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

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 2022 as compared to fiscals 2021 and 2020 see Item 7 of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022, filed with the SEC on December 13, 2022.

Overview

ESSA is a clinical stage pharmaceutical company, focused on developing novel and proprietary therapies for the treatment of prostate cancer with an initial focus on patients whose disease is progressing despite treatment with current standard of care therapies, including second-generation antiandrogen drugs such as abiraterone, enzalutamide, apalutamide, and darolutamide. The Company believes its latest series of investigational compounds, including its product candidate masofaniten (EPI-7386), have the potential to significantly expand the interval of time in which patients with castration-resistant prostate cancer can benefit from anti-hormone-based therapies. Specifically, the compounds are designed to disrupt the androgen receptor signaling pathway, the primary pathway that drives prostate cancer growth and prevent AR activation through selective binding to the N-terminal domain of the AR. In this respect, the Company's compounds are designed to differ from classical non-steroid antiandrogens. These antiandrogens interfere either with androgen synthesis (i.e., abiraterone), or with the binding of androgens to the ligand-binding domain, located at the opposite end of the receptor from the NTD (i.e., lutamides). A functional NTD is essential for activation of the AR; blocking the NTD inhibits AR-driven transcription and therefore androgen-driven biology.

General Development of the Business

Significant Business Developments for the Year Ended September 30, 2023

On October 26-28, 2023, the Company presented updated dose escalation data from 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 first 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.

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 was reported to be enrolling.

On October 20-24, 2023, the Company presented the same 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.

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.

On 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 naïve 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 its Board.

On April 12, 2023, the Company announced it had entered into a clinical trial support agreement with Janssen. ESSA will sponsor and conduct 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 will supply 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’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 xenograph 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.

Financing and Capital

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.

ESSA has never been profitable and has incurred net losses since inception. ESSA's net losses were $26,567,596 and $35,161,917 for the years ended September 30, 2023 and 2022, 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, 2023 and 2022:

(US$) Income Statement Data	Year Ended September 30, 2023	Year Ended September 30, 2022
Revenue	—	—
Research and development, net of recoveries	21,322,530	24,415,246
Financing costs	6,942	13,746
General and administration, net of recoveries	10,811,574	12,544,760
Total operating expenses	(32,141,046)	(36,973,752)
Net loss for the year	(26,582,343)	(35,103,251)
Loss and comprehensive loss	(26,567,596)	(35,161,917)
Balance Sheet Data		
Cash	33,701,912	57,076,475
Prepaids and other current assets	115,094,966	111,982,866
Deposits	257,245	259,455
Right-of-use assets	68,008	186,499
Total assets	149,122,131	169,505,295
Accounts payable and accrued liabilities	3,414,743	2,176,565
Income tax payable	—	—
Lease liabilities	80,328	210,252
Shareholders' equity	145,627,060	167,118,478
Total liabilities and shareholders' equity	149,122,131	169,505,295

Results of Operations for the Fiscal Years Ended September 30, 2023 and 2022

There was no revenue in any of the fiscal years as reported. The Company incurred a comprehensive loss of $26,567,596 for the year ended September 30, 2023 compared to a comprehensive loss of $35,161,917 for the year ended September 30, 2022. Variations in ESSA's expenses and net loss for the periods resulted primarily from the following factors described below.

Research and Development Expenditures

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

	Year ended	
	September 30, 2023	September 30, 2022
Preclinical and data analysis	$ 6,081,575	$ 8,134,161
Clinical	5,780,660	4,872,268
Salaries and benefits	2,712,168	2,073,188
Share-based payments	2,627,505	4,322,844
Manufacturing	2,356,472	2,946,412
Legal patents and license fees	919,859	1,123,319
Consulting	430,260	511,590
Other	213,972	204,334
Travel and other	137,285	144,645
Royalties	62,774	82,485
Total	$ 21,322,530	$ 24,415,246

The overall R&D expense for the year ended September 30, 2023 was $21,322,530 compared to $24,415,246 for the year ended September 30, 2022 and includes non-cash expense related to share-based payments expense of $2,627,505 (2022 - $4,322,844). R&D expense in 2023 reflects the ongoing clinical trial of masofaniten (EPI-7386).

Preclinical costs of $6,081,575 (2022 - $8,134,161) were generated in relation to expenditures for pharmacokinetic data analysis on data from the clinical trial related to the Phase 1 study and work on preclinical pipeline and Anitac compounds.

Clinical costs of $5,780,660 (2022 - $4,872,268) were generated in relation to expenditures associated with the Company's clinical research organizations conducting the Phase 1 clinical trial of masofaniten (EPI-7386).

Salaries and benefits, related to preclinical and clinical staff, have increased to $2,712,168 (2022 - $2,073,188) as a result of an increased number of preclinical and clinical staff.

The share-based payments expense of $2,627,505 (2022 - $4,322,844), which is a non-cash expense, relates to the value assigned to stock options and employee share purchase rights granted to key management personnel 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.

Manufacturing costs of $2,356,472 (2022 - $2,946,412) for the year ended September 30, 2023 includes amount for cGMP manufacturing of masofaniten (EPI-7386) drug supply to support the ongoing clinical trial as well as costs incurred in formulation and chemistry work around the Company's pharmaceutical characteristics of masofaniten (EPI-7386).

Legal patents and license fees decreased to $919,859 (2022 - $1,123,319). 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 reflect that ongoing investment and the timing of associated maintenance costs. The Company anticipates that there will be continued investment into patent applications.

Consulting costs decreased to $430,260 (2022 - $511,590) for the year ended September 30, 2023 primarily resulting from contract project management services.

General and Administration Expenditures

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

	Year ended	
	September 30, 2023	**September 30, 2022**
Salaries and benefits	$ 4,303,570	$ 3,710,999
Share-based payments	2,379,965	3,565,241
Insurance	1,724,746	2,088,637
Professional fees	1,019,989	901,282
Investor relations	602,645	577,350
Office, insurance, IT and communications	529,301	554,255
Director fees	392,667	343,083
Regulatory fees and transfer agent	202,525	197,877
Travel and other	179,302	146,603
Rent	22,567	9,443
Consulting and subcontractor fees	8,700	185,292
Amortization/(Accretion)	(554,403)	264,698
Total	$ 10,811,574	$ 12,544,760

General and administration expenses decreased to $10,811,574 for the year ended September 30, 2023 from $12,544,760 in the year ended September 30, 2022 and included non-cash expense related to share-based payments of $2,379,965 (2022 - $3,565,241). This 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.

Salaries and benefits expense increased to $4,303,570 (2022 - $3,710,999) reflecting merit related salary adjustment and bonuses paid to employees and additional support staff costs.

Insurance expense of $1,724,746 (2022 - $2,088,637) decreased in the current year following lower insurance renewal premiums relative to the Company's activities, risk mitigation choices and insurance market pricing trends.

Professional fees of $1,019,989 (2022 - $901,282) were incurred for legal and accounting services in conjunction with ongoing corporate activities.

Consulting and subcontractor fees of $8,700 (2022 - $185,292) decreased following the termination of a support services contract in late fiscal 2022.

Amortization/(Accretion) recognized varies relative to the Company's investment holdings and market conditions for expected investment returns. Over the periods presented, the Company had a larger investment holding and had benefited from higher interest rates.

Liquidity and Capital Resources

ESSA is a clinical stage company and does not currently generate revenue.

As at September 30, 2023, the Company had working capital of $145,301,807 (2022 - $166,748,942). Operational activities during the year ended September 30, 2023 were financed mainly by proceeds from financings in July 2020 and February 2021. At September 30, 2023, the Company had available cash reserves and short-term investments of $148,076,401 (2022 - $167,237,504) to settle current liabilities of $3,495,071 (2022 - $2,310,399). At September 30, 2023, 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. The Company expects its current cash runway to fund its operations and ESSA-sponsored clinical programs through 2025, including under Clinical Trial – EPI-7386-CS-001, the Part B Combination – Cohort 1 – Combination with abiraterone acetate/prednisone and the Part B Combination – Cohort 2 – Window of opportunity with clinical endpoints followed by combination with apalutamide study, also under Clinical Trial – EPI-7386-CS-010, the Phase 2 combination study with enzalutamide, and an investigator-sponsored study of masofaniten (EPI-7386) and darolutamide.

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.

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 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 stage pharmaceutical 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.

Safe Harbor

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

Item 7A. Quantitative and Qualitative Disclosures 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.