# ESSA Pharma Provides Corporate Update and Reports Financial Results for Fiscal Fourth Quarter and Year Ended September 30, 2022

**South San Francisco, California and Vancouver, Canada, December 13, 2022 -** 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 year ended September 30, 2022. All references to "\$" in this release refer to United States dollars, unless otherwise indicated.

"ESSA achieved major milestones in 2022 with the release of Phase 1 monotherapy and combination data for our lead candidate EPI-7386 from three clinical trials in patients with metastatic castration-resistant prostate cancer ("mCRPC"), which demonstrated initial anti-tumor activity in certain patients, and EPI-7386's favorable safety profile as a single agent and in combination with second-generation antiandrogens," stated David Parkinson, MD, President and CEO of ESSA. "Early data from these clinical studies demonstrated notable PSA reductions in the Phase 1 study of EPI-7386 and Astellas' Xtandi® (enzalutamide) and in the Phase 1 study of EPI-7386 and Janssen's antiandrogens Erleada® (apalutamide) and Zytiga® (abiraterone acetate). In addition, the Phase 1a dose escalation monotherapy results showed tumor volume decreases and PSA declines in a subset of heavily pretreated mCRPC patients who had progressed on standard-of-care therapies."

Dr. Parkinson continued: "Looking ahead to 2023, we expect a busy year as we advance clinical studies of EPI-7386 as a monotherapy and in combination with approved antiandrogens in a number of prostate cancer patient populations. Our cash runway is strong and expected to fund our operations and clinical programs through 2025, including the Phase 1b monotherapy expansion and Window of Opportunity studies, a Phase 2 combination study with enzalutamide, additional cohorts in a Phase 1 study evaluating EPI-7386 with Janssen's antiandrogens, and an investigator-sponsored study of EPI-7386 and darolutamide."

#### Clinical and Corporate Highlights for 2022 Fiscal Year

#### **EPI-7386 Combination Studies**

- Updated clinical data from the first two cohorts of the Phase 1/2 study of EPI-7386 in combination with enzalutamide were presented at the 2022 Prostate Cancer Foundation ("PCF") Scientific Retreat. The data showed preliminary evidence of anti-tumor activity, with five of six patients achieving PSA90 and four of six patients achieving PSA90 within 90 days.
- In October 2022, the Company announced that Janssen Research and Development is suspending enrollment into the Phase 1 clinical study of EPI-7386 with apalutamide or EPI-7386 with abiraterone acetate plus prednisone in mCRPC patients as a result of operational recruitment challenges. Before suspending enrollment, Janssen treated three mCRPC patients (chemotherapy naive) for up to four months of therapy, with two of the three patients achieving PSA90 within 90 days. ESSA anticipates enrolling additional cohorts in the Phase 1 study in 2023 to further assess the safety and tolerability of abiraterone acetate plus prednisone or apalutamide (administered at the dose recommended in their prescribing information) when administered in combination with EPI-7386 and to establish recommended Phase 2 dosing for these combinations.
- Preclinical data for the Company's lead first generation androgen receptor ANITen bAsed Chimera ("ANITAC"™) N-terminal domain degrader were presented in a poster session at the 34th EORTC-NCI-AACR Annual Symposium on Molecular Targets and Cancer Therapeutics.

#### **EPI-7386 Monotherapy**

• In June 2022, the Company presented a clinical update on EPI-7386 monotherapy and combination therapy clinical development. Initial data from 33 heavily pretreated mCRPC patients enrolled in the Phase 1a dose escalation monotherapy study demonstrated that EPI-7386 was well-tolerated and reached clinically relevant exposures at all dose levels tested. Clinically important signals of anti-tumor activity were observed in a subset of these patients (less than 3 lines of treatment for mCRPC, lack of visceral disease, no prior chemotherapy and lack or few non-AR mutations).

#### **Corporate Updates**

 In September 2022, the Company announced the appointment of Philip Kantoff, M.D., to its Board of Directors. Dr. Kantoff is a renowned medical oncologist and leader in the clinical development of new prostate cancer treatments.

# Summary Financial Results

- **Net Loss**. ESSA recorded a net loss of \$35.1 million for the year ended September 30, 2022, compared to a net loss of \$36.8 million for the year ended September 30, 2021. For the year ended September 30, 2022, this included non-cash share-based payments of \$7.9 million compared to \$9.5 million for the prior year, recognized for stock options granted and vesting. The net loss for the fourth quarter ended September 30, 2022 was \$6.3 million compared to a net loss of \$8.5 million for the fourth quarter ended September 30, 2021. The decrease in the fourth quarter was primarily attributed to a decrease in research and development expenditures.
- Research and Development ("R&D") expenditures. R&D expenditures for the year ended September 30, 2022 were \$24.4 million compared to \$24.3 million for the year ended September 30, 2021 and include non-cash costs related to share-based payments (\$4.3 million for the year ended 2022 compared to \$3.6 million for the year ended 2021). The R&D expenditures for the year ended September 30, 2022 largely remained consistent when compared to the year ended September 30, 2021, as the increased expense in preclinical and data analysis was offset by the decreased expense in manufacturing costs related to the Phase 1 clinical trial of EPI-7386. For the fourth quarter ended September 30, 2022, R&D expenditures were \$4.4 million (net and gross), compared to \$6.3 million (net and gross) for the fourth quarter ended September 30, 2021. The decrease in the fourth quarter was primarily attributed to a decrease in non-cash share-based payments, manufacturing costs and travel costs.
- General and administration ("G&A") expenditures. G&A expenditures for the year ended September 30, 2022 were \$12.5 million compared to \$12.9 million for the year ended September 30, 2021 and include non-cash costs related to share-based payments of \$3.6 million for the year ended 2022 compared to \$5.8 million for the year ended 2021. For the fourth quarter ended September 30, 2022, G&A expenditures were \$2.8 million, compared to \$2.9 million for the fourth quarter ended September 30, 2021. The decrease in the full year and fourth quarter is the result of decreased professional fees as well as the decrease in non-cash share-based payments.

### Liquidity and Outstanding Share Capital

At September 30, 2022, the Company had available cash reserves and short-term investments of \$167.2 million reflecting the gross proceeds of the February 2021 financing of approximately \$150.0 million and July 2020 financing of \$48.9 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 September 30, 2022, the Company had 44,073,076 common shares issued and outstanding.

In addition, as of September 30, 2022 there were 3,234,750 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 314,750 warrants at a weighted average exercise price of \$49.69. There were 7,902,061 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$5.13 per common share.

#### **About EPI-7386**

EPI-7386 is an investigational, highly-selective, oral, small molecule inhibitor of the N-terminal domain of the androgen receptor. EPI-7386 is currently being studied in a Phase 1 clinical trial (NCT04421222) in men with castration-resistant prostate cancer ("CRPC") whose tumors have progressed on standard-of-care therapies and a Window of Opportunity study in patients with non-metastatic CRPC. The U.S. FDA has granted Fast Track designation to EPI-7386 for the treatment of adult male patients with mCRPC resistant to standard-of-care treatment. ESSA is also conducting a Phase 1/2 clinical trial (NCT05075577) of EPI-7386 in combination with enzalutamide in metastatic CRPC patients who have not yet been treated with second-generation antiandrogen therapies. ESSA retains all rights to EPI-7386 worldwide.

#### 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 <a href="www.essapharma.com">www.essapharma.com</a> and follow us on Twitter under <a href="www.essapharma.com">@ESSAPharma</a>.

#### **About Prostate Cancer**

Prostate cancer is estimated to be the second-most commonly diagnosed cancer among men and the fifth most common cause of male cancer death worldwide (Globocan, 2020). Adenocarcinoma of the prostate is dependent on androgen for tumor progression, and depleting or blocking androgen action has been a mainstay of hormonal treatment for over six decades. Although tumors are often initially sensitive to medical or surgical therapies that decrease levels of testosterone, disease progression despite castrate levels of testosterone can lead to mCRPC. The treatment of mCRPC patients has evolved rapidly over the past ten years. Despite these advances, many patients with mCRPC fail or develop resistance to existing treatments, leading to continued disease progression and limited survival rates.

## **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 results of initial clinical data, including the favorable pharmaceutical properties of EPI-7386, the planned advancement and development of EPI-7386 as a monotherapy and in combination with approved antiandrogens, the Phase 1b monotherapy expansion and Window of Opportunity studies, the Phase 2 study and combination studies, the planned study evaluating EPI-7386 with Janssen's antiandrogens, the ESSA-sponsored study of EPI-7386 and darolutamide, 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 <a href="www.sec.gov.com">www.sec.gov.com</a> and on the SEDAR website at <a href="www.sedar.com">www.sedar.com</a>, 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.
CONSOLIDATED BALANCE SHEETS
Amounts in thousands of United States dollars

	Septem 30, 2		September 30, 2021
Cash and cash equivalents Prepaids and other current assets	\$ 57, 112,	076 \$ 4 <u>29</u>	137,825 60,341
Total assets	\$ 169,	505 \$	198,166
Current liabilities Operating lease liabilities Derivative liabilities Shareholders' equity	167,	310 76 - 118 _	3,930 210 20 194,006
Total liabilities and shareholders' equity	\$ 169,	505 \$	198,166

**ESSA PHARMA INC.**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS Amounts in thousands of United States dollars, except share and per share data

	Т	hree months	T	hree months					
	ended		ended		Year ended		Year ended		
	September 30,		September 30,		Se	September 30,		September 30,	
		2022		2021		2022		2021	
OPERATING EXPENSES									
Research and development	\$	4,351	\$	6,273	\$	24,415	\$	24,259	
Financing costs		3		4		14		22	
General and administration	_	2,770	_	2,942	_	12,545	_	12,885	
Total operating expenses	_	(7,124)		(9,219)		(36,974)	_	(37,166)	
Gain (loss) on derivative liability		-		577		20		107	
Other items	_	734	_	121	_	1,738	_	219	
Net loss before taxes		(6,390)		(8,521)		(35,215)		(36,840)	
Income tax recovery		66		-		112		34	
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Net loss for the period	\$	(6,324)	\$	(8,521)	\$	(35,103)	\$	(36,805)	
Basic and diluted loss per									
common share	\$	(0.14)	\$	(0.20)	\$	(0.80)	\$	(0.96)	
Weighted average number of				<u> </u>					
common shares outstanding		44,073,076		42,044,664		44,038,241		38,480,378	

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