020 the Company is required to report with the SEC on domestic forms and comply with domestic company rules in the United States. The transition to U.S. GAAP was made retrospectively for all periods from the Company's inception.

The accompanying consolidated financial statements have been prepared on a historical cost basis except for certain financial assets measured at fair value.

All amounts expressed in these accompanying consolidated financial statements and the accompanying notes are expressed in United States dollars, except per share data and where otherwise indicated. References to "$" are to United States dollars and references to "C$" are to Canadian dollars.

Basis of Consolidation and Functional Currency

Consolidation

The accounts of subsidiaries are prepared for the same reporting period as the parent company, using consistent accounting policies. Inter-company transactions, balances and unrealized gains or losses on transactions are eliminated upon consolidation. The consolidated financial statements comprise the accounts of ESSA Pharma Inc., the parent company, and its wholly owned subsidiaries.

Functional Currency

The functional currency of an entity is the currency of the primary economic environment in which the entity operates.

The functional currency of the Company and its subsidiaries have been determined as follows:

	Country of Incorporation	Effective Interest	Functional Currency
ESSA Pharma Inc.	Canada	—	US Dollar
ESSA Pharmaceuticals Corp.	USA	100 %	US Dollar
Realm Therapeutics plc [(1)]	United Kingdom	100 %	Pound Sterling
Realm Therapeutics Inc. [(1)]	USA	100 %	US Dollar

(1) In the process of liquidation and dissolution as at September 30, 2020.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions about future events that affect the reported amounts of assets, liabilities, expenses, contingent assets and contingent liabilities as at the end of, or during, the reporting period. Actual results could significantly differ from those estimates. Significant areas requiring management to make estimates include the derivative liabilities, the valuation of equity instruments issued for services, income taxes and the product development and relocation grant. Further details of the nature of these assumptions and conditions may be found in the relevant notes to these consolidated financial statements.

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:

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.

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 loss and comprehensive loss. The Black-Scholes model is based on significant assumptions such as volatility, dividend yield, expected term and liquidity discounts (Note 10).

Share-based payments and compensation

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

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the fair value of the underlying common shares, the expected life of the share option, volatility and dividend yield and making assumptions about them. The assumptions and models used for estimating fair value for share-based payment transactions are discussed in Note 11.

3. SIGNIFICANT ACCOUNTING POLICIES

Cash and cash equivalents

Cash and cash equivalents consist primarily of cash in banks and high-interest savings accounts and are recorded at cost, which approximates fair value.

Short-term investments

The Company's short-term investments consist of guaranteed investment certificates and term deposits with original maturities exceeding three months and less than one year. The investments are recorded at cost plus accrued interest, which approximates fair value.

Foreign exchange

Transactions in currencies other than the United States dollar are recorded at exchange rates prevailing on the dates of the transactions. At the end of each reporting period, monetary assets and liabilities of the Company that are denominated in foreign currencies are translated at the period end exchange rate while non-monetary assets and liabilities are translated at historical rates. Revenues and expenses are translated at the exchange rates approximating those in effect on the date of the transactions. Exchange gains and losses arising on translation are included in comprehensive loss.

On translation of the entities whose functional currency is other than the United States dollar, revenues and expenses are translated at the exchange rates approximating those in effect on the date of the transactions. Assets and liabilities are translated at the rate of exchange at the reporting date.

Translation gains and losses are recorded in other comprehensive income (loss) as the cumulative translation adjustment along with the historical effects of a change in the functional currency.

Government assistance

Government grants, including grants from similar bodies, consisting of investment tax credits are recorded as a reduction of the related expense or cost of the asset acquired. Government grants are recognized when there is reasonable assurance that the Company has met the requirements of the approved grant program and there is reasonable assurance that the grant will be received.

Research grants that compensate the Company for expenses incurred are recognized in the statement of operations and comprehensive loss on a systematic basis in the same years in which the expenses are recognized. Grants that compensate the Company for the cost of an asset are recognized on a systematic basis over the useful life of the asset.

Research and development costs

Expenditures on research and development activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, are recognized in profit or loss as incurred. Investment tax credits related to current expenditures are included in the determination of net income as the expenditures are incurred when there is reasonable assurance they will be realized.

Fair Value of financial instruments

The Company's financial instruments consist of cash and cash equivalents, short-term investments, receivables, accounts payable and accrued liabilities, long-term debt and derivative liabilities.

The Company provides disclosures that enable users to evaluate (a) the significance of financial instruments for the entity's financial position and performance; and (b) the nature and extent of risks arising from financial instruments to which the entity is exposed during the period and at the date of the statement of financial position, and how the entity manages these risks.

The Company provides information about its financial instruments measured at fair value at one of three levels according to the relative reliability of the inputs used to estimate the fair value:

Level 1 – quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 – inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either

directly (i.e., as prices) or indirectly (i.e., derived from prices); and

Level 3 – inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The fair value of cash and cash equivalents, receivables and accounts payable and accrued liabilities approximates their carrying values due to their short term to maturity. The derivative liabilities are measured using level 3 inputs (Note 10).

Share-based payments

Share based payment arrangements in which the Company receives goods or services as consideration for its own equity instruments are accounted for as equity settled share-based payment transactions and measured at the fair value of at grant date.

Share-based compensation

The Company grants stock options to acquire common shares of the Company to directors, officers, employees and consultants. The Company has elected to early adopt ASU 2018-07 which treats the measurement of employee and nonemployee options similarly and has been applied to all periods presented.

The fair value of stock options is measured on the date of grant, using the Black-Scholes option pricing model, and is recognized over the requisite service or vesting period as applicable. Consideration paid for the shares on the exercise of stock options is credited to share capital. Such value is recognized as expense over the requisite service period, net of actual forfeitures, using the accelerated attribution method. The Company recognizes forfeitures as they occur. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results, or updated estimates, differ from current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised.

Basic and diluted loss per share

Basic loss per share is computed by dividing the loss available to common shareholders by the weighted average number of common shares outstanding during the year. The computation of diluted earnings per share assumes the conversion, exercise or contingent issuance of securities only when such conversion, exercise or issuance would have a dilutive effect on earnings per share. The dilutive effect of convertible securities is reflected in diluted earnings per share by application of the “if converted” method. The dilutive effect of outstanding options and warrants and their equivalents is reflected in diluted earnings per share by application of the weighted-average method. Since the Company has losses, the exercise of outstanding options and warrants has not been included in this calculation as it would be anti-dilutive.

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") established Topic 842, Leases, by issuing Accounting Standards Update (ASU) No. 2016-02, which supersedes ASC 840, Leases, and requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements.

Topic 842, as amended, (the "new lease standard") establishes a right-of-use model (ROU) that requires a lessee to recognize a ROU asset and lease liability on the consolidated balance sheets for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the consolidated statements of operation.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as ROU assets and short-term and long-term lease liabilities, as applicable. ROU assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. The Company typically only includes an initial lease term in its assessment of a lease arrangement. It also considers termination options and factors those into the determination of lease payments. Options to renew a lease are not included in the assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the ROU asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which it could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

The Company adopted the new lease standard on October 1, 2019 and used the effective date as the date of initial adoption. Consequently, financial information will not be updated, and the disclosures required under the new standard will not be provided for earlier periods. Adoption of ASU 2016-02 resulted in the recording of operating lease right-of-use assets and associated lease liabilities of $165,486 (Note 8) as of October 1, 2019 on the consolidated balance sheet with no cumulative impact to accumulated deficit and did not have a material impact on the Company’s result of operations or cash flows.

Income taxes

Income tax is recognized in profit or loss except to the extent that it relates to items recognized directly in equity, in which case it is recognized in equity. Current tax expense is the expected tax payable on the taxable income for the year, using tax rates enacted at period end.

Deferred tax is recognized in respect of temporary differences, between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. The following temporary differences are not provided for: goodwill not deductible for tax purposes and an excess of the amount for financial reporting over the tax basis of an investment in a foreign subsidiary that is essentially permanent in duration. The amount of deferred tax provided is based on the expected manner of realization or settlement of the carrying amount of assets and liabilities, using tax rates enacted at the financial position reporting date.

A valuation allowance is recognized for deferred tax assets if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets are reviewed at each reporting date and a valuation allowance is recorded to the extent that it is no longer more likely than not that the related tax benefit will be realized.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income taxes levied by the same taxation authority and the Company intends to settle its current tax assets and liabilities on a net basis.

Recently accounting pronouncements not yet adopted

ASU 2018-13 – Fair Value Measurement (Topic 820-10)

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820-10): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"), which changes the fair value measurement disclosure requirements of ASC Topic 820, Fair Value Measurements and Disclosures. Under this ASU, certain disclosure requirements for fair value measurements are eliminated, amended or added. These changes aim to improve the overall usefulness of disclosures to financial statement users and reduce unnecessary costs to companies when preparing the disclosures. The guidance is effective for the Company beginning on October 1, 2020 and prescribes different transition methods for the various provisions. The Company does not expect the adoption of ASU 2018-13 to have a material impact on its financial statements and disclosures.

ASU 2019-12 – Income Taxes (Topic 740)

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which simplifies the accounting for income taxes by removing certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new ASU also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates. These changes aim to improve the overall usefulness of disclosures to financial statement users and reduce unnecessary costs to companies when preparing the disclosures. The guidance is effective for the Company beginning on October 1, 2021 and prescribes different transition methods for the various provisions. The Company does not expect the adoption of ASU 2019-12 to have a material impact on its financial statements and related disclosures.

ASU 2016-13 – Financial Instruments-Credit Losses (Topic 326)

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost, including trade receivables. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. This guidance is effective for annual reporting periods beginning after December 15, 2019, with early adoption permitted. Entities will apply the amendments using a modified retrospective approach. The Company does not expect the adoption of ASU 2016-13 to have a material impact on its financial statements and related disclosures.

ASU 2020-06 – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)

In August 2020, the FASB issued ASU No. 2020-06 ("ASU 2020-06") "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity." ASU 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective January 1, 2024, for the Company. Early adoption is permitted, but no earlier than January 1, 2021, including interim periods within that year. Management is currently evaluating the effect of the adoption of ASU 2020-06 on the consolidated financial statements, but currently does not believe ASU 2020-06 will have a significant impact on the Company's accounting.

Recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

4. REALM ACQUISITION

On July 31, 2019, the Company acquired all of the issued and outstanding shares of Realm. Realm shareholders received a total of 6,718,150 common shares of the Company ("New ESSA Shares") at a ratio of 0.05763 of a New ESSA Share per share of Realm (or 1.4409 New ESSA Shares for every one Realm ADS, representing 25 Realm shares). The fair value of the Realm net assets on July 31, 2019, substantially all of which consisted of cash, was $20,247,296. Additionally, the Company incurred issuance costs of $1,925,145.

Realm is not considered to be a business under the definitions of ASU 2017-01; accordingly, the Realm Acquisition is accounted for as a financing transaction. The shares issued in connection with the acquisition of Realm were valued on the basis of the value of assets received.

Net assets of Realm acquired:	
Cash	$ 22,244,248
Receivables and other current assets	240,000
Accounts payable and accrued liabilities	(2,236,952)
Total net assets	$ 20,247,296

5. SHORT-TERM INVESTMENTS

Short-term investments consist of guaranteed investment certificates ("GICs") held at financial institutions purchased in accordance with the Company's treasury policy. These GICs and term deposits bear interest at 0.25%-0.45% per annum and have maturities of up to 12 months.

6. PREPAIDS

	2020	2019
Prepaid insurance	$ 825,014	$ 524,257
Prepaid preclinical and clinical expenses and deposits	650,586	8,260
Other deposits and prepaid expenses	124,528	82,968
Balance, end of year	$ 1,600,128	$ 615,485

7. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

	2020	2019
Accounts payable	$ 678,643	$ 1,358,554
Accrued expenses	310,604	151,182
Accrued vacation	154,983	56,053
Balance, end of year	$ 1,144,230	$ 1,565,789

8. OPERATING LEASE

In March 2018, the Company signed an office lease with a three-year term. With the adoption of ASC 842, the Company has recorded an operating lease right-of-use asset and corresponding lease liability. Operating lease cost under this lease is recognized on a straight-line basis over the term of the lease.

The Company's operating leases included on the balance sheet are as follows:

Operating lease right-of-use asset	
Balance, September 30, 2018 and 2019	$ —
Adoption of ASC 842 (Note 3)	165,486
Amortization	(110,324)
Balance, September 30, 2020	$ 55,162
Operating lease liabilities	
Balance, September 30, 2018 and 2019	$ —
Adoption of ASC 842 (Note 3)	165,486
Accretion	12,992
Lease payments	(119,384)
Balance, September 30, 2020	$ 59,094

The Company recognizes a right-of-use asset for the right to use the underlying asset for the lease term, and a lease liability, which represents the present value of the Company's obligation to make payments over the lease term. The present value of the lease payments is calculated using an incremental borrowing rate as the Company's leases do not provide an implicit interest rate. At September 30, 2020, the Company's incremental borrowing rate was 12.0% and the remaining lease term was 6 months.

Operating lease costs of $119,384 and accretion expense of $12,992 have been recorded in "general and administrative expenses" and "financing costs" in the statement of operations and comprehensive loss respectively.

9. LONG-TERM DEBT

On November 18, 2016, Silicon Valley Bank ("SVB") entered into a $10,000,000 capital term loan facility agreement ("SVB Term Loan") with the Company. The Company drew down $8,000,000 from the SVB Term Loan. The option to draw an additional $2,000,000 lapsed on July 31, 2017.

The SVB Term Loan bore interest at the Wall Street Journal Prime Rate ("WSJ Prime Rate") plus 3% per annum and with a maturity date of September 1, 2020. The SVB Term Loan required a final payment of 8.6% of the amount advanced ("Final Payment"), due upon the earlier of the maturity or termination of the SVB Term Loan. The Company was required to make interest only payments until December 31, 2017. The SVB Term Loan contained a voluntary prepayment option whereby the principal amount can be prepaid in whole, or in part, for a fixed fee if a prepayment is made on or before the second anniversary of the SVB Term Loan. In the year ended September 30, 2020, the Company repaid the SVB Term Loan in full totalling $3,708,955, comprising $3,199,799 in principal, $32,235 in accrued interest, $211,079 in financing costs and the Final Payment of $688,000.

In connection with the $8,000,000 draw, the Company granted an aggregate of 7,477 warrants to SVB (the "SVB Warrants"), exercisable at a price of $42.80 per share for a period of seven years until November 18, 2023, with a fair value of $167,022. The Company incurred total additional transaction costs of $220,898 related to the SVB Term Loan and First Amendment. The transaction costs and Final Payment were being amortized into profit and loss over the estimated term of the facility, being the legal term, resulting in an effective interest rate of 12.6% (2019 - 12.19%).

The SVB Term Loan was fully repaid during the fiscal year.

	SVB Term Loan
Balance, September 30, 2018	$ 6,316,963
Principal repaid	(2,808,823)
Interest paid	(401,929)
Accretion	602,744
Balance, September 30, 2019	$ 3,708,955
Principal repaid	(3,199,799)
Interest paid	(32,235)
Accretion	211,079
Final payment	(688,000)
Balance, September 30, 2020	$ —

10. DERIVATIVE LIABILITIES

In January 2016, the Company completed a private placement of 227,273 units of the Company at $66.00 per unit ("Unit") for gross proceeds of $14,999,992. Each Unit consisted of one common share of the Company, one 7-year cash and cashless exercise warrant (the "7-Year Warrants"), and one half of one 2-year cash exercise warrant (the "2-Year Warrants"). The 7-Year Warrants and 2-Year Warrants have an exercise price of $66.00 per common share (collectively, the "2016 Warrants"). The holders of the 7-Year Warrants may elect, in lieu of exercising the 7-Year Warrants for cash, a cashless exercise option, in whole or in part, to receive common shares equal to the fair value of the 7-Year Warrants based on the number of 7-Year Warrants to be exercised multiplied by a ten-day weighted average market price less the exercise price with the difference divided by the weighted average market price. If a warrant holder exercises this option, there will be variability in the number of shares issued per 7-Year Warrant.

Additionally, the 2016 Warrants contain provisions which may require the Company to redeem the 2016 Warrants, at the option of the holder, in the event of a major transaction, such as a change of control or sale of the Company's assets ("Major Transaction"). The redemption value would be subject to a Black-Scholes valuation at the time of exercise. In the event the consideration for a Major Transaction payable to the common shareholders is in cash, in whole or in part, the redemption of the 2016 Warrants would be made in cash pro-rata to the composition of the consideration. The potential for a cash settlement for the 2016 Warrants outside the control of the Company, in accordance with U.S. GAAP, requires the 2016 Warrants to be treated as financial liabilities measured at fair value through profit or loss. The 2016 Warrants are not traded in an active market.

Valuation

The Company uses the Black-Scholes option pricing model to estimate fair value. The following weighted average assumptions were used to estimate the fair value of the derivative warrant liabilities on September 30, 2019 and 2020:

	2020	2019
Risk-free interest rate	0.22 %	1.55 %
Expected life	2.28 years	3.29 years
Expected annualized volatility	97.3 %	74.8 %
Dividend	—	—
Liquidity discount	20 %	20 %

Sensitivity

The derivative warrants are a recurring Level 3 fair value measurement. The key level 3 inputs used by management to determine the fair value are the market price, expected volatility and liquidity discount. If the market price were to increase by a factor of 10% this would increase the obligation by approximately $37,109 as at September 30, 2020. If the market price were to decrease by a factor of 10% this would decrease the obligation by approximately $19,071 as at September 30, 2020. If the volatility were to increase by 10%, this would increase the obligation by approximately $68,172 as at September 30, 2020. If the volatility were to decrease by 10%, this would decrease the obligation by approximately $42,877 as at September 30, 2020.

The following table is a continuity schedule of changes to the Company's derivative liabilities:

	Total
Balance, September 30, 2018	$ 17,679
Change in fair value	(1,159)
Balance, September 30, 2019	$ 16,520
Change in fair value	110,856
Balance, September 30, 2020	$ 127,376
Derivatives with expected life of less than one year	$ —
Derivatives with expected life greater than one year	$ 127,376

11. SHAREHOLDERS' EQUITY

Authorized

Unlimited common shares, without par value.

Unlimited preferred shares, without par value.

July 2020 Financing

On July 31, 2020, the Company completed an underwritten public offering for aggregate gross proceeds of US$48,990,000 (the "**July 2020 Financing**"). The Company issued a total of 7,100,000 common shares of the Company at a public offering price of US$6.00 per share. Additionally, the underwriters exercised a 30-day option to purchase up to an additional 1,065,000 common shares. In connection with the July 2020 Financing, the Company paid cash commissions of $2,939,400 and incurred other transaction costs of $193,951.

August 2019 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 and 11,919,404 pre-funded warrants 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 cash commissions of $1,978,770 and incurred other transaction costs of $698,162.

Realm Acquisition

On July 31, 2019, the Company issued 6,718,150 shares in relation to the Realm Acquisition (Note 4).

Nomination Rights

In connection with a January 2016 private placement of 227,273 Units, a Unit consisting of one common share, one 7-year warrant and one-half of one 2-year warrant, of the Company, Clarus Lifesciences III, L.P. ("**Clarus**") acquired 106,061 common shares. Clarus is entitled to nominate two directors to the board of directors of the Company, one of which must be an independent director and preapproved by the Company. These nomination rights will continue for so long as Clarus holds greater than or equal to 53,030 common shares, subject to adjustment in certain circumstances.

Equity incentive plans

Restricted share units plan

The Company has adopted a Restricted Share Unit Plan ("RSU Plan") consistent with the policies and rules of the TSX-V and Nasdaq. Pursuant to the RSU Plan, RSUs may be granted with vesting criteria and periods are approved by the Board of Directors at its discretion. The RSUs issued under the RSU Plan may be accounted for as either equity-settled or cash-settled share-based payments. At September 30, 2020, there are no RSUs outstanding.

As at September 30, 2020 the Stock Option Plan and RSU Plan have a combined maximum of 6,251,469 common shares which may be reserved for issuance.

Employee Share Purchase Plan

The Company has adopted an Employee Share Purchase Plan ("ESPP") under which qualifying employees may be granted purchase rights ("Purchase Rights") to the Company's common shares at not less of 85% of the market price at the lesser of the date the Purchase Right is granted or exercisable. The Company currently holds offerings consisting of six-month periods commencing on January 1 and July 1 and ending on June 30 and December 31 of each calendar year. As at September 30, 2020, the ESPP has a maximum of 268,381 (2019 – 284,887) common shares reserved for issuance.

Eligible employees are able to contribute up to 15% of their gross base earnings for purchases under the ESPP through regular payroll deductions. Purchase of shares under the ESPP are limited for each employee at $25,000 worth of the Company's common shares (determined using the lesser of (i) the market price of a common share on the first day of an applicable purchase period and (ii) the market price of a common share on the purchase date) for each calendar year in which a purchase right is outstanding.

During the year ended September 30, 2020, the Company issued a total of 16,506 (2019 – Nil) common shares upon the exercise of Purchase Rights. The Company recognizes compensation expense for purchase rights on a straight-line basis over the service period.

	2020	2019
Research and development expense	$ 24,984	$ —
General and administrative	46,033	—
	$ 71,016	$ —

The Company measures the purchase rights based on their estimated grant date fair value using the Black-Scholes option pricing model and the estimated number of shares that can be purchased. The following weighted average assumptions were used for the valuation of purchase rights:

	2020	2019
Risk-free interest rate	1.44 %	—
Expected life of options	6 months	—
Expected annualized volatility	90.34 %	—
Dividend	—	—

Stock options

The Company has adopted a Stock Option Plan consistent with the policies and rules of the TSX-V and Nasdaq. Pursuant to the Stock Option Plan, options may be granted with expiry terms of up to 10 years, and vesting criteria and periods are approved by the Board of Directors at its discretion. The options issued under the Stock Option Plan are accounted for as equity-settled share-based payments.

Stock option transactions are summarized as follows:

	Number of Options	Weighted Average Exercise Price*
Balance, September 30, 2018	900,459	$ 4.88
Options granted	255,000	3.77
Options expired/forfeited	(32,998)	(4.10)
Balance, September 30, 2019	1,122,461	$ 4.59
Options granted	4,218,000	3.31
Options exercised	(416)	(2.20)
Options expired/forfeited	(30,461)	(28.46)
Balance outstanding, September 30, 2020	5,309,584	$ 3.42
Balance exercisable, September 30, 2020	1,859,826	$ 3.52

* Options exercisable in Canadian dollars as at September 30, 2020 are translated at current rates to reflect the current weighted average exercise price in US dollars for all outstanding options.

At September 30, 2020, options were outstanding enabling holders to acquire common shares as follows:

Exercise price		Number of options	Weighted average remaining contractual life (years)
$	2.20	4,584	8.70
$	3.23	3,953,000	8.96 *
$	3.58	12,000	0.05 *
$	3.59	40,000	9.05
$	3.81	193,000	8.15 *
$	4.00	552,500	7.22 *
$	4.67	225,000	9.09 *
C$	4.90	284,500	7.06
C$	5.06	45,000	8.36
		5,309,584	8.63

* 42,000 options expired unexercised and 42,207 options exercised subsequent to September 30, 2020.

Share-based compensation

During the year ended September 30, 2020, the Company granted a total of 4,218,000 (2019 – 255,000) stock options with a weighted average fair value of $3.31 per option (2019 – $3.00).

The Company recognized share-based payments expense for options granted and vesting, net of recoveries on cancellations of unvested options, during the years ended September 30, 2020 and 2019 with allocations to its functional expense as follows:

	2020	2019
Research and development expense	$ 1,853,390	$ 304,786
General and administrative	5,598,202	841,921
	$ 7,451,592	$ 1,146,707

The following weighted average assumptions were used for the Black-Scholes option-pricing model valuation of stock options granted:

	2020	2019
Risk-free interest rate	1.55 %	2.55 %
Expected life of options	10.00 years	10.00 years
Expected annualized volatility	77.00 %	79.33 %
Dividend	—	—

Warrants

Warrant transactions are summarized as follows:

	Number of Warrants	Weighted Average Exercise Price*
Balance, September 30, 2018	2,663,937	$ 6.13
Warrants granted	11,919,404	0.0001
Warrants exercised	(2,188,999)	(0.002)
Warrants expired	(1,250)	(31.17)
Balance, September 30, 2019	12,393,092	$ 1.31
Warrants exercised	(3,120,115)	(0.08)
Balance outstanding and exercisable, September 30, 2020	9,272,977	$ 1.73

* Warrants exercisable in Canadian dollars as at September 30, 2020 are translated at current rates to reflect the current weighted average exercise price in US dollars for all outstanding warrants.

At September 30, 2020, warrants were outstanding enabling holders to acquire common shares as follows:

Number of Warrants		Exercise Price		Expiry Date
227,273 [1]	US$	66.00	January 14, 2023
7,477	US$	42.80	November 18, 2023
129,723	US$	4.00	January 9, 2023
45,000	US$	4.00	January 16, 2023
8,863,504	US$	0.0001	August 23, 2024
9,272,977			

[1] Detailed terms of the 2016 Warrants are included in Note 10.

12. SUPPLEMENTAL DISCLOSURE WITH RESPECT TO CASH FLOWS

There were no significant non-cash financing or investing activities during the year ended September 30, 2020.

During the year ended September 30, 2019, the Company:

a) issued 1,652,530 common shares upon the cashless exercise of 1,653,999 pre-funded warrants;

b) incurred $64,804 in transaction costs related to the Realm Transaction through accounts payable and accrued liabilities (Note 4); and

c) incurred $303,951 in share issuance costs through accounts payable and accrued liabilities.

13. RELATED PARTY TRANSACTIONS

Included in accounts payable and accrued liabilities at September 30, 2020 is $87,846 (2019 - $108,331) due to related parties with respect to key management personnel compensation and expense reimbursements. Amounts due to related parties are non-interest bearing, with no fixed terms of repayment.

14. INCOME TAXES

A reconciliation of income taxes at statutory rates is as follows:

For the years ended September 30	2020	2019
Loss for the year before income tax	$ (23,734,017)	$ (12,718,912)
Tax recovery at statutory income tax rates	$ (6,408,000)	$ (3,434,000)
Non-deductible share-based payments	2,031,000	227,000
Taxable capital gains	—	346,000
Other permanent differences including foreign exchange	21,000	3,000
Share issue costs	(849,000)	(720,000)
Change in statutory, foreign tax, foreign exchange rates and other	1,013,353	457,920
Adjustment to prior years provision versus statutory tax returns and expiry of non-capital losses	(307,000)	(196,000)
Change in valuation allowance	4,210,000	3,354,000
Total income tax expense	$ (288,647)	$ 37,920

In September 2017, the British Columbia (BC) Government proposed changes to the general corporate income tax rate to increase the rate from 11% to 12% effective January 1, 2018 and onwards. This change in tax rate was substantively enacted on October 26, 2017. The relevant deferred tax balances have been remeasured to reflect the increase in the Company's combined Federal and Provincial (BC) general corporate income tax rate from 26% to 27%.

In December 2017, the United States Government proposed changes to the Federal corporate income tax rate to reduce the rate from 34% to 21% effective January 1, 2018 and onwards. This change in tax rate was enacted on December 22, 2017. The relevant deferred tax balances have been remeasured to reflect the decrease in the Company's Federal income tax rate from 34% to 21% applicable to the Company's US subsidiary. Operating losses carried forward as at September 30, 2020 expire from 2031 – 2039. Financing costs expire from 2040 to 2044. Investment tax credits expire in 2035.

Tax attributes are subject to review, and potential adjustment, by tax authorities. The Company has recorded an income tax recovery of $288,647 for the year ended September 30, 2020 (2019 – expense of $37,920) in relation to taxable income generated by its US subsidiary.

For the years ended September 30, 2020 and 2019, the Company did not record a provision for income taxes due to a full valuation allowance against our deferred tax assets. The significant components of the Company's deferred tax assets are as follows:

Deferred tax assets	**2020**	**2019**
Operating losses carried forward	$ 21,297,000	$ 17,306,000
Equipment and intangible assets	77,000	77,000
Investment tax credits	39,000	137,000
Financing costs	1,462,000	1,159,000
	22,875,000	18,679,000
Valuation allowance	(22,875,000)	(18,679,000)
Net future tax assets	$ —	$ —

15. SEGMENTED INFORMATION

The Company works in one industry being the development of small molecule drugs for prostate cancer. The Company's right of use asset is located in the USA.

16. FINANCIAL INSTRUMENTS AND RISK

The Company's financial instruments consist of cash and cash equivalents, short-term investments, receivables, accounts payable and accrued liabilities, long-term debt and derivative liabilities. The fair value of cash and cash equivalents, receivables and accounts payable and accrued liabilities approximates their carrying values due to their short term to maturity. The derivative liabilities are measured using level 3 inputs (Note 10).

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 cash equivalents, short-term investments and receivables. The Company's receivables is mainly the balance remaining on the CPRIT Grant. The Company limits its exposure to credit loss by placing its cash with major financial institutions. The Company considers highly liquid investments with a maturity of up to twelve months when purchased to be short-term investments. As at September 30, 2020, cash and cash equivalents consisted of cash in Canada and the United States. and term deposits in Canada. Balances exceed amounts insured by the Canada Deposit Insurance Corporation for up to C$100,000 and by the Federal Deposit Insurance Corporation for up to $250,000. Amounts due from government agencies are considered to have minimal credit risk.

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, 2020, the Company had working capital of $79,093,604. The Company does not generate revenue and will be reliant on external financing to fund operations. Debt and equity financing 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, 2020, the Company has cash and cash equivalents balances and GICs 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.

(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 and cash equivalents 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 in relation to Canadian dollars held at September 30, 2020 would result in a fluctuation of $4,676 in the net loss recognized for the period. The Company does not currently engage in hedging activities.

17. COMMITMENTS

Product Development and Relocation Grant

In February 2014 the Company was awarded a product development and relocation grant by CPRIT whereby the Company received $12,000,000 on eligible expenditures over a three-year period related to the development of the Company's androgen receptor n-terminus blocker program for prostate cancer. A final payment of $229,201 has been recorded as a receivable as at September 30, 2019 and 2020.

If the Company is found to have used any grant proceeds for purposes other than intended, is in violation of the terms of the grant, or fails to maintain the required level of operations in the State of Texas for three years following the final payment of grant funds, then the Company could be required to repay any grant proceeds received.

Under the terms of the grant, the Company is also required to pay a royalty to CPRIT, comprised of 4% of revenues the Company receives from sale of commercial product or commercial service, until aggregate royalty payments equal $24,000,000, and 2% of revenues thereafter. The Company has the option to terminate the grant agreement by paying a one-time, non-refundable buyout fee, based on certain factors including the grant proceeds, and the number of months between the termination date and the buyout fee payment date.

License Agreement

The NTD Technology is held under a license agreement signed in fiscal 2010 (the "License Agreement"). As consideration for the License Agreement, the Company issued common shares of the Company. The License Agreement contains an annual royalty as a percentage of annual net revenue and a percentage of any annual sublicensing revenue earned with respect to the NTD Technology. The License Agreement stipulates annual minimum advance royalty payments of C$85,000. In addition, there are certain milestone payments for the first compound, to be paid in stages as to C$50,000 at the start of a Phase II clinical trial, C$900,000 at the start of a Phase III clinical trial, C$1,450,000 at application for marketing approval, and with further milestone payments on the second and additional compounds

The Company has the following obligations over the next five years:

Contractual obligations	2021	2022	2023	2024	2025
Minimum annual royalty per License Agreement	C$ 85,000	C$ 85,000	C$ 85,000	C$ 85,000	C$ 85,000
Vendor Agreement	C$ 25,000	C$ 25,000	C$ —	C$ —	C$ —
Consulting Agreement	$ 35,000	$ 35,000	$ —	$ —	$ —
Lease on US office spaces	$ 70,670	$ —	$ —	$ —	$ —

Advisory Contract

In April 2019 the Company executed an Engagement Letter with Oppenheimer & Co. Inc. ("Oppenheimer"), an investment bank, to retain their services to act as its lead financial advisor for which it obtained a percentage of funds raised on successful completion of the financing in August 2019. Oppenheimer would receive compensation on certain capital transactions while the Engagement Letter is in effect. The Company may terminate the agreement on 30 days' written notice. Oppenheimer retains a right of first refusal as a lead agent on all future financings occurring up to December 31, 2020.

18. SUBSEQUENT EVENTS

On October 14, 2020, the Company issued 1,493,504 common shares upon the cashless exercise of 1,493,504 pre-funded warrants.

On December 3, 2020, the Company issued 42,207 common shares for stock options exercised for gross proceeds of $153,701.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of end of the period covered by this Annual Report on Form 10-K, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the design and operating effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Any such information is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on our evaluation of our disclosure controls and procedures as of the end of the period covered by this report, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were, in design and operation, effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over our financial reporting, defined in Rule 13a-15(f) and Rule 15d-15(f) of the Exchange Act.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute, assurances. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate. Management has assessed the effectiveness of our internal control over financial reporting as at September 30, 2020. In making its assessment, management used the criteria set forth in the internal control – integrated framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 COSO framework) to evaluate the effectiveness of our internal control over financial reporting. Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of September 30, 2020.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by Item 10. of Form 10-K is incorporated by reference to our proxy statement for the 2021 annual meeting of shareholders (the "2021 Proxy Statement"), to be filed with the SEC within 120 days after the end of the fiscal year ended September 30, 2020.

Item 11. Executive Compensation

The information required by Item 11. of Form 10-K is incorporated by reference to our 2021 Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended September 30, 2020.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters

The information required by Item 12. of Form 10-K is incorporated by reference to our 2021 Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended September 30, 2020.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by Item 13. of Form 10-K is incorporated by reference to our 2021 Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended September 30, 2020.

Item 14. Principal Accounting Fees and Services

The information required by Item 14. of Form 10-K is incorporated by reference to our 2021 Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended September 30, 2020.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements—The financial statements included in Item 8 are filed as part of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules—All schedules have been omitted because they are not applicable or required, or the information required to be set forth therein is included in the consolidated Financial Statements or notes thereto included in Item 8 of this Annual Report on Form 10-K.

(a)(3) Exhibits—The exhibits required by Item 601 of Regulation S-K are listed in paragraph (b) below.

(b) Exhibits—The exhibits listed on the Exhibit Index below are filed herewith or are incorporated by reference to exhibits previously filed with the SEC.

EXHIBITS INDEX

Exhibit No.

1.1	Open Market Sales Agreement, dated April 13, 2020 (incorporated by reference to Exhibit 99.1 to the Company's Report on Form 6-K (File No. 001-37410), originally filed with the SEC on April 14, 2020)
1.2	Underwriting Agreement, dated July 28, 2020 (incorporated by reference to Exhibit 99.1 to the Company's Report on Form 6-K (File No. 001-37410), originally filed with the SEC on August 6, 2020)
3.1	Articles of Incorporation (incorporated by reference to Exhibit 1 to the Company's Registration Statement on Form 20-F (File No. 377-00939), originally filed with the SEC on February 24, 2015)
4.1	Specimen common share certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8, filed with the Commission on May 18, 2018 (File No. 333-225056))
4.2	Description of Capital Stock
10.1	Cancer Research Contract between CPRIT and the Company, dated July 9, 2014 (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 20-F (File No. 377-00939), originally filed with the SEC on February 24, 2015)
10.2	License Agreement between the BC Cancer Agency, UBC and the Company, dated December 22, 2010, as amended on February 10, 2011 and May 27, 2014† (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form 20-F (File No. 377-00939), originally filed with the SEC on February 24, 2015)
10.3	Sublease for 2130 West Holcombe Boulevard, Houston, Texas, United States dated April 7, 2015 (incorporated by reference to Exhibit 4.8 to the Company's Annual Report on Form 20-F (File No. 001-37410), originally filed with the SEC on December 11, 2015)
10.4	Employment Agreement for David Wood (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form 20-F (File No. 377-00939), originally filed with the SEC on April 7, 2015)
10.5	Employment Agreement for David Parkinson (incorporated by reference to Exhibit 4.9 to the Company's Annual Report on Form 20-F (File No. 001-37410), originally filed with the SEC on December 14, 2016)
10.6	Employment Agreement for Peter Virsik (incorporated by reference to Exhibit 4.10 to the Company's Annual Report on Form 20-F File (No. 001-37410), originally filed with the SEC on December 14, 2016)
10.7	Employment Agreement for Alessandra Cesano (incorporated by reference to Exhibit 4.7 to the Company's Annual Report on Form 20-F (File No. 001-37410), originally filed with the SEC on December 20, 2019)
10.8	Subscription Agreement between the Company and Clarus Lifesciences III, L.P. dated January 14, 2016 (incorporated by reference to Exhibit 4.8 to the Company's Annual Report on Form 20-F (File No. 001-37410), originally filed with the SEC on December 13, 2018)
10.9	Consulting Agreement for Dr. Marianne Sadar (incorporated by reference to Exhibit 4.10 to the Company's Annual Report on Form 20-F (File No. 001-37410), originally filed with the SEC on December 13, 2018)
10.10	Consulting Agreement for Dr. Raymond Andersen (incorporated by reference to Exhibit 4.11 to the Company's Annual Report on Form 20-F (File No. 001-37410), originally filed with the SEC on December 13, 2018)
10.11	Lease for 400 Oyster Point Boulevard, South San Francisco, California, United States dated March 5, 2018 (incorporated by reference to Exhibit 4.12 to the Company's Annual Report on Form 20-F (File No. 001-37410), originally filed with the SEC on December 13, 2018)
21.1	List of Subsidiaries
23.1	Consent of Davidson & Company LLP, an Independent Registered Public Accounting Firm
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities and Exchange Act of 1934, as amended
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities and Exchange Act of 1934, as amended
32.1	Certification by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as added by Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document – The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document. *

101.SCH	Inline XBRL Taxonomy Extension Schema Document *
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document *
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document *
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document *
104	Cover page from the Company's Annual Report on Form 10-K for the year ended September 30, 2020 formatted in Inline XBRL (included in Exhibit 101).

†Confidential treatment has been requested for portions of this document. The omitted portions of this document have been filed with the Securities and Exchange Commission.

* Filed herewith.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: December 10, 2020

ESSA PHARMA INC.
(Registrant)

Date: December 10, 2020

By: /s/ DAVID PARKINSON
Name: David Parkinson
Title: Chief Executive Officer

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Signature	**Title**
/s/ *David Parkinson* David Parkinson	President and Chief Executive Officer and Director (Principal Executive Officer)
/s/ *David Wood* David Wood	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ *Richard M. Glickman* Richard M. Glickman	Chairman of the Board
/s/ *Marella Thorell* Marella Thorell	Director
/s/ *Alex Martin* Marella Thorell	Director
/s/ *Sandy Zweifach* Sandy Zweifach	Director
/s/ *Franklin Berger* Franklin Berger	Director
/s/ *Scott Requadt* Scott Requadt	Director
/s/ *Gary Sollis* Gary Sollis	Director