

ESSA Pharma Provides Corporate Update and Reports Financial Results for Fiscal Third Quarter Ended June 30, 2023

Completion of the Phase 1 EPI-7386 combination study with Xtandi® (enzalutamide) expected in the third calendar quarter of 2023 followed by initiation of the randomized Phase 2 part of the study

Entered into clinical trial support agreement with Janssen to supply Erleada® (apalutamide) and Zytiga® (abiraterone acetate) for an ESSA-sponsored Phase 1 study of EPI-7386 combination therapies; enrollment expected to begin 2H2023

Phase 1b EPI-7386 monotherapy expansion study in mCRPC patients ongoing

South San Francisco, California and Vancouver, Canada, August 8, 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 fiscal third quarter ended June 30, 2023. All references to "\$" in this release refer to United States dollars, unless otherwise indicated.

"Over the past months we have ramped up preparations to initiate the randomized Phase 2 combination study of EPI-7386 and Astellas and Pfizer's antiandrogen Xtandi® (enzalutamide), and we expect to complete the Phase 1 part of the study in the coming quarter," stated David Parkinson, MD, President and CEO of ESSA. "In the past quarter, we finalized our clinical collaboration with Janssen to evaluate EPI-7386 in combination with Janssen's antiandrogens Erleada® (apalutamide) and Zytiga® (abiraterone acetate) in two Phase 1 cohorts, building on initial Phase 1 clinical data demonstrating promising prostate-specific antigen ("PSA") declines following combination treatment. ESSA is in a strong cash position as we advance our EPI-7386 studies, with our cash runway expected to fund operations and programs through 2025."

Clinical and Corporate Highlights for the Third Quarter Ended June 30, 2023

EPI-7386 Clinical Collaborations

- The Company is preparing to initiate the open-label, randomized Phase 2 study of EPI-7386 and Astellas and Pfizer's antiandrogen Xtandi® (enzalutamide) in patients with metastatic castration-resistant prostate cancer ("mCRPC") naïve to second-generation antiandrogens. The Phase 2 study will assess the anti-tumor activity of EPI-7386 in combination with enzalutamide at the recommended Phase 2 doses versus single agent enzalutamide at the standard-of-care dose. The study is expected to enroll approximately 120 patients. The Company expects to complete the Phase 1 part of the study and establish the recommended Phase 2 combination doses (for both EPI-7386 and enzalutamide when used in combination) in the third calendar quarter of 2023, followed by initiation of the Phase 2 part of the study.
- In April 2023, the Company entered into a clinical trial support agreement with Janssen Research & Development, LLC ("Janssen") under which Janssen will supply apalutamide and abiraterone acetate for a Phase 1 clinical study sponsored and conducted by ESSA evaluating EPI-7386 combination therapies in two cohorts. The two cohorts will be evaluated as additional cohorts in the Company's ongoing Phase 1 study of EPI-7386 (Clinical Trials Identifier: NCT04421222). Cohort 1 will assess EPI-7386 in combination with abiraterone acetate plus prednisone in patients with mCRPC and high-risk metastatic castration-sensitive prostate cancer. Cohort 2 is a Window of Opportunity study in which patients with non-metastatic castration-resistant prostate cancer ("nmCRPC") will receive up to 12 weeks of single agent EPI-7386 before adding standard-of-care apalutamide. ESSA will retain all rights to EPI-7386. The Company expects enrollment to begin in the second half of calendar 2023.

EPI-7386 Monotherapy

- The Phase 1b EPI-7386 monotherapy dose expansion study is ongoing and is evaluating two doses/schedules of single agent EPI-7386 in mCRPC patients with less than three prior lines of therapy, no visceral disease and no prior chemotherapy who have progressed on at least one second-generation antiandrogen. The Company is also enrolling nmCRPC patients in the Window of Opportunity cohort of the study, in which patients will receive 12 weeks of EPI-7386 monotherapy treatment before starting standard-of-care therapy.

Corporate Updates

- In June 2023, the Company announced the appointment of Lauren Merendino, M.B.A., to its Board of Directors. Ms. Merendino is a leading biopharmaceutical executive who brings over 25 years of commercial experience spanning 20+ disease states, including 15 years of leadership for oncology-specific portfolios.

Summary Financial Results

- **Net Loss.** ESSA recorded a comprehensive loss of \$7.3 million for the third quarter ended June 30, 2023, compared to a comprehensive loss of \$8.8 million for the third quarter ended June 30, 2022. For the third quarter ended June 30, 2023, this included non-cash share-based payments of \$1.2 million compared to \$1.6 million for the prior year, recognized for stock options granted and vesting. The decrease in the third quarter was primarily attributed to decreases in research and development expenditures and general and administration expenditures in addition to an increase of \$1.2 in interest and other income.
- **Research and Development (“R&D”) expenditures.** R&D expenditures for the third quarter ended June 30, 2023 were \$6.3 million compared to \$6.4 million for the third quarter ended June 30, 2022 and include non-cash costs related to share-based payments (\$599,621 for the third quarter ended 2023 compared to \$872,531 for the third quarter ended 2022). The decrease in R&D expenditures for the year ended June 30, 2023 is the result of decreased non-cash share-based payments, legal patents and license fees and manufacturing costs related to the Phase 1 clinical trial of EPI-7386.
- **General and administration (“G&A”) expenditures.** G&A expenditures for the third quarter ended June 30, 2023 were \$2.6 million compared to \$2.9 million for the third quarter ended June 30, 2022 and include non-cash costs related to share-based payments of \$561,452 for the third quarter ended 2023 compared to \$718,469 for the third quarter ended 2022. The decrease in the third quarter is the result of decreased non-cash share-based payments, salaries and benefits and consulting and subcontractor fees.

Liquidity and Outstanding Share Capital

At June 30, 2023, the Company had available cash reserves and short-term investments of \$152.5 million reflecting the gross proceeds of the February 2021 financing of approximately \$150.0 million, less operating expenses in the intervening period. The Company’s cash position is expected to be sufficient to fund current and planned operations through 2025.

As of June 30, 2023, the Company had 44,092,374 common shares issued and outstanding.

In addition, as of June 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 8,150,274 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$5.05 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 under [@ESSAPharma](https://twitter.com/ESSAPharma).

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 completion of the Phase 1 combination study with enzalutamide and initiation of the randomized Phase 2 part of the study, enrollment in the monotherapy and combination studies, the assessment of anti-tumor activity in the Phase 2 combination study, the clinical trial support agreement, the supply of apalutamide and abiraterone acetate, the rights to EPI-7386, the testing of new antiandrogen combinations with EPI-7386, the treatments under Cohort 1 and Cohort 2 of the Phase 1 clinical trial, the Phase 1b dose expansion study and the Window of Opportunity Study, and the Company's expected cash runway into 2025.

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 13, 2022 under the heading "Risk Factors", a copy of which is available on ESSA's profile on EDGAR at www.sec.gov.com and on the SEDAR website at www.sedar.com, 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.

ESSA PHARMA INC.

CONDENSED CONSOLIDATED INTERIM BALANCE SHEETS

(Unaudited)

Amounts in thousands of United States dollars

	June 30, 2023	September 30, 2022
Cash and cash equivalents	\$ 38,467	\$ 57,076
Prepays and other assets	<u>115,183</u>	<u>112,429</u>
Total assets	\$ 153,650	\$ 169,505
Current liabilities	3,407	2,310
Long-term debt	—	76
Shareholders' equity	<u>150,243</u>	<u>167,118</u>

Total liabilities and shareholders' equity	\$	153,650	\$	169,505
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ESSA PHARMA INC.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

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

	Three months ended June 30, 2023	Three months ended June 30, 2022	Nine months ended June 30, 2023	Nine months ended June 30, 2022
OPERATING EXPENSES				
Research and development	\$ 6,271	\$ 6,395	\$ 16,096	\$ 20,064
Financing costs	2	3	6	11
General and administration	<u>2,639</u>	<u>2,896</u>	<u>8,889</u>	<u>9,775</u>
Total operating expenses	<u>(8,912)</u>	<u>(9,294)</u>	<u>(24,991)</u>	<u>(29,850)</u>
Gain on derivative liability	—	2	—	20
Interest and other items	<u>1,613</u>	<u>419</u>	<u>3,892</u>	<u>1,005</u>
Net loss before taxes	(7,299)	(8,873)	(21,099)	(28,825)
Income tax expense (recovery)	<u>—</u>	<u>46</u>	<u>(2)</u>	<u>46</u>
Net loss for the period	\$ (7,299)	\$ (8,827)	\$ (21,101)	\$ (28,779)
OTHER COMPREHENSIVE LOSS				
Unrealized gain (loss) on short-term investments	<u>43</u>	<u>(3)</u>	<u>13</u>	<u>(52)</u>
Loss and comprehensive loss for the period	\$ (7,256)	\$ (8,830)	\$ (21,088)	\$ (28,831)
Basic and diluted loss per common share				
	\$ (0.17)	\$ (0.20)	\$ (0.48)	\$ (0.65)
Weighted average number of common shares outstanding				
	44,092,374	44,059,700	44,085,941	44,026,502

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