

at the DNA (AR amplification or LBD mutations) or RNA level (emergence of AR splice variants). With respect to the development of alternative pathway mechanisms of AR activation, tumors may also become insensitive to antiandrogen activity. Finally, in patients who have been treated for years with various antiandrogen therapies, genomic changes may lead to additional, non-AR-related oncogenic drivers, also insensitive to inhibition of AR biology.²⁰ Table of Contents The Company believed that through their potential to block androgen-driven gene transcription by using a unique mechanism involving the NTD and thereby bypassing these known mechanisms of resistance to current antiandrogens, the Aniten series of compounds might have held the potential to be effective in cases where LBD-based mechanisms of resistance to second generation antiandrogens in otherwise AR-driven disease are operating. The results from both extensive preclinical studies and the initial clinical experience, prior to October 2024, supported the Company's belief. In preclinical studies, the Aniten series of compounds was observed to shrink AR-dependent prostate cancer xenografts, including tumors both sensitive and resistant to the second-generation antiandrogens, such as enzalutamide. Plasma PSA level declines and increases in PSA doubling time as well as declines in circulating tumor DNA and decreases in radiographic tumor measurements were observed in a subset of patients enrolled in the Phase 1 study of masofaniten (EPI-7386) as described below. Importantly with respect to the potential clinical application of NTD inhibition during the natural history of the disease, earlier studies by the Company and its collaborators had also suggested the potential advantage for combinations of the Company's Aniten compounds with currently approved antiandrogens to inhibit AR-driven biology more completely than AR inhibition from either end of the receptor alone. This hypothesis was then-supported by the clinical trial results obtained in recent years of the superior overall survival obtained in the hormone-sensitive prostate cancer (HSPC) setting by combining ADT and the latest generation antiandrogens earlier in the course of the disease versus the administration of these two therapies sequentially. 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 clinical-stage NTD AR inhibitors that are in development by other drug development companies. The nature of the binding of the Aniten compounds to the NTD, and the biological consequences of that binding, have been defined in 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 1 trial of EPI-506. Subsequent to this trial and following the decision to pursue masofaniten (EPI-7386) as the Company's lead product candidate, the Company completed a series of biophysical and biological studies revealing the interaction and binding of masofaniten (EPI-7386) to the NTD of the AR and presented these findings at several medical conferences in 2021. See "Completed Phase 1 Clinical Study of EPI-506 and Next generation Aniten molecules" below. The incidence of prostate cancer continues to rise. In 2024, 35,250 men are estimated to die of prostate cancer with 299,010 new estimated cases of the disease¹. According to a prostate cancer market mapping assessment conducted by IQVIA, there were approximately 260,000 men with prostate cancer treated in the U.S. in 2023 with systemic treatments who had not yet received a second-generation antiandrogen². The Company believed that the Aniten series of compounds could ultimately hold potential benefit for many of those patients. In its early clinical development, the Company focused on patients who have failed second-generation antiandrogen 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 a potentially large market;—the Company believed 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 expected that the relatively large number of patients with an apparent unmet therapeutic need in this area will facilitate timely enrollment in its clinical trials. The Company believed that the demonstration of favorable safety and tolerability in the initial Aniten Phase 1 clinical trial, together with the compelling preclinical rationale, enabled and emphasized the importance of the study of the combination of masofaniten (EPI-7386) with second-generation antiandrogens. Furthermore, the Company believed that 1 National Cancer Institute, Surveillance Epidemiology, and End Results Program (SEER), 2024. (<https://seer.cancer.gov/statfacts/html/prost.html>) IQVIA: Oncology Analytics Platform and analytics for the period 2019-2024 reflecting estimates of real-world activity.²¹ Table of Contents this 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 antiandrogens in combination with classic ADT, consistent with the premise that more effective androgen suppression may yield clinical benefit. The Company believed that the introduction of NTD inhibitors, such as masofaniten (EPI-7386), therefore had the potential to improve androgen suppression, delay the emergence of resistance, and result in improved clinical benefit. Completed Phase 1 Clinical Study of EPI-506 The Company conducted an initial proof-of-concept Phase 1 clinical study utilizing the first-generation Aniten compound, EPI-506 from 2015 to 2017. The objective of the EPI-506 Phase 1 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 1/2 clinical trial of EPI-506 are available on the U.S. National Institutes of Health clinical trials website (see <https://clinicaltrials.gov> under identifier NCT02606123). The IND application to the FDA for EPI-506 to begin a Phase 1 clinical trial was allowed in September²² 2015, with the first clinical patient enrolled in November²³ 2015. The Company's Clinical Trial Application (CTA) submission to Health Canada was subsequently also cleared. Based on allometric scaling, an initial dose level of EPI-506 of 80 mg was determined. However, following the enrollment of the initial cohorts, it became apparent that EPI-506 exposure was much lower in humans than projected. EPI-506 dosing was escalated aggressively to allow patients in the clinical study greater exposure to the drug. The highest dose patients ultimately received was 3600 mg of EPI-506, administered in a single dose or split into two doses daily. The initial data from the Phase 1 clinical trial was presented at the European Society of Medical Oncology meeting in September²⁴ 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 (4% to 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 believed 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 have provided 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 September²⁵ 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. This next generation Aniten compound included significantly more potent drugs designed to exhibit increased resistance to metabolism and therefore a longer predicted circulating half-life. The Company's planned product candidate, masofaniten (EPI-7386), demonstrated these and other favorable characteristics in extensive preclinical 22 Table of Contents characterization and clinical studies which the Company has presented in a series of poster presentations at scientific meetings. Next generation Aniten molecules The Company's family of next-generation investigational Aniten compounds incorporated multiple chemical scaffold changes to the first-generation drugs which in preclinical studies retained NTD inhibition of the AR. In addition, they showed improvement in a range of attributes when compared to the first-generation compound, EPI-506, in preclinical studies. 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 demonstrated increased metabolic stability in preclinical studies, suggesting the potential for longer half-lives in humans. Lastly, the compounds demonstrated more favorable pharmaceutical properties relative to EPI-506. The Company believed that these product candidates, if successfully developed and approved, may have offered advancements in ease and cost of large-scale manufacture, drug product stability, and suitability for commercialization globally. Of these next-generation Anitens, masofaniten (EPI-7386) was selected for IND filing and a Phase 1 clinical trial. As discussed further herein, ESSA has decided to withdraw its IND and the CTAs relating to masofaniten (EPI-7386) that have been submitted to date. Our Strategy In October 2024, ESSA announced that it decided to terminate its clinical trials evaluating masofaniten (EPI-7386), and that the remaining company-sponsored and investigator-sponsored clinical studies evaluating masofaniten (EPI-7386) will be terminated. ESSA has also decided to withdraw its IND and CTAs that have been submitted to date. In connection with these events, ESSA is undergoing a comprehensive review process to review its strategic options to maximize shareholder value. In developing possible therapeutics that involve binding to the NTD of the AR, the Company's strategic approach previously involved combining Aniten compounds with second generation antiandrogens in earlier lines of therapy. The Company, with industry partners, had been conducting clinical trials of combinations of masofaniten (EPI-7386) and second-generation antiandrogens in prostate cancer patients with nmCRPC, mCRPC, mHSPC and neo-adjuvant prostate cancer surgical treatment setting whose disease is thought to be still predominantly AR dependent. The Company was also completing the clinical development of masofaniten (EPI-7386) as a monotherapy treatment for patients with mCRPC, who are resistant to the current standard of care, to assess the drug's performance as a single agent as completely as possible, with regards to safety, tolerability, and anti-tumor activity together with detailed pharmacological and biological studies. In parallel, the Company was continuing preclinical studies, including work on other Aniten molecules and other potential applications for AR NTD inhibitors. The identification and characteristics of masofaniten (EPI-7386) The purpose of the next-generation program had 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 had resulted in the generation of a new series of compounds demonstrating higher potency and predicted longer half-lives. Multiple changes in the chemical scaffold were 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 March²⁶ 2019, the Company announced the nomination of masofaniten (EPI-7386) as its lead clinical candidate for the treatment of mCRPC through inhibition of the NTD of the androgen receptor. In preclinical studies, masofaniten (EPI-7386) had displayed activity *in vitro* in numerous AR-dependent prostate cancer models including models where second-generation antiandrogens are inactive. In addition, masofaniten (EPI-7386) had shown to be significantly more potent, metabolically stable and more effective in preclinical studies compared to ESSA's first-generation compound, EPI-506. Lastly, masofaniten (EPI-7386) had demonstrated a favorable tolerability profile in all animal studies of the compound conducted to that date. 23 Table of Contents From this series of next-generation compounds, masofaniten (EPI-7386) was selected as the lead candidate for the initial clinical development in mCRPC. 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. Clinical testing of masofaniten (EPI-7386) commenced in July 2020, allowing for accommodations to the planned timeline as a result of the impact of COVID-19 on clinical trial sites (see "Risk Factors" - Widespread health concerns, pandemics or epidemics, and other outbreaks of illness may negatively affect the Company's ability to maintain operations and execute its business plan) in our Annual Report on Form 10-K). In October 2024, ESSA announced that it decided to terminate its clinical trials evaluating masofaniten (EPI-7386), and that the remaining company-sponsored and investigator-sponsored clinical studies evaluating masofaniten (EPI-7386) will be terminated. ESSA has also decided to withdraw its IND and CTAs that have been submitted to date. In connection with these events, ESSA is undergoing a comprehensive review process to review its strategic options to maximize shareholder value. 24 Table of Contents Advancing masofaniten (EPI-7386) through clinical development In October 2024, the Company announced its decision to terminate its clinical trials evaluation masofaniten (EPI-7386), including each of the clinical trials described below. The Company was previously advancing masofaniten (EPI-7386) through two clinical trials: EPI-7386-CS-001 and EPI-7386-CS-010. The clinical trial of EPI-7386-CS-001 had two arms that represent a monotherapy and combination component of the study schema, as outlined below: Notes: ^a means mCRPC; ^b means metastatic castration-resistant prostate cancer; ^c means abiraterone acetate/prednisone; ^d means mHSPC; ^e means metastatic hormone-sensitive prostate; and ^f means nmCRPC; ^g means non-metastatic castration-resistant prostate cancer The clinical trial of EPI-7386-CS-010 was a combination trial with enzalutamide with a Phase 1 dose equilibration component and Phase 2 head-to-head comparison component, as outlined in the study schema below: Notes: ^a means ENZ; ^b means enzalutamide; ^c means Phase 1 Clinical Trial - EPI-7386-CS-001 The Phase 1 clinical trial of masofaniten (EPI-7386) ^d in Patients With Castration-Resistant Prostate Cancer (EPI-7386) ^e completed enrollment in the Part A Monotherapy component of the study and, until October 31, 2024, was actively enrolling patients in the Part B Combination component of the study in two separate cohorts: Cohort 1 in combination with abiraterone acetate and prednisone in patients with either mHSPC or mCRPC for whom abiraterone acetate with prednisone is standard of care, and Cohort 2, in nmCRPC patients ^f to second generation antiandrogens 25 Table of Contents in combination with apalutamide. The primary objectives of these two combination cohorts was to assess the safety and possible drug-drug interactions between masofaniten (EPI-7386) and abiraterone or apalutamide to inform the recommended doses of masofaniten (EPI-7386) ^g when used in combination with these standard of care drugs. This study was conducted in the U.S. and Canada ([www.clinicaltrials.gov](https://clinicaltrials.gov) under identifier NCT04421222). Part A Monotherapy - Phase 1a ^a Dose Escalation ^b The open-label, dose-escalation Phase 1a clinical trial was designed to determine the safety, tolerability, pharmacokinetics, maximum tolerated dose and/or a recommended Phase 2 range of doses in line with the FDA's Project Optimus, and to assess preliminary anti-tumor activity of the drug. The design of the Phase 1 clinical trial included the standard 3+3 design per dose cohort for the Part 1a dose escalation phase, with subjects receiving a daily oral dose of masofaniten (EPI-7386) once a day QD until there is objective evidence of clinical disease progression, and/or occurrence of an unacceptable toxicity. The dose escalation Part 1a of the study completed enrollment. Patients enrolled in the Part 1a of the study were selected clinically, on the basis of having progressive mCRPC as exemplified by rising PSA values and/or radiological disease progression despite latest generation antiandrogen treatment. However, all patients were also retrospectively biologically characterized for underlying tumor genomic characteristics, for evidence of AR pathway activation as well as non-AR oncogenic pathways and during the conduct of the trial, for dose-related biological, pharmacological and pharmacodynamic effects. The protocol amendments filed with the FDA in September 2021 and July 2022 allow for monotherapy development in less heavily pretreated patients (as described above) in whom the androgen receptor pathway is more likely to be the primary driver of tumor growth. The Company's goal was to establish, one or more doses/schedules to be tested in the expansion Phase 1b study in alignment with the FDA Project Optimus guidance, based on multiple inputs, including pharmacokinetic and biological observations, in addition to clinical experience. Two dose levels were advanced to Phase 1b dose expansion testing: 600 mg QD and 600 mg BID. Part A Monotherapy - Phase 1b ^c Dose Expansion The primary objective of Phase 1b was to further evaluate the safety, tolerability, pharmacokinetics, and preliminary anti-tumor activity (as measured by changes in tumor burden measured by imaging and changes in PSA levels over time) of masofaniten (EPI-7386) at 600 mg BID and 600 mg QD in a patient population enrolled under eligibility criteria similar to the one adopted for the Phase 1a with a focus on chemo-naïve mCRPC patients whose diseases have progressed after two lines of treatment including at least one line of second-generation antiandrogens. The 600 mg BID cohort and the 600 mg QD cohorts were fully enrolled at the time of the study termination. Combination studies Demonstration of the favorable safety and tolerability profile of masofaniten (EPI-7386) in the Phase 1a, together with clinical evidence for its mechanism of action and efficacy, were necessary to enable the study of patient populations with less advanced and less heavily pre-treated prostate cancer. The experience in the initial Phase 1a trial provided evidence for both an antiandrogen biological effect as well as some clinically relevant anti-tumor activity. The biological characterization of these patients also demonstrated favorable safety profiles. The Company's preclinical data and other evidence suggest earlier patient populations are more homogeneously AR-driven, and the favorable safety profile demonstrated in the Phase 1a dose escalation trial justified the study of the combination

of masofaniten (EPI-7386) with classic antiandrogens. As a result, the Company, together with its collaborators, conducted, and prior to October 2024, planned to continue to conduct, a series of clinical trials in this regard. As mentioned above the Phase 1 clinical trial of masofaniten α -Oral EPI-7386 in Patients With Castration-Resistant Prostate Cancer (EPI-7386) was amended to include a Part B evaluating the combination of masofaniten (EPI-7386) with abiraterone acetate or apalutamide in earlier patient populations to assess safety and potential drug interactions of these combinations. In addition, a separate Phase 1/2 study was being conducted to evaluate the safety and efficacy of 26Table of Contentsmasofaniten (EPI-7386) in combination with enzalutamide in patients with mCRPC na \vee to second generation antiandrogens. A activated AR is required for the growth and survival of most prostate cancer. Unlike current antiandrogen therapies which can only inhibit full-length AR, NTD inhibition of AR-directed biology occurs both in full length AR and splice variant ARs. The Company believed that the AR-NTD was an ideal target for next-generation antiandrogen hormone therapy. Clinical Trial - EPI-7386-CS-010 α - Combination Treatment with Enzalutamide α . The Company was also running a Phase 1/2 study of masofaniten (EPI-7386) in combination with enzalutamide compared with enzalutamide alone in patients with mCRPC. Phase 1 of the study was a single-arm dose escalation study of masofaniten (EPI-7386) in combination with a fixed dose of enzalutamide. α A collaboration and supply agreement with Astellas Pharma Inc. (α -Astellas α) to evaluate masofaniten (EPI-7386) in combination with Astellas and Pfizer Inc. α (the α -Pfizer α) AR inhibitor, enzalutamide, in patients with mCRPC was announced on February 24, 2021. ESSA was paying for and was operationally conducting this trial, with an initial Phase 1 dose equilibration followed by a randomized Phase 2 trial planned to involve 120 patients. The enzalutamide for this trial was supplied by Astellas. The first patient in this Phase 1/2 study was dosed in January 2022 and the safety, tolerability, pharmacokinetics, and initial PSA responses were originally reported in the June 2022 clinical update in poster presentations at the Prostate Cancer Foundation Retreat in October 2022 and the American Society of Clinical Oncology Genitourinary Cancers Symposium in February 2023. In the Phase 1 dose equilibration, masofaniten (EPI-7386) was evaluated at escalating dose levels including 600 mg QD, 800 mg QD and 600 mg BID in combination with 120 mg and 160 mg enzalutamide in patients with mCRPC na \vee to second generation antiandrogens. The Phase 1 part of the study had completed enrollment at the time of the study termination. The recommended Phase 2 combination doses for the Phase 2 randomized phase was 600 mg BID masofaniten (EPI-7386) with 160 mg enzalutamide (the highest dose levels tested). The Phase 2 study, planned to involve 120 patients and had two arms consisting of the following: a planned 80 patients with doses of 600 mg BID masofaniten and 160 mg QD ENZ, and 40 patients with a dose of 160 mg ENZ. The Phase 2 study was enrolling patients in the U.S., Canada certain countries in Europe, and Australia at the time of the study termination. α Clinical Trial - EPI-7386-CS-001 α - Combination Treatments with Abiraterone and with Apalutamide α . The first collaboration, with Janssen Research & Development, LLC (α -Janssen α). A to study in clinical trials the safety and potential benefit of the combination of masofaniten (EPI-7386) with abiraterone acetate with prednisone as well as the combination of masofaniten (EPI-7386) with apalutamide in patients with mCRPC, was announced on January 13, 2021. Under the collaboration agreement with Janssen, Janssen would pay for and conduct a clinical trial with masofaniten (EPI-7386) and in separate cohorts each of their antiandrogens, apalutamide and abiraterone acetate. This combination trial was initiated in March 2022. Enrollment was suspended by Janssen in October 2022 due to operational recruitment challenges. On April 12, 2023, ESSA announced that it had entered into a clinical trial support agreement with Janssen, with ESSA paying for and conducting a study of the combinations, in an earlier patient population, and with Janssen supplying apalutamide and abiraterone acetate. α The Company α 's earlier protocol amendment in June 2023, modified the protocol design of this study by adding combination treatment with second-generation antiandrogens. Specifically, the amended protocol consisted of two parts: a Part A Monotherapy study and a Part B Combination study. Part A had two phases: a Phase 1a Dose Escalation and a Phase 1b Dose Expansion, as discussed above, with Part B conducted in two cohorts, Cohort 1 evaluating masofaniten (EPI-7386) in combination with abiraterone acetate/prednisone for patients with mHSPC or mCRPC who receive abiraterone acetate/prednisone as part of their standard of care treatment and Cohort 2, previously the α -window of opportunity cohort α , evaluating single agent masofaniten (EPI-7386) for 12 weeks in patients with nmCRPC before apalutamide was added. α 27Table of ContentsPart B Combination - Cohort 1 α - Combination with Abiraterone acetate/prednisoneThe Company planned, before October 2024, to evaluate the combination of masofaniten (EPI-7386) with abiraterone acetate/prednisone (AAP) in patients with mHSPC or mCRPC. AAP was to be provided by Janssen under a clinical trial support agreement as described above. α Part B Combination - Cohort 2 α - Window of opportunity with clinical endpoints followed by combination with Apalutamide The primary objective of Cohort 2 was to assess the anti-tumor activity (as measured by changes of PSA over time) of masofaniten (EPI-7386) administered at 600 mg BID for a limited window of time (up to 12 weeks before patients start standard of care therapy) in nmCRPC patients whose disease is unperturbed by previous second-generation antiandrogen therapies or chemotherapy. Following the dosage of masofaniten (EPI-7386) as a single agent after the 12-week window, the Company planned to evaluate the combination of masofaniten (EPI-7386) with apalutamide. Apalutamide was to be provided by Janssen under the same clinical trial support agreement. In addition to the agreements announced with Pfizer, and Janssen, a third collaboration was announced with Bayer. Bayer was to pay for and conduct a Phase 1/2 clinical trial with masofaniten (EPI-7386) to evaluate masofaniten (EPI-7386) in combination with darolutamide in earlier line mCRPC patients. ESSA planned to provide masofaniten (EPI-7386) for the combination trial. This clinical trial has not yet been initiated and the Company no longer plans to pursue initiation of the trial. Preclinical Development of Anitens and other indicationsThe Company has decided to terminate its preclinical development programs and related work during the pendency of its strategic options review discussed further herein. Prior to October 2024, the Company was conducting research on other emerging potential clinical applications for NTD inhibitors. As part of that preclinical work on Anit compounds, the Company also studied NTD degraders and presented data for its first generation of AR ANITAC NTD degraders at the AACR annual meeting on April 10, 2022 in a poster titled α -Androgen receptor (AR) N-Terminal Domain degraders can degrade AR full length and AR splice variants in CRPC preclinical models. α Recent DevelopmentsTermination of Clinical Studies and Evaluation of Strategic OptionsOn October 31, 2024, ESSA announced that it decided to terminate its Phase 2 clinical trial evaluating in a 2:1 randomization masofaniten (EPI-7386) combined with enzalutamide versus enzalutamide single agent in patients with mCRPC na \vee to second-generation antiandrogens. This decision, mutually agreed upon by both senior management and the Board, was based on a protocol-specified interim review of the safety, PK and efficacy data, which showed a much higher rate of PSA90 response in patients treated with enzalutamide monotherapy (which is standard of care for this patient population) than were expected based upon historical data. In addition, there was no clear efficacy benefit seen with the combination of masofaniten (EPI-7386) plus enzalutamide compared to enzalutamide single agent. A futility analysis determined a low likelihood of meeting the prespecified primary endpoint of the study. As part of its efforts to focus its resources, ESSA also announced the remaining company-sponsored and investigator-sponsored clinical studies evaluating masofaniten (EPI-7386) either as a monotherapy or in combination with other agents, including each of the clinical studies described herein will be terminated. ESSA also decided to withdraw its IND and CTAs that have been submitted to date. In connection with these events, ESSA has initiated a comprehensive review process to review its strategic options to maximize shareholder value. ESSA expects to devote significant time and resources to its review of strategic options. There can be no assurances that the strategic review process will deliver the anticipated benefits thereof or enhance shareholder value. Strategic options may include, but are not limited to, a merger, amalgamation, arrangement, reverse take-over, business combination, asset sale or acquisition, shareholder distribution, wind-down, liquidation and dissolution or other strategic transaction or the operation of its business and election to seek new product candidates for development. 28Table of ContentsThere can be no assurance that ESSA will be able to successfully consummate any particular strategic transaction, or any transaction at all. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we may incur significant costs related to this continued evaluation. ESSA may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in ESSA α 's business and may diminish or delay any future distributions to our shareholders. 2024 On September 13-17, 2024, the Company updated dose escalation data from its Phase 1/2 study evaluating masofaniten (formerly EPI-7386) in combination with enzalutamide at the 2024 European Society for Medical Oncology (ESMO). The updated dose escalation data included that in patients evaluable for safety (n=18), masofaniten combined with enzalutamide, was well-tolerated at the dose levels tested through 32 cycles of dosing in some patients. Most frequent adverse events were Grades 1 and 2, related to either AR inhibition or gastrointestinal tract irritation. In Cohort 4, one patient experienced a Grade 3 rash, which was observed immediately following administration of masofaniten combined with enzalutamide and deemed probably related, resulting in the expansion of the cohort from four to seven patients. No additional dose-limiting toxicities (DLTs) were observed, therefore the maximum tolerated dose (MTD) was not reached. The recommended Phase 2 combination doses (RP2CDs) were identified as masofaniten 600 mg twice daily (BID) in combination with enzalutamide 160 mg once daily (QD). At such time, in the patients evaluable for efficacy (n=16), rapid, deep and durable reductions in PSA were observed, regardless of previous chemotherapy status, including in patients who received lower than the full dose of enzalutamide (120 mg). Across all dose cohorts, 88% of patients (14 of 16) achieved PSA50, 88% of patients (14 of 16) achieved PSA90, 69% of patients (11 of 16) achieved PSA90 in less than 90 days, and 63% of patients (10 of 16) achieved PSA <0.2ng/mL. With a median follow up of 15.2 months, the median time to PSA progression and radiographic progression free survival had not yet been reached. The randomized, open-label, two arm, Phase 2 dose expansion portion of the study was underway and designed to evaluate the combination of masofaniten and enzalutamide versus single agent enzalutamide in patients with mCRPC na \vee to 29Table of Contentssecond generation anti-androgens. The study planned to enroll patients in the U.S., Canada, certain countries in Europe, and Australia. 2023 On October 26-28, 2023, the Company presented an update to the poster previously presented at the European Society of Medical Oncology (ESMO) 2023 Congress for its Phase 1/2 study evaluating masofaniten (EPI-7386) in combination with enzalutamide at the 30th Annual Prostate Cancer Foundation Scientific Retreat. The data presented were from the four cohorts of patients in the Phase 1 dose escalation portion of the study. The data indicated that masofaniten (EPI-7386) had no effect on enzalutamide exposure, thus allowing the use of full dose per label (160mg) of enzalutamide in combination. It also indicated that enzalutamide reduces masofaniten (EPI-7386) exposure but twice daily dosing of masofaniten (EPI-7386) appears to mitigate the reduction and maintains clinically relevant drug exposures. In patients evaluable for safety (n=18), masofaniten (EPI-7386) combined with enzalutamide, was well-tolerated at the doses tested through 21 cycles of dosing in some patients. The most frequent adverse events were Grade 1 and 2, related to either AR inhibition or gastrointestinal tract irritation. In Cohort 4, one patient experienced a Grade 3 rash, which was observed immediately following administration of masofaniten (EPI-7386) combined with enzalutamide and deemed probably related, resulting in the expansion of the cohort from four to seven patients. No additional dose-limiting toxicities were observed, therefore the maximum tolerated dose was not reached. The recommended Phase 2 combination doses were identified as masofaniten 600 mg BID in combination with enzalutamide 160 QD. In the patients evaluable for efficacy (n=16), rapid, deep and durable reductions in PSA were observed, regardless of previous chemotherapy status, including in patients who received lower than the full dose of enzalutamide (120 mg). Across all dose cohorts, 88% of patients (14 of 16) achieved PSA50, 81% of patients (13 of 16) achieved PSA90, 69% of patients (11 of 16) achieved PSA90 in less than 90 days, and 63% of patients (10 of 16) achieved PSA <0.2ng/mL. While the data for disease progression were still maturing with a median follow up of 11.1 months, the median time to PSA progression was at 16.6 months. The randomized, open-label, two arm, Phase 2 dose expansion portion of the study was underway and designed to evaluate the combination of masofaniten and enzalutamide versus single agent enzalutamide in patients with mCRPC na \vee to 29Table of Contentssecond generation anti-androgens. The study planned to enroll patients in the U.S., Canada, certain countries in Europe, and Australia. 2023 On October 20-24, 2023, the Company presented updated dose escalation data from its Phase 1/2 study evaluating masofaniten (EPI-7386) in combination with enzalutamide at the European Society of Medical Oncology (ESMO) 2023 Congress. The data presented included that in patients evaluable for safety (n=18), masofaniten combined with enzalutamide, was well-tolerated at the doses tested through 21 cycles of dosing in some patients. The most frequent adverse events were Grade 1 and 2, related to either AR inhibition or gastrointestinal tract irritation. In Cohort 4, one patient experienced a Grade 3 rash, which was observed immediately following administration of masofaniten (EPI-7386) combined with enzalutamide and deemed probably related. In the patients evaluable for efficacy (n=16), rapid, deep and durable reductions in PSA were observed, regardless of previous chemotherapy status, including in patients who received lower than the full dose of enzalutamide (120 mg). In the first three cohorts, 90% of patients (9 of 10) achieved PSA50 and PSA90, 80% of patients (8 of 10) achieved PSA90 in less than 90 days, and 70% of patients (7 of 10) achieved PSA <0.2ng/mL. Across all dose cohorts including patients in the recently enrolled Cohort 4, 88% of patients (14 of 16) achieved PSA50, 81% of patients (13 of 16) achieved PSA90, 69% of patients (11 of 16) achieved PSA90 in less than 90 days, and 56% of patients (9 of 16) achieved PSA <0.2ng/mL. The randomized Phase 2 dose expansion portion of the study has been discontinued. On October 3, 2023, the Company filed a prospectus supplement to its registration statement on Form S-3, including a base prospectus, with the SEC. Further to this, on November 6, 2023, the Company announced that it had entered into the ATM Sales Agreement with Jefferies LLC, effective as of November 3, 2023. Under the ATM Sales Agreement, ESSA may, within the period that the ATM Sales Agreement is in effect, sell its Common Shares from time to time for up to US\$50.0 million in aggregate sales proceeds. No offers or sales of Common Shares will be made in Canada, to anyone known by Jefferies LLC to be a resident of Canada or on or through the facilities of any stock exchange or trading markets in Canada. 30Table of ContentsOn September 18, 2023, the Company announced the initiation of the Phase 2 portion of its Phase 1/2 study evaluating its lead candidate, masofaniten (EPI-7386), in combination with Astellas and Pfizer's enzalutamide in patients with mCRPC na \vee to second-generation antiandrogens. On August 31, 2023, the Company announced the establishment of Automatic Securities Disposition Plans for its President and Chief Executive Officer, David R. Parkinson and its Executive Vice President and Chief Operating Officer, Peter Virsik. On June 6, 2023, the Company appointed Lauren Merendino to the Board. On April 12, 2023, the Company announced it had entered into a clinical trial support agreement with Janssen. ESSA was sponsoring and conducting a Phase 1 clinical trial evaluating the safety, pharmacokinetics, drug-drug interactions, and preliminary anti-tumor activity of masofaniten (EPI-7386) when administered in combination with either apalutamide or abiraterone acetate plus prednisone. Janssen was supplying apalutamide and abiraterone acetate. On February 16-19, 2023, the Company presented analyses of initial clinical data from two Phase 1 studies of masofaniten (EPI-7386) in patients with mCRPC at the American Society of Clinical Oncology Genitourinary Cancers Symposium. The Company presented an update to the Phase 1 monotherapy study demonstrating that masofaniten (EPI-7386) single agent showed a favorable safety profile and was well-tolerated up to a daily dose of 1200 mg (600 mg BID), achieved target clinical exposures and showed preliminary signals of anti-tumor activity in heavily pretreated mCRPC patients. The second poster presented preliminary results to the Phase 1/2 trial of masofaniten (EPI-7386) in combination with Astellas and Pfizer α 's AR inhibitor, enzalutamide. Ten patients had been enrolled in the first three cohorts: three in cohort 1 (600 mg QD masofaniten (EPI-7386) and 120 mg QD enzalutamide), four in cohort 2 (800 mg QD masofaniten (EPI-7386) and 120 mg QD enzalutamide) and three in cohort 3 (600 mg BID masofaniten (EPI-7386) and 120 mg QD enzalutamide). At that time, the DLT period had not cleared for cohort 3. For the first 2 cohorts that cleared the DLT period, no DLTs were observed, and the safety profile was consistent with second-generation antiandrogens (e.g., Grade 1 or 2 AEs of fatigue and hot flushes). Pharmacokinetic results from cohorts 1 and 2 had demonstrated that enzalutamide exposure was minimally impacted by masofaniten (EPI-7386), while, as expected, masofaniten (EPI-7386) exposure was reduced by approximately 60% by enzalutamide (a well established CYP3A4 inducer). The observed masofaniten (EPI-7386) exposures remained in the clinically relevant range suggested by pre-clinical xenograft studies. Five out of six evaluable patients enrolled in the first two cohorts showed a PSA decrease >90% regardless of the patients previous chemotherapy status, and four out of six evaluable patients PSA levels reached < 0.2 ng/mL. All five patients that experienced biochemical responses showed stable disease by imaging. Future Clinical Development ProgramPrior to the October 2024 discontinuation of ESSA α 's clinical studies, the Company planned to conduct further clinical development which would have required randomized clinical trials in earlier patient populations (potentially ranging from newly diagnosed through non-metastatic and metastatic hormone-sensitive or pre-latest generation

antiandrogen CRPC populations).⁴⁶ As part of its efforts to focus its resources, ESSA also announced that the other remaining company-sponsored and investigator-sponsored clinical studies evaluating masofaniten (EPI-7386) either as a monotherapy or in combination with other agents will be terminated. ESSA also decided to withdraw its IND and CTAs that have been submitted to date. In connection with these events, ESSA has initiated a comprehensive review process to review its strategic options to maximize shareholder value.⁴⁷ 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 31Table of Contentsalready 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:⁴⁸ ⁴⁹ ⁵⁰ ⁵¹ ⁵² ⁵³ ⁵⁴ ⁵⁵ ⁵⁶ ⁵⁷ ⁵⁸ ⁵⁹ ⁶⁰ ⁶¹ ⁶² ⁶³ ⁶⁴ ⁶⁵ ⁶⁶ ⁶⁷ ⁶⁸ ⁶⁹ ⁷⁰ ⁷¹ ⁷² ⁷³ ⁷⁴ ⁷⁵ ⁷⁶ ⁷⁷ ⁷⁸ ⁷⁹ ⁸⁰ ⁸¹ ⁸² ⁸³ ⁸⁴ ⁸⁵ ⁸⁶ ⁸⁷ ⁸⁸ ⁸⁹ ⁹⁰ ⁹¹ ⁹² ⁹³ ⁹⁴ ⁹⁵ ⁹⁶ ⁹⁷ ⁹⁸ ⁹⁹ ¹⁰⁰ ¹⁰¹ ¹⁰² ¹⁰³ ¹⁰⁴ ¹⁰⁵ ¹⁰⁶ ¹⁰⁷ ¹⁰⁸ ¹⁰⁹ ¹¹⁰ ¹¹¹ ¹¹² ¹¹³ ¹¹⁴ ¹¹⁵ ¹¹⁶ ¹¹⁷ ¹¹⁸ ¹¹⁹ ¹²⁰ ¹²¹ ¹²² ¹²³ ¹²⁴ ¹²⁵ ¹²⁶ ¹²⁷ ¹²⁸ ¹²⁹ ¹³⁰ ¹³¹ ¹³² ¹³³ ¹³⁴ ¹³⁵ ¹³⁶ ¹³⁷ ¹³⁸ ¹³⁹ ¹⁴⁰ ¹⁴¹ ¹⁴² ¹⁴³ ¹⁴⁴ ¹⁴⁵ ¹⁴⁶ ¹⁴⁷ ¹⁴⁸ ¹⁴⁹ ¹⁵⁰ ¹⁵¹ ¹⁵² ¹⁵³ ¹⁵⁴ ¹⁵⁵ ¹⁵⁶ ¹⁵⁷ ¹⁵⁸ ¹⁵⁹ ¹⁶⁰ ¹⁶¹ ¹⁶² ¹⁶³ ¹⁶⁴ ¹⁶⁵ ¹⁶⁶ ¹⁶⁷ ¹⁶⁸ ¹⁶⁹ ¹⁷⁰ ¹⁷¹ ¹⁷² ¹⁷³ ¹⁷⁴ ¹⁷⁵ ¹⁷⁶ ¹⁷⁷ ¹⁷⁸ ¹⁷⁹ ¹⁸⁰ ¹⁸¹ ¹⁸² ¹⁸³ ¹⁸⁴ ¹⁸⁵ ¹⁸⁶ ¹⁸⁷ ¹⁸⁸ ¹⁸⁹ ¹⁹⁰ ¹⁹¹ ¹⁹² ¹⁹³ ¹⁹⁴ ¹⁹⁵ ¹⁹⁶ ¹⁹⁷ ¹⁹⁸ ¹⁹⁹ ²⁰⁰ ²⁰¹ ²⁰² ²⁰³ ²⁰⁴ ²⁰⁵ ²⁰⁶ ²⁰⁷ ²⁰⁸ ²⁰⁹ ²¹⁰ ²¹¹ ²¹² ²¹³ ²¹⁴ ²¹⁵ ²¹⁶ ²¹⁷ ²¹⁸ ²¹⁹ ²²⁰ ²²¹ ²²² ²²³ ²²⁴ ²²⁵ ²²⁶ ²²⁷ ²²⁸ ²²⁹ ²³⁰ ²³¹ ²³² ²³³ ²³⁴ ²³⁵ ²³⁶ ²³⁷ ²³⁸ ²³⁹ ²⁴⁰ ²⁴¹ ²⁴² ²⁴³ ²⁴⁴ ²⁴⁵ ²⁴⁶ ²⁴⁷ ²⁴⁸ ²⁴⁹ ²⁵⁰ ²⁵¹ ²⁵² ²⁵³ ²⁵⁴ ²⁵⁵ ²⁵⁶ ²⁵⁷ ²⁵⁸ ²⁵⁹ ²⁶⁰ ²⁶¹ ²⁶² ²⁶³ ²⁶⁴ ²⁶⁵ ²⁶⁶ ²⁶⁷ ²⁶⁸ ²⁶⁹ ²⁷⁰ ²⁷¹ ²⁷² ²⁷³ ²⁷⁴ ²⁷⁵ ²⁷⁶ ²⁷⁷ ²⁷⁸ ²⁷⁹ ²⁸⁰ ²⁸¹ ²⁸² ²⁸³ ²⁸⁴ ²⁸⁵ ²⁸⁶ ²⁸⁷ ²⁸⁸ ²⁸⁹ ²⁹⁰ ²⁹¹ ²⁹² ²⁹³ ²⁹⁴ ²⁹⁵ ²⁹⁶ ²⁹⁷ ²⁹⁸ ²⁹⁹ ³⁰⁰ ³⁰¹ ³⁰² ³⁰³ ³⁰⁴ ³⁰⁵ ³⁰⁶ ³⁰⁷ ³⁰⁸ ³⁰⁹ ³¹⁰ ³¹¹ ³¹² ³¹³ ³¹⁴ ³¹⁵ ³¹⁶ ³¹⁷ ³¹⁸ ³¹⁹ ³²⁰ ³²¹ ³²² ³²³ ³²⁴ ³²⁵ ³²⁶ ³²⁷ ³²⁸ ³²⁹ ³³⁰ ³³¹ ³³² ³³³ ³³⁴ ³³⁵ ³³⁶ ³³⁷ ³³⁸ ³³⁹ ³⁴⁰ ³⁴¹ ³⁴² ³⁴³ ³⁴⁴ ³⁴⁵ ³⁴⁶ ³⁴⁷ ³⁴⁸ ³⁴⁹ ³⁵⁰ ³⁵¹ ³⁵² ³⁵³ ³⁵⁴ ³⁵⁵ ³⁵⁶ ³⁵⁷ ³⁵⁸ ³⁵⁹ ³⁶⁰ ³⁶¹ ³⁶² ³⁶³ ³⁶⁴ ³⁶⁵ ³⁶⁶ ³⁶⁷ ³⁶⁸ ³⁶⁹ ³⁷⁰ ³⁷¹ ³⁷² ³⁷³ ³⁷⁴ ³⁷⁵ ³⁷⁶ ³⁷⁷ ³⁷⁸ ³⁷⁹ ³⁸⁰ ³⁸¹ ³⁸² ³⁸³ ³⁸⁴ ³⁸⁵ ³⁸⁶ ³⁸⁷ ³⁸⁸ ³⁸⁹ ³⁹⁰ ³⁹¹ ³⁹² ³⁹³ ³⁹⁴ ³⁹⁵ ³⁹⁶ ³⁹⁷ ³⁹⁸ ³⁹⁹ ⁴⁰⁰ ⁴⁰¹ ⁴⁰² ⁴⁰³ ⁴⁰⁴ ⁴⁰⁵ ⁴⁰⁶ ⁴⁰⁷ ⁴⁰⁸ ⁴⁰⁹ ⁴¹⁰ ⁴¹¹ ⁴¹² ⁴¹³ ⁴¹⁴ ⁴¹⁵ ⁴¹⁶ ⁴¹⁷ ⁴¹⁸ ⁴¹⁹ ⁴²⁰ ⁴²¹ ⁴²² ⁴²³ ⁴²⁴ ⁴²⁵ ⁴²⁶ ⁴²⁷ ⁴²⁸ ⁴²⁹ ⁴³⁰ ⁴³¹ ⁴³² ⁴³³ ⁴³⁴ ⁴³⁵ ⁴³⁶ ⁴³⁷ ⁴³⁸ ⁴³⁹ ⁴⁴⁰ ⁴⁴¹ ⁴⁴² ⁴⁴³ ⁴⁴⁴ ⁴⁴⁵ ⁴⁴⁶ ⁴⁴⁷ ⁴⁴⁸ ⁴⁴⁹ ⁴⁵⁰ ⁴⁵¹ ⁴⁵² ⁴⁵³ ⁴⁵⁴ ⁴⁵⁵ ⁴⁵⁶ ⁴⁵⁷ ⁴⁵⁸ ⁴⁵⁹ ⁴⁶⁰ ⁴⁶¹ ⁴⁶² ⁴⁶³ ⁴⁶⁴ ⁴⁶⁵ ⁴⁶⁶ ⁴⁶⁷ ⁴⁶⁸ ⁴⁶⁹ ⁴⁷⁰ ⁴⁷¹ ⁴⁷² ⁴⁷³ ⁴⁷⁴ ⁴⁷⁵ ⁴⁷⁶ ⁴⁷⁷ ⁴⁷⁸ ⁴⁷⁹ ⁴⁸⁰ ⁴⁸¹ ⁴⁸² ⁴⁸³ ⁴⁸⁴ ⁴⁸⁵ ⁴⁸⁶ ⁴⁸⁷ ⁴⁸⁸ ⁴⁸⁹ ⁴⁹⁰ ⁴⁹¹ ⁴⁹² ⁴⁹³ ⁴⁹⁴ ⁴⁹⁵ ⁴⁹⁶ ⁴⁹⁷ ⁴⁹⁸ ⁴⁹⁹ ⁵⁰⁰ ⁵⁰¹ ⁵⁰² ⁵⁰³ ⁵⁰⁴ ⁵⁰⁵ ⁵⁰⁶ ⁵⁰⁷ ⁵⁰⁸ ⁵⁰⁹ ⁵¹⁰ ⁵¹¹ ⁵¹² ⁵¹³ ⁵¹⁴ ⁵¹⁵ ⁵¹⁶ ⁵¹⁷ ⁵¹⁸ ⁵¹⁹ ⁵²⁰ ⁵²¹ ⁵²² ⁵²³ ⁵²⁴ ⁵²⁵ ⁵²⁶ ⁵²⁷ ⁵²⁸ ⁵²⁹ ⁵³⁰ ⁵³¹ ⁵³² ⁵³³ ⁵³⁴ ⁵³⁵ ⁵³⁶ ⁵³⁷ ⁵³⁸ ⁵³⁹ ⁵⁴⁰ ⁵⁴¹ ⁵⁴² ⁵⁴³ ⁵⁴⁴ ⁵⁴⁵ ⁵⁴⁶ ⁵⁴⁷ ⁵⁴⁸ ⁵⁴⁹ ⁵⁵⁰ ⁵⁵¹ ⁵⁵² ⁵⁵³ ⁵⁵⁴ ⁵⁵⁵ ⁵⁵⁶ ⁵⁵⁷ ⁵⁵⁸ ⁵⁵⁹ ⁵⁶⁰ ⁵⁶¹ ⁵⁶² ⁵⁶³ ⁵⁶⁴ ⁵⁶⁵ ⁵⁶⁶ ⁵⁶⁷ ⁵⁶⁸ ⁵⁶⁹ ⁵⁷⁰ ⁵⁷¹ ⁵⁷² ⁵⁷³ ⁵⁷⁴ ⁵⁷⁵ ⁵⁷⁶ ⁵⁷⁷ ⁵⁷⁸ ⁵⁷⁹ ⁵⁸⁰ ⁵⁸¹ ⁵⁸² ⁵⁸³ ⁵⁸⁴ ⁵⁸⁵ ⁵⁸⁶ ⁵⁸⁷ ⁵⁸⁸ ⁵⁸⁹ ⁵⁹⁰ ⁵⁹¹ ⁵⁹² ⁵⁹³ ⁵⁹⁴ ⁵⁹⁵ ⁵⁹⁶ ⁵⁹⁷ ⁵⁹⁸ ⁵⁹⁹ ⁶⁰⁰ ⁶⁰¹ ⁶⁰² ⁶⁰³ ⁶⁰⁴ ⁶⁰⁵ ⁶⁰⁶ ⁶⁰⁷ ⁶⁰⁸ ⁶⁰⁹ ⁶¹⁰ ⁶¹¹ ⁶¹² ⁶¹³ ⁶¹⁴ ⁶¹⁵ ⁶¹⁶ ⁶¹⁷ ⁶¹⁸ ⁶¹⁹ ⁶²⁰ ⁶²¹ ⁶²² ⁶²³ ⁶²⁴ ⁶²⁵ ⁶²⁶ ⁶²⁷ ⁶²⁸ ⁶²⁹ ⁶³⁰ ⁶³¹ ⁶³² ⁶³³ ⁶³⁴ ⁶³⁵ ⁶³⁶ ⁶³⁷ ⁶³⁸ ⁶³⁹ ⁶⁴⁰ ⁶⁴¹ ⁶⁴² ⁶⁴³ ⁶⁴⁴ ⁶⁴⁵ ⁶⁴⁶ ⁶⁴⁷ ⁶⁴⁸ ⁶⁴⁹ ⁶⁵⁰ ⁶⁵¹ ⁶⁵² ⁶⁵³ ⁶⁵⁴ ⁶⁵⁵ ⁶⁵⁶ ⁶⁵⁷ ⁶⁵⁸ ⁶⁵⁹ ⁶⁶⁰ ⁶⁶¹ ⁶⁶² ⁶⁶³ ⁶⁶⁴ ⁶⁶⁵ ⁶⁶⁶ ⁶⁶⁷ ⁶⁶⁸ ⁶⁶⁹ ⁶⁷⁰ ⁶⁷¹ ⁶⁷² ⁶⁷³ ⁶⁷⁴ ⁶⁷⁵ ⁶⁷⁶ ⁶⁷⁷ ⁶⁷⁸ ⁶⁷⁹ ⁶⁸⁰ ⁶⁸¹ ⁶⁸² ⁶⁸³ ⁶⁸⁴ ⁶⁸⁵ ⁶⁸⁶ ⁶⁸⁷ ⁶⁸⁸ ⁶⁸⁹ ⁶⁹⁰ ⁶⁹¹ ⁶⁹² ⁶⁹³ ⁶⁹⁴ ⁶⁹⁵ ⁶⁹⁶ ⁶⁹⁷ ⁶⁹⁸ ⁶⁹⁹ ⁷⁰⁰ ⁷⁰¹ ⁷⁰² ⁷⁰³ ⁷⁰⁴ ⁷⁰⁵ ⁷⁰⁶ ⁷⁰⁷ ⁷⁰⁸ ⁷⁰⁹ ⁷¹⁰ ⁷¹¹ ⁷¹² ⁷¹³ ⁷¹⁴ ⁷¹⁵ ⁷¹⁶ ⁷¹⁷ ⁷¹⁸ ⁷¹⁹ ⁷²⁰ ⁷²¹ ⁷²² ⁷²³ ⁷²⁴ ⁷²⁵ ⁷²⁶ ⁷²⁷ ⁷²⁸ ⁷²⁹ ⁷³⁰ ⁷³¹ ⁷³² ⁷³³ ⁷³⁴ ⁷³⁵ ⁷³⁶ ⁷³⁷ ⁷³⁸ ⁷³⁹ ⁷⁴⁰ ⁷⁴¹ ⁷⁴² ⁷⁴³ ⁷⁴⁴ ⁷⁴⁵ ⁷⁴⁶ ⁷⁴⁷ ⁷⁴⁸ ⁷⁴⁹ ⁷⁵⁰ ⁷⁵¹ ⁷⁵² ⁷⁵³ ⁷⁵⁴ ⁷⁵⁵ ⁷⁵⁶ ⁷⁵⁷ ⁷⁵⁸ ⁷⁵⁹ ⁷⁵⁰ ⁷⁵¹ ⁷⁵² ⁷⁵³ ⁷⁵⁴ ⁷⁵⁵ ⁷⁵⁶ ⁷⁵⁷ ⁷⁵⁸ ⁷⁵⁹ ⁷⁶⁰ ⁷⁶¹ ⁷⁶² ⁷⁶³ ⁷⁶⁴ ⁷⁶⁵ ⁷⁶⁶ ⁷⁶⁷ ⁷⁶⁸ ⁷⁶⁹ ⁷⁶⁰ ⁷⁶¹ ⁷⁶² ⁷⁶³ ⁷⁶⁴ ⁷⁶⁵ ⁷⁶⁶ ⁷⁶⁷ ⁷⁶⁸ ⁷⁶⁹ ⁷⁷⁰ ⁷⁷¹ ⁷⁷² ⁷⁷³ ⁷⁷⁴ ⁷⁷⁵ ⁷⁷⁶ ⁷⁷⁷ ⁷⁷⁸ ⁷⁷⁹ ⁷⁷⁰ ⁷⁷¹ ⁷⁷² ⁷⁷³ ⁷⁷⁴ ⁷⁷⁵ ⁷⁷⁶ ⁷⁷⁷ ⁷⁷⁸ ⁷⁷⁹ ⁷⁸⁰ ⁷⁸¹ ⁷⁸² ⁷⁸³ ⁷⁸⁴ ⁷⁸⁵ ⁷⁸⁶ ⁷⁸⁷ ⁷⁸⁸ ⁷⁸⁹ ⁷⁸⁰ ⁷⁸¹ ⁷⁸² ⁷⁸³ ⁷⁸⁴ ⁷⁸⁵ ⁷⁸⁶ ⁷⁸⁷ ⁷⁸⁸ ⁷⁸⁹ ⁷⁹⁰ ⁷⁹¹ ⁷⁹² ⁷⁹³ ⁷⁹⁴ ⁷⁹⁵ ⁷⁹⁶ ⁷⁹⁷ ⁷⁹⁸ ⁷⁹⁹ ⁷⁹⁰ ⁷⁹¹ ⁷⁹² ⁷⁹³ ⁷⁹⁴ ⁷⁹⁵ ⁷⁹⁶ ⁷⁹⁷ ⁷⁹⁸ ⁷⁹⁹ ⁸⁰⁰ ⁸⁰¹ ⁸⁰² ⁸⁰³ ⁸⁰⁴ ⁸⁰⁵ ⁸⁰⁶ ⁸⁰⁷ ⁸⁰⁸ ⁸⁰⁹ ⁸⁰⁰ ⁸⁰¹ ⁸⁰² ⁸⁰³ ⁸⁰⁴ ⁸⁰⁵ ⁸⁰⁶ ⁸⁰⁷ ⁸⁰⁸ ⁸⁰⁹ ⁸¹⁰ ⁸¹¹ ⁸¹² ⁸¹³ ⁸¹⁴ ⁸¹⁵ ⁸¹⁶ ⁸¹⁷ ⁸¹⁸ ⁸¹⁹ ⁸¹⁰ ⁸¹¹ ⁸¹² ⁸¹³ ⁸¹⁴ ⁸¹⁵ ⁸¹⁶ ⁸¹⁷ ⁸¹⁸ ⁸¹⁹ ⁸²⁰ ⁸²¹ ⁸²² ⁸²³ ⁸²⁴ ⁸²⁵ ⁸²⁶ ⁸²⁷ ⁸²⁸ ⁸²⁹ ⁸²⁰ ⁸²¹ ⁸²² ⁸²³ ⁸²⁴ ⁸²⁵ ⁸²⁶ ⁸²⁷ ⁸²⁸ ⁸²⁹ ⁸³⁰ ⁸³¹ ⁸³² ⁸³³ ⁸³⁴ ⁸³⁵ ⁸³⁶ ⁸³⁷ ⁸³⁸ ⁸³⁹ ⁸³⁰ ⁸³¹ ⁸³² ⁸³³ ⁸³⁴ ⁸³⁵ ⁸³⁶ ⁸³⁷ ⁸³⁸ ⁸³⁹ ⁸⁴⁰ ⁸⁴¹ ⁸⁴² ⁸⁴³ ⁸⁴⁴ ⁸⁴⁵ ⁸⁴⁶ ⁸⁴⁷ ⁸⁴⁸ ⁸⁴⁹ ⁸⁴⁰ ⁸⁴¹ ⁸⁴² ⁸⁴³ ⁸⁴⁴ ⁸⁴⁵ ⁸⁴⁶ ⁸⁴⁷ ⁸⁴⁸ ⁸⁴⁹ ⁸⁵⁰ ⁸⁵¹ ⁸⁵² ⁸⁵³ ⁸⁵⁴ ⁸⁵⁵ ⁸⁵⁶ ⁸⁵⁷ ⁸⁵⁸ ⁸⁵⁹ ⁸⁵⁰ ⁸⁵¹ ⁸⁵² ⁸⁵³ ⁸⁵⁴ ⁸⁵⁵ ⁸⁵⁶ ⁸⁵⁷ ⁸⁵⁸ ⁸⁵⁹ ⁸⁶⁰ ⁸⁶¹ ⁸⁶² ⁸⁶³ ⁸⁶⁴ ⁸⁶⁵ ⁸⁶⁶ ⁸⁶⁷ ⁸⁶⁸ ⁸⁶⁹ ⁸⁶⁰ ⁸⁶¹ ⁸⁶² ⁸⁶³ ⁸⁶⁴ ⁸⁶⁵ ⁸⁶⁶ ⁸⁶⁷ ⁸⁶⁸ ⁸⁶⁹ ⁸⁷⁰ ⁸⁷¹ ⁸⁷² ⁸⁷³ ⁸⁷⁴ ⁸⁷⁵ ⁸⁷⁶ ⁸⁷⁷ ⁸⁷⁸ ⁸⁷⁹ ⁸⁷⁰ ⁸⁷¹ ⁸⁷² ⁸⁷³ ⁸⁷⁴ ⁸⁷⁵ ⁸⁷⁶ ⁸⁷⁷ ⁸⁷⁸ ⁸⁷⁹ ⁸⁸⁰ ⁸⁸¹ ⁸⁸² ⁸⁸³ ⁸⁸⁴ ⁸⁸⁵ ⁸⁸⁶ ⁸⁸⁷ ⁸⁸⁸ ⁸⁸⁹ ⁸⁸⁰ ⁸⁸¹ ⁸⁸² ⁸⁸³ ⁸⁸⁴ ⁸⁸⁵ ⁸⁸⁶ ⁸⁸⁷ ⁸⁸⁸ ⁸⁸⁹ ⁸⁹⁰ ⁸⁹¹ ⁸⁹² ⁸⁹³ ⁸⁹⁴ ⁸⁹⁵ ⁸⁹⁶ ⁸⁹⁷ ⁸⁹⁸ ⁸⁹⁹ ⁸⁹⁰ ⁸⁹¹ ⁸⁹² ⁸⁹³ ⁸⁹⁴ ⁸⁹⁵ ⁸⁹⁶ ⁸⁹⁷ ⁸⁹⁸ ⁸⁹⁹ ⁹⁰⁰ ⁹⁰¹ ⁹⁰² ⁹⁰³ ⁹⁰⁴ ⁹⁰⁵ ⁹⁰⁶ ⁹⁰⁷ ⁹⁰⁸ ⁹⁰⁹ ⁹⁰⁰ ⁹⁰¹ ⁹⁰² ⁹⁰³ ⁹⁰⁴ ⁹⁰⁵ ⁹⁰⁶ ⁹⁰⁷ ⁹⁰⁸ ⁹⁰⁹ ⁹¹⁰ ⁹¹¹ ⁹¹² ⁹¹³ ⁹¹⁴ ⁹¹⁵ ⁹¹⁶ ⁹¹⁷ ⁹¹⁸ ⁹¹⁹ ⁹¹⁰ ⁹¹¹ ⁹¹² ⁹¹³ ⁹¹⁴ ⁹¹⁵ ⁹¹⁶ ⁹¹⁷ ⁹¹⁸ ⁹¹⁹ ⁹²⁰ ⁹²¹ ⁹²² ⁹²³ ⁹²⁴ ⁹²⁵ ⁹²⁶ ⁹²⁷ ⁹²⁸ ⁹²⁹ ⁹²⁰ ⁹²¹ ⁹²² ⁹²³ ⁹²⁴ ⁹²⁵ ⁹²⁶ ⁹²⁷ ⁹²⁸ ⁹²⁹ ⁹³⁰ ⁹³¹ ⁹³² ⁹³³ ⁹³⁴ ⁹³⁵ ⁹³⁶ ⁹³⁷ ⁹³⁸ ⁹³⁹ ⁹³⁰ ⁹³¹ ⁹³² ⁹³³ ⁹³⁴ ⁹³⁵ ⁹³⁶ ⁹³⁷ ⁹³⁸ ⁹³⁹ ⁹⁴⁰ ⁹⁴¹ ⁹⁴² ⁹⁴³ ⁹⁴⁴ ⁹⁴⁵ ⁹⁴⁶ ⁹⁴⁷ ⁹⁴⁸ ⁹⁴⁹ ⁹⁴⁰ ⁹⁴¹ ⁹⁴² ⁹⁴³ ⁹⁴⁴ ⁹⁴⁵ ⁹⁴⁶ ⁹⁴⁷ ⁹⁴⁸ ⁹⁴⁹ ⁹⁵⁰ ⁹⁵¹ ⁹⁵² ⁹⁵³ ⁹⁵⁴ ⁹⁵⁵ ⁹⁵⁶ ⁹⁵⁷ ⁹⁵⁸ ⁹⁵⁹ ⁹⁵⁰ ⁹⁵¹ ⁹⁵² ⁹⁵³ ⁹⁵⁴ ⁹⁵⁵ ⁹⁵⁶ ⁹⁵⁷ ⁹⁵⁸ ⁹⁵⁹ ⁹⁶⁰ ⁹⁶¹ ⁹⁶² ⁹⁶³ ⁹⁶⁴ ⁹⁶⁵ ⁹⁶⁶ ⁹⁶⁷ ⁹⁶⁸ ⁹⁶⁹ ⁹⁶⁰ ⁹⁶¹ ⁹⁶² ⁹⁶³ ⁹⁶⁴ ⁹⁶⁵ ⁹⁶⁶ ⁹⁶⁷ ⁹⁶⁸ ⁹⁶⁹ ⁹⁷⁰ ⁹⁷¹ ⁹⁷² ⁹⁷³ ⁹⁷⁴ ⁹⁷⁵ ⁹⁷⁶ ⁹⁷⁷ ⁹⁷⁸ ⁹⁷⁹ ⁹⁷⁰ ⁹⁷¹ ⁹⁷² ⁹⁷³ ⁹⁷⁴ ⁹⁷⁵ ⁹⁷⁶ ⁹⁷⁷ ⁹⁷⁸ ⁹⁷⁹ ⁹⁸⁰ ⁹⁸¹ ⁹⁸² ⁹⁸³ ⁹⁸⁴ ⁹⁸⁵ ⁹⁸⁶ ⁹⁸⁷ ⁹⁸⁸ ⁹⁸⁹ ⁹⁸⁰ ⁹⁸¹ ⁹⁸² ⁹⁸³ ⁹⁸⁴ ⁹⁸⁵ ⁹⁸⁶ ⁹⁸⁷ ⁹⁸⁸ ⁹⁸⁹ ⁹⁹⁰ ⁹⁹¹ ⁹⁹² ⁹⁹³ ⁹⁹⁴ ⁹⁹⁵ ⁹⁹⁶ ⁹⁹⁷ ⁹⁹⁸ ⁹⁹⁹ ⁹⁹⁰ ⁹⁹¹ ⁹⁹² ⁹⁹³ ⁹⁹⁴ ⁹⁹⁵ ⁹⁹⁶ ⁹⁹⁷ ⁹⁹⁸ ⁹⁹⁹ ⁹⁹⁰ ⁹⁹¹ ⁹⁹² ⁹⁹³ ⁹⁹⁴ ⁹⁹⁵ ⁹⁹⁶ ⁹⁹⁷ ⁹⁹⁸ ⁹⁹⁹ ⁹⁹⁰ ⁹⁹¹ ⁹⁹² ⁹

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 36Table of Contentsfacilities 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 nine 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 RequirementsDrugs 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: a—restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls; 37Table of Contents a—fines, warning letters or holds on post-approval clinical trials; a—refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals; a—product seizure or detention, or refusal to permit the import or export of products; or a—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 ExclusivityUnder 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. 38Table of Contents Selected Quarterly Financial InformationThe following table sets forth ESSA's unaudited consolidated financial data for each of the last eight quarters, prepared in accordance with U.S. GAAP. The Company has not earned any revenues or declared dividends as of December 31.

exercisable outstanding stock options, 2,036,342 common shares issuable pursuant to 2,036,342 outstanding options that were not exercisable at that date, and no outstanding restricted stock units. Safe Harbor See **Cautionary Note** Regarding Forward-Looking Statements in the introduction to this Quarterly Report. **Table of Contents** Item 3. Quantitative and Qualitative Disclosures About Market Risk We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the **Exchange Act**) and are not required to provide the information required under this item. Item 4. **Controls and Procedures** Evaluation of Disclosure Controls and Procedures As of end of the period covered by this Quarterly Report on Form 10-Q, 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. 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 of December 31, 2024. 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 December 31, 2024. **Changes in Internal Control Over Financial Reporting** There were no changes in our internal control over financial reporting during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. **Table of Contents** PART II. OTHER INFORMATION Item 1A. **Legal Proceedings** On January 24, 2025, a putative class action lawsuit was filed against the Company, its Chief Executive Officer and its Chief Financial Officer in federal district court for the Eastern District of Wisconsin. The complaint, which purports to be brought on behalf of a class of persons and/or entities who purchased or otherwise acquired Common Shares between December 12, 2023 to October 31, 2024, alleges violations by the defendants of Sections 10(b) and 20(a) of the Exchange Act by making material misstatements and/or omissions in the Company's public statements with respect to its then-ongoing clinical trials of masofaniten. The Company believes that it has valid defenses to the claims alleged in the complaint and intends to defend the lawsuit vigorously, but there is no guarantee that the Company will prevail. At the time of filing, the outcome of this matter and any possible related losses are not estimable or probable. From time to time, we may become involved in other legal proceedings or be subject to claims arising in the ordinary course of our business. Except as described herein and below, we are not a party to any such other 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 1A. **Risk Factors** There have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the year ended September 30, 2024. **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds** None. **Item 3. Defaults Upon Senior Securities** None. **Item 4. Mine Safety Disclosures** Not applicable. **Item 5. Other Information** Trading Plans of Directors or Officers During the three months ended December 31, 2024, no director or officer of the Company adopted or terminated a 10b-5 trading arrangement or a non-Rule 10b-5 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K. **Table of Contents** Item 6. **Exhibits** Exhibit A No. **Amended Articles of Incorporation of ESSA Pharma Inc.** (incorporated by reference to Exhibit 1 to the Company's Registration Statement on Form 20-F (File No. A 377-00939), originally filed with the SEC on February 24, 2015) **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) **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** **XBRL Instance Document** **101.SCH** **XBRL Taxonomy Extension Schema Document** **101.CAL** **XBRL Taxonomy Extension Calculation Linkbase Document** **101.LAB** **XBRL Taxonomy Extension Label Linkbase Document** **101.PRE** **XBRL Taxonomy Extension Presentation Linkbase Document** **101.DEF** **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, 2024** **formatted in Inline XBRL (included in Exhibit 101.* Filed herewith.** **46Table of Contents** **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: February 11, 2025 **ESSA** **PHARMA INC.** **Registrant** **By:** **S/ DAVID PARKINSON** **Name:** **David Parkinson** **Title:** **Chief Executive Officer** **By:** **S/ DAVID WOOD** **Name:** **David Wood** **Title:** **Chief Financial Officer** **At:** **47** **Exhibit 31.1 CERTIFICATION** **PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**, David Parkinson, certify that: 1. I have reviewed this Quarterly Report on Form 10-Q of ESSA Pharma Inc.; 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report; 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report; 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f) for the registrant and have: (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions): (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting. **At:** **February 11, 2025** **s/ David Parkinson** **Chief Executive Officer** **Exhibit 31.2 CERTIFICATION** **PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**, David Wood, certify that: 1. I have reviewed this Quarterly Report on Form 10-Q of ESSA Pharma Inc.; 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report; 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report; 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have: (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions): (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting. **At:** **February 11, 2025** **s/ David Wood** **Chief Financial Officer** **Exhibit 32.1** **CERTIFICATION OF CEO AND CFO** **PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002** **In connection with the quarterly report of ESSA Pharma Inc. (the "Registrant") filed under cover of Form 10-Q for the period ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), David Parkinson as Chief Executive Officer of the Registrant and David Wood as Chief Financial Officer of the Registrant, each hereby certifies, pursuant to 18 U.S.C. **§1350**, as adopted pursuant to **§906** of the Sarbanes-Oxley Act of 2002, to the best of his knowledge that: (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant. **s/ David Parkinson** **Name:** **David Parkinson** **Title:** **Chief Executive Officer** **Date:** **February 11, 2025** **s/ David Wood** **Name:** **David Wood** **Title:** **Chief Financial Officer** **A Date:** **February 11, 2025** **This certification accompanies the Report pursuant to **§906** of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Registrant for purposes of **§18** of the Securities Exchange Act of 1934, as amended.****