# ESSA Pharma Provides Corporate Update and Reports Financial Results for Fiscal First Quarter Ended December 31, 2021

**Vancouver, Canada and Houston, Texas, February 3, 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 first quarter ended December 31, 2021. All references to "\$" in this release refer to United States dollars, unless otherwise indicated.

"In the last quarter ESSA continued to execute on all aspects of the development program of EPI-7386, our highlyselective, oral, small molecule inhibitor of the N-terminal domain of the androgen receptor for the treatment of patients with metastatic castration-resistant prostate cancer ("mCRPC")," stated David Parkinson, M.D., President and CEO of ESSA. "We are currently dosing patients in the Phase 1a dose escalation study evaluating EPI-7386 as a monotherapy at 800 mg administered as 400 mg BID. We look forward to presenting a clinical update of the monotherapy trial in the first half of 2022. We expect to establish a recommended Phase 2 dose ("RP2D") for EPI-7386 monotherapy during the first half of 2022 and commence the Phase 1b expansion study soon thereafter. In addition, we are dosing patients in our first cohort of patients in the Company-sponsored combination Phase 1/2 study of EPI-7386 with Astellas Pharma Inc.'s ("Astellas") and Pfizer Inc.'s ligand-binding domain androgen receptor inhibitor, enzalutamide, in patients with mCRPC. Additional Phase 1/2 combination studies we announced last year with Janssen Research and Development LLC ("Janssen") and Bayer, which will evaluate EPI-7386 in combination with the companies' respective antiandrogen therapies in earlier line mCRPC patients, remain on track to begin in 2022. The full EPI-7386 clinical development program, including a Phase 2 study and preparatory work for a Phase 3 confirmatory study, is supported by our cash runway into 2024."

### Clinical and Corporate Highlights

- On January 19, 2022, the Company announced the first patient dosed in the Company-sponsored Phase 1/2 study to evaluate the safety, tolerability, and preliminary efficacy of ESSA's lead product candidate, EPI-7386, a first-in-class N-terminal domain androgen receptor inhibitor, in combination with Astellas and Pfizer Inc.'s ligand-binding domain androgen receptor inhibitor, enzalutamide, in patients with mCRPC.
- At the 2021 American Association for Cancer Research, National Cancer Institute, and European Organisation for Research and Treatment of Cancer Virtual International Conference on Molecular Targets and Cancer Therapeutics, the Company presented preclinical data characterizing the mechanism of action of EPI-7386, including the results of NMR studies which confirm the binding of the compound to the N-terminal domain of the androgen receptor ("AR"), a region not currently targeted by other antiandrogen therapies. The data also demonstrate that the combination of EPI-7386 with enzalutamide results in complete inhibition of genome-wide androgen-induced AR binding, supporting the rationale for Phase 1/2 combination trials of EPI-7386 with approved antiandrogens in patients with mCRPC.

### Summary Financial Results

- Net Loss. ESSA recorded a net loss of \$9.1 million (\$0.21 loss per common share based on 43,989,773 weighted average common shares outstanding) for the quarter ended December 31, 2021, compared to a net loss of \$6.5 million (\$0.20 loss per common share based on 33,343,488 weighted average common shares outstanding) for the quarter ended December 31, 2020. For the quarter ended December 31, 2021, this included non-cash share-based payments of \$2.5 million compared to \$1.2 million for the comparable period in 2020, recognized for stock options granted and vesting.
- Research and Development ("R&D") expenditures. R&D expenditures for the quarter ended December 31, 2021 were \$6.0 million compared to \$4.5 million for the quarter ended December 31, 2020 and includes non-cash costs related to share-based payments (\$1.3 million for the quarter ended December 31,2021 compared to \$287,424 for the quarter ended December 31, 2020). The increase in R&D expenditures for the first fiscal quarter ended December 31, 2021 were primarily related to clinical data analysis associated with the Phase 1a clinical study, as well as increased expenses related to intellectual property and salaries, as well as the non-cash share-based expenses.

• General and administration ("G&A") expenditures. G&A expenditures for the quarter ended December 31, 2021 were \$3.1 million compared to \$2.2 million for the quarter ended December 31, 2020 and include non-cash costs related to share-based payments of \$1.2 million for the quarter ended December 31, 2021 compared to \$917,561 for the comparable period in 2020. The increased expenditure is the result of increased professional fees related to transitioning to be a large accelerated filer, higher salaries and benefits, as well as the non-cash share-based payments.

# Liquidity and Outstanding Share Capital

At December 31, 2021, the Company had available cash reserves and short-term investments of \$189.2 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.

As of December 31, 2021, the Company had 44,015,870 common shares issued and outstanding.

In addition, as of December 31, 2021 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 \$4.84. There were 6,789,566 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$5.30 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 mCRPC whose tumors have progressed on current standard-of-care therapies. The Phase I clinical trial of EPI-7386 began in calendar Q3 of 2020 following FDA allowance of our Investigational New Drug application and Health Canada acceptance. EPI-7386 is also being studied in earlier line mCRPC patients in a Phase 1/2 trial in combination with enzalutamide. 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 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 <u>www.essapharma.com</u> and follow us on Twitter under <u>@ESSAPharma</u>.

### **About Prostate Cancer**

Prostate cancer is the second-most commonly diagnosed cancer among men and the fifth most common cause of male cancer death worldwide (Globocan, 2018). 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 Company's clinical evaluation of EPI-7386, including the advancement and development of EPI-7386 in the current Phase 1 study, expectations to explore additional higher dose cohorts, our goal to establish a RP2D for monotherapy by the first-half of 2022 and the expectation of presenting a complete clinical summary of the Phase 1a monotherapy trial in the first half of 2022, results of preclinical data regarding EPI-7386, the start date and sponsorship of Phase 1/2 combination studies with Janssen, Bayer and Astellas, and the Company's expected cash runway.

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,

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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 Quarterly Report on Form 10-Q dated February 3, 2022 under the heading "Risk Factors", a copy of which is available on ESSA's profile on EDGAR at <u>www.sec.gov</u> and on the SEDAR website at <u>www.sedar.com</u>, 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.

CONDENSED CONSOLIDATED INTERIM BALANCE SHEETS

(Unaudited)

Amounts in thousands of United States dollars

	De	ecember 31, 2021	Se	eptember 30, 2021
Cash and cash equivalents Prepaids and other assets	\$	121,058 70,428	\$	137,825 60,341
Total assets	\$	191,486	\$	198,166
Current liabilities Long-term debt Derivative liability Shareholders' deficiency		3,658 169 120 187,539		3,930 210 20 194,006
Total liabilities and shareholders' equity	\$	191,486	\$	198,166

# 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 December 31,			
	2021		2020	
\$	6,020	\$	4,486	
_	4 <u>3,062</u>		1 2,209	
	<u>(9,086)</u>		(6,696)	
_	(99) 87		89 43	
_	(9,098) <u>1</u>		(6,564) <u>35</u>	
\$	(9,097)	\$	(6,529)	
\$	(0.21)	\$	(0.20)	
	13 080 773		33,343,488	
	De \$ 	ended December 31, 2021 \$ 6,020 4 3,062 (9,086) (9,086) (9,098) 1 \$ (9,097)	ended December 31, De 2021 De \$ 6,020 \$ 4 3,062 _ (9,086)	



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