



ESSA Pharma Provides Corporate Update and Reports Financial Results for Fiscal Fourth Quarter and Year Ended September 30, 2023

Phase 1 dose escalation complete for masofaniten (EPI-7386)/enzalutamide combination study in patients with mCRPC; compelling safety and efficacy data reported at Prostate Cancer Foundation 2023 Scientific Retreat and ESMO 2023

Head-to-head Phase 2 dose expansion underway evaluating masofaniten (EPI-7386)/enzalutamide combination versus enzalutamide monotherapy in patients with mCRPC

SOUTH SAN FRANCISCO, California and VANCOUVER, Canada, December 12, 2023 – ESSA Pharma Inc. ("ESSA", or the "Company") (NASDAQ: EPIX), a clinical-stage pharmaceutical company, focused on developing novel therapies for the treatment of prostate cancer, today provided a corporate update and reported financial results for the fourth quarter and fiscal year ended September 30, 2023.

"We are pleased with the progress made in 2023 with masofaniten (EPI-7386), our first-in-class N-terminal domain androgen receptor inhibitor for the treatment of prostate cancer, which culminated recently in the presentation of Phase 1 dose escalation data at two medical meetings where we showed that the combination of masofaniten with enzalutamide was well-tolerated and demonstrated deep and durable reductions in prostate-specific antigen ("PSA") in patients with metastatic castration-resistant prostate cancer ("mCRPC")," said David Parkinson, MD, President and CEO of ESSA. "Looking ahead, we will be focused on executing the Phase 2 combination study of masofaniten and enzalutamide in mCRPC patients as well as investigating masofaniten in combination with other standard of care antiandrogens to further elucidate its potential as a new treatment for prostate cancer patients at earlier stages of the disease. We are entering 2024 with a strong cash balance and a runway that is expected to fund our planned operations through 2025."

Fourth Quarter Fiscal 2023 and Recent Highlights

Masofaniten Combination Studies

- Reported updated Phase 1 dose escalation data from the four cohorts of its ongoing Phase 1/2 study evaluating masofaniten in combination with enzalutamide in patients with mCRPC naïve to second-generation antiandrogens but may have been treated with chemotherapy in the metastatic castration-sensitive setting. The results demonstrated that the combination continues to be well-tolerated with deep and durable reductions in PSA. Across all dose cohorts (n=16) including patients in the recently enrolled Cohort 4, 88% of patients achieved PSA50, 81% of patients achieved PSA90, 69% of patients achieved PSA90 in less than 90 days, and 56% of patients achieved PSA <0.2ng/mL. These data were presented at the [2023 Prostate Cancer Foundation Scientific Retreat](#) and at the [European Society for Medical Oncology 2023 Congress](#).



- Initiated the Phase 2 portion of its Phase 1/2 study evaluating the combination of masofaniten and enzalutamide compared to enzalutamide monotherapy in patients with mCRPC naïve to second-generation antiandrogens but may have been treated with chemotherapy in the metastatic castration-sensitive setting. The Phase 2 portion of the study is an open-label randomized study comparing 160 mg once-daily of single agent enzalutamide to the combination of masofaniten with enzalutamide, and is expected to enroll approximately 120 patients. The recommended Phase 2 combination dose was identified as masofaniten 600 mg twice-daily combined with enzalutamide 160 mg once daily. ESSA plans to provide guidance for timing of the public disclosure of initial data once the Phase 2 portion has been underway for several months.
- Initiated two additional masofaniten combination arms as part of the ongoing Phase 1 masofaniten study. One arm will evaluate masofaniten in combination with abiraterone acetate and prednisone in patients with either metastatic castration-sensitive prostate cancer ("mCSPC") or mCRPC while the second arm will evaluate masofaniten in combination with apalutamide in patients with non-metastatic CRPC after 12 weeks of masofaniten single agent.
- An investigator-sponsored neoadjuvant study was also initiated evaluating neoadjuvant use of the combination of masofaniten and darolutamide compared to darolutamide monotherapy in high-risk patients undergoing prostatectomy.

Masofaniten Monotherapy Study

- On track to complete the Phase 1b masofaniten monotherapy study evaluating masofaniten in patients with late-line mCRPC. The initial results from the study were reported at the [2023 American Society of Clinical Oncology Genitourinary Cancers Symposium](#) and demonstrated that masofaniten monotherapy was well-tolerated, achieved clinically significant exposures, and showed preliminary signals of anti-tumor activity in a subset of patients. ESSA plans to present the complete Phase 1a and 1b monotherapy results in 2024 at a medical conference.

Summary Financial Results **(Amounts expressed in U.S. dollars)**

- **Net Loss.** ESSA recorded a net loss of \$26.6 million for the year ended September 30, 2023 compared to a net loss of \$35.1 million for the year ended September 30, 2022. For the year ended September 30, 2023, this included non-cash share-based payments of \$5.0 million compared to \$7.9 million for the prior year, recognized for stock options granted and vesting. Net loss for the fourth quarter ended September 30, 2023 was \$5.5 million compared to a net loss of \$6.3 million for the fourth quarter ended September 30, 2022. The decrease in the fourth quarter was primarily attributed to a decrease in general and administration expenditures and an increase in interest and other income.
- **Research and Development ("R&D") expenditures.** R&D expenditures for the year ended September 30, 2023 were \$21.3 million compared to \$24.4 million for the year ended September 30, 2022, and include non-cash costs related to share-based payments (\$2.6 million for the year ended 2023 compared to \$4.3 million for the year ended 2022). The decrease in R&D expenditures for the year ended September 30, 2023 was primarily attributed to decreases in preclinical and data



analysis, share-based payments and manufacturing costs. R&D expenditures for the fourth quarter ended September 30, 2023 were \$5.2 million compared to \$4.4 million for the fourth quarter ended September 30, 2022. The primary drivers for the increase were due to increased clinical costs as the Company advances masofaniten through its clinical trials.

- **General and administration ("G&A") expenditures.** G&A expenditures for the year ended September 30, 2023 were \$10.8 million compared to \$12.5 million for the year ended September 30, 2022, and include non-cash costs related to share-based payments of \$2.4 million for the year ended 2023 compared to \$3.6 million for the year ended 2022. G&A expenditures for the fourth quarter ended September 30, 2023 were \$1.9 million compared to \$2.8 million for the fourth quarter ended September 30, 2022. The decrease for the fourth quarter was primarily due to decreased share-based payments and lower insurance renewal premiums.

Liquidity and Outstanding Share Capital

- At September 30, 2023, the Company had available cash reserves and short-term investments of \$148.1 million. The Company's cash position is expected to be sufficient to fund current and planned operations through 2025.
- On November 6, 2023, the Company announced that it had entered into an Open Market Sale AgreementSM (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 \$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.
- As of September 30, 2023, the Company had 44,100,838 common shares issued and outstanding.
- In addition, as of September 30, 2023, there were 2,927,477 common shares issuable upon the exercise of warrants and broker warrants. This includes 2,920,000 prefunded warrants at an exercise price of \$0.0001, and 7,477 warrants at a weighted average exercise price of \$42.80. There were 8,112,774 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$4.97 per common share.

About ESSA Pharma Inc.

ESSA is a clinical-stage pharmaceutical company focused on developing novel and proprietary therapies for the treatment of patients with prostate cancer. For more information, please visit www.essapharma.com, and follow us on [Twitter](#) and [LinkedIn](#).

Forward-Looking Statement Disclaimer

This release contains certain information which, as presented, constitutes "forward-looking information" within the meaning of the Private Securities Litigation Reform Act of 1995 and/or applicable Canadian



securities laws. Forward-looking information involves statements that relate to future events and often addresses expected future business and financial performance, containing words such as "anticipate", "believe", "plan", "estimate", "expect", and "intend", statements that an action or event "may", "might", "could", "should", or "will" be taken or occur, or other similar expressions and includes, but is not limited to, statements regarding the favorable pharmaceutical properties of masofaniten, the potential clinical benefits of masofaniten in combination with other antiandrogens, the Company's expected cash runway into 2025, tolerability and PSA reductions in patients with mCRPC, the presentation of the results of the monotherapy and combination studies, the timing of and enrollment in the combination studies, public disclosure of initial data from the Phase 2 combination study, sales of the Company's common shares under the ATM Sales Agreement and other statements surrounding the Company's evaluation of masofaniten.

Forward-looking statements and information are subject to various known and unknown risks and uncertainties, many of which are beyond the ability of ESSA to control or predict, and which may cause ESSA's actual results, performance or achievements to be materially different from those expressed or implied thereby. Such statements reflect ESSA's current views with respect to future events, are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by ESSA as of the date of such statements, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. In making forward looking statements, ESSA may make various material assumptions, including, but not limited to, (i) the accuracy of ESSA's financial projections; (ii) obtaining positive results of clinical trials; (iii) obtaining necessary regulatory approvals; and (iv) general business, market and economic conditions.

Forward-looking information is developed based on assumptions about such risks, uncertainties and other factors set out herein and in ESSA's Annual Report on Form 10-K dated December 12, 2023, under the heading "Risk Factors", a copy of which is available on ESSA's profile on EDGAR at www.sec.gov and on SEDAR+ at www.sedarplus.ca, and as otherwise disclosed from time to time on ESSA's EDGAR and SEDAR+ profiles. Forward-looking statements are made based on management's beliefs, estimates and opinions on the date that statements are made and ESSA undertakes no obligation to update forward-looking statements if these beliefs, estimates and opinions or other circumstances should change, except as may be required by applicable United States and Canadian securities laws. Readers are cautioned against attributing undue certainty to forward-looking statements.

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**ESSA PHARMA INC.****CONSOLIDATED BALANCE SHEETS***Amounts in thousands of United States dollars*

	September 30, 2023	September 30, 2022
Cash	\$ 33,702	\$ 57,076
Short-term investments	114,374	110,161
Prepays and other assets	<u>1,046</u>	<u>2,268</u>
Total assets	<u>\$ 149,122</u>	<u>\$ 169,505</u>
Current liabilities	3,495	2,310
Operating lease liabilities	-	76
Shareholders' deficiency	<u>145,627</u>	<u>167,119</u>
Total liabilities and shareholders' equity	<u>\$ 149,122</u>	<u>\$ 169,505</u>



ESSA PHARMA INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

Amounts in thousands of United States dollars, except share and per share data

	Three months ended September 30, 2023	Three months ended September 30, 2022	Year ended September 30, 2023	Year ended September 30, 2022
OPERATING EXPENSES				
Research and development	\$ 5,226	\$ 4,351	\$ 21,323	\$ 24,415
Financing costs	1	3	7	14
General and administration	<u>1,922</u>	<u>2,770</u>	<u>10,812</u>	<u>12,545</u>
Total operating expenses	<u>(7,149)</u>	<u>(7,124)</u>	<u>(32,142)</u>	<u>(36,974)</u>
Gain on derivative liability	—	—	—	20
Interest and other items	<u>1,668</u>	<u>734</u>	<u>5,560</u>	<u>1,739</u>
Net loss before taxes	(5,481)	(6,390)	(26,582)	(35,215)
Income tax expense (recovery)	<u>—</u>	<u>66</u>	<u>(2)</u>	<u>112</u>
Net loss for the period	\$ (5,483)	\$ (6,324)	\$ (26,584)	\$ (35,103)
OTHER COMPREHENSIVE LOSS				
Unrealized gain (loss) on short-term investments	<u>2</u>	<u>(7)</u>	<u>15</u>	<u>(59)</u>
Loss and comprehensive loss for the period	\$ (5,479)	\$ (6,331)	\$ (26,569)	\$ (35,162)
Basic and diluted loss per common share	\$ (0.12)	\$ (0.14)	\$ (0.60)	\$ (0.80)
Weighted average number of common shares outstanding	44,092,374	44,073,076	44,089,557	44,038,241