

ESSA Pharma Provides Corporate Update and Reports Financial Results for Fiscal Fourth Quarter and Year Ended September 30, 2021

Vancouver, Canada and Houston, Texas, November 18, 2021 - 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, 2021. All references to "\$" in this release refer to United States dollars, unless otherwise indicated.

"2021 has been a year of meaningful execution on all aspects of the development program of EPI-7386, our highly-selective, oral, small molecule inhibitor that uniquely targets the N-terminal domain of the androgen receptor for the treatment of patients with metastatic castration-resistant prostate cancer ("mCRPC")," stated David Parkinson, MD, President and CEO of ESSA. "During the year, we presented initial clinical data at a scientific conference that suggest a favorable pharmacological profile and provide clinical proof of concept for EPI-7386. In addition, we demonstrated through nuclear magnetic resonance ("NMR") studies that EPI-7386 binds to the N-terminal domain of the androgen receptor—the primary driver of prostate cancer growth. We were pleased to announce this year clinical collaborations with Janssen Research and Development LLC ("Janssen"), Astellas Pharma Inc. ("Astellas"), and Bayer, three leading companies with approved antiandrogen treatments for prostate cancer. These Phase 1/2 studies, anticipated to begin in late 2021 or early 2022, will evaluate EPI-7386 in combination with the companies' respective antiandrogen therapies in earlier line mCRPC patients."

Dr. Parkinson continued: "As a result of the successful financing earlier this year, our cash and short-term investments of \$195 million are expected to provide us a cash runway into 2024 and fully fund the current development programs, including the Phase 1a/1b monotherapy studies, Phase 2, preparatory work for a Phase 3 confirmatory study as well as commitments around the four Phase 1/2 combination studies with approved antiandrogens. In the Phase 1 monotherapy dose escalation study, we are currently dosing patients with EPI-7386 at 800 mg administered as 400mg BID, and our goal remains to establish a recommended Phase 2 dose ("RP2D") for monotherapy during the first half of 2022, while commencing the expansion Phase 1b study soon thereafter. We look forward to presenting a clinical readout of the Phase 1a monotherapy trial in the first half of 2022."

Clinical and Corporate Highlights for 2021 Fiscal Year

- On October 7, 2021, at the 2021 American Association for Cancer Research ("AACR"), National Cancer Institute ("NCI"), and European Organisation for Research and Treatment of Cancer ("EORTC") 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 ("NTD") 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.
- On April 28, 2021, the Company announced a clinical collaboration with Bayer to evaluate EPI-7386 in combination with Bayer's androgen receptor inhibitor darolutamide in patients with mCRPC. Under the terms of the agreement, Bayer may sponsor and conduct a Phase 1/2 study to evaluate the safety, pharmacokinetics and efficacy of the combination of EPI-7386 and darolutamide in mCRPC patients. ESSA will supply EPI-7386 for the trial and will retain all rights to EPI-7386.
- On April 10, 2021, the Company reported new preclinical data on EPI-7386 at the 2021 AACR Annual Meeting demonstrating that in vitro EPI-7386 can prevent the androgen receptor from binding to genomic DNA and can inhibit AR related transcription in prostate cancer cell lines expressing AR splice variants including the AR-v567es variant. The results also demonstrate that combining EPI-7386 with enzalutamide in vitro results in a broader and deeper inhibition of the AR pathway.
- On February 25, 2021, the Company announced a clinical collaboration with Astellas Pharma Inc. to evaluate the combination of EPI-7386 and Astellas/Pfizer's androgen receptor inhibitor enzalutamide for patients with mCRPC. Under the terms of the agreement, ESSA will sponsor and conduct a Phase 1/2 study to evaluate the safety, tolerability and preliminary efficacy of the combination of EPI-7386 and enzalutamide in mCRPC patients who have not yet been treated with second-generation antiandrogen therapies. Astellas will supply enzalutamide for the trial. ESSA will retain all rights to EPI-7386.

- On February 22, 2021, the Company completed an underwritten public offering for aggregate gross proceeds of \$149,999,985, issuing a total of 5,555,555 common shares, at a public offering price of \$27.00 per share.
- On February 11, 2021, the Company presented favorable initial Phase 1 clinical pharmacology data of EPI-7386 for advanced forms of prostate cancer at the 2021 ASCO Genitourinary Cancers Symposium.
- On January 13, 2021, the Company announced a clinical collaboration with Janssen to evaluate EPI-7386 in combination with abiraterone acetate/prednisone or apalutamide for patients with mCRPC. Under the terms of the agreement, Janssen may sponsor and conduct up to two Phase 1/2 studies evaluating the safety, tolerability and preliminary efficacy of the combination of EPI-7386 and apalutamide as well as the combination of EPI-7386 with abiraterone acetate plus prednisone in patients with mCRPC. Janssen will assume all costs associated with these studies other than the manufacturing costs associated with the clinical drug supply of EPI-7386. The parties will form a joint oversight committee for the clinical studies. ESSA will retain all rights to EPI-7386.

Summary Financial Results

- **Net Loss.** ESSA recorded a net loss of \$36.8 million (\$0.96 loss per common share based on 38,480,378 weighted average common shares outstanding) for the year ended September 30, 2021, compared to a net loss of \$23.4 million (\$1.04 loss per common share based on 22,443,893 weighted average common shares outstanding) for the year ended September 30, 2020. For the year ended September 30, 2021, this included non-cash share-based payments of \$9.5 million compared to \$7.5 million for the prior year, recognized for stock options granted and vesting. The net loss for the fourth quarter ended September 30, 2021 was \$8.5 million compared to a net loss of \$4.6 million for the fourth quarter ended September 30, 2020.
- **Research and Development (“R&D”) expenditures.** R&D expenditures for the year ended September 30, 2021 were \$24.3 million compared to \$12.1 million for the year ended September 30, 2020 and includes non-cash costs related to share-based payments (\$3.6M for year ended 2021 compared to \$1.9M for year ended 2020). For the fourth quarter ended September 30, 2021, R&D expenditures were \$6.3 million (net and gross), as compared to \$2.2 million (net and gross) for the fourth quarter ended September 30, 2020. The increase in R&D expenditures for the full year and fourth quarter were primarily related to preclinical work leading to the filing of the IND for EPI-7386 in March 2020, the increased expenditure on chemistry and manufacturing of drug product, and clinical costs related to the Phase 1 clinical trial of EPI-7386 which commenced with the dosing of the first patient in July 2020.
- **General and administration (“G&A”) expenditures.** G&A expenditures for the year ended September 30, 2021 were \$12.9 million compared to \$11.4 million for the year ended September 30, 2020 and include non-cash costs related to share-based payments of \$5.8M for the year ended 2021 compared to \$5.6M for the year ended 2020. For the fourth quarter ended September 30, 2021, G&A expenditures were \$2.9 million, compared to \$2.2 million for the fourth quarter ended September 30, 2020. The increase in the full year and fourth quarter is the result of increased professional fees related to transitioning to be a domestic filer, higher salaries and benefits, as well as the non-cash share-based payments.

Liquidity and Outstanding Share Capital

At September 30, 2021, the Company had available cash reserves and short-term investments of \$194.9 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 September 30, 2021, the Company had 43,984,346 common shares issued and outstanding.

In addition, as of September 30, 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 6,803,230 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$5.20 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. 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 www.essapharma.com and follow us on Twitter under [@ESSAPharma](https://twitter.com/ESSAPharma).

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 suggesting that EPI-7386 can inhibit AR related transcription and EPI-7386 in combination with enzalutamide may result in broader and deeper inhibition of the AR pathway, statements regarding the sponsorship of Phase 1/2 combination studies with Bayer and Astellas, and the anticipated start date in 2021 of those studies and the Company's expected cash runway into 2024.

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 November 18, 2021 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.
CONSOLIDATED BALANCE SHEETS
Amounts in thousands of United States dollars

	September 30, 2021	September 30, 2020
Cash	\$ 137,825	\$ 56,321
Prepays and other assets	<u>60,341</u>	<u>24,254</u>
Total assets	\$ 198,166	\$ 80,575
Current liabilities	3,930	1,204
Long-term debt	210	-
Derivative liability	20	127
Shareholders' deficiency	<u>194,006</u>	<u>79,244</u>
Total liabilities and shareholders' equity	\$ 198,166	\$ 80,575

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, 2021	Three months ended September 30, 2020	Year ended September 30, 2021	Year ended September 30, 2020
OPERATING EXPENSES				
Research and development	\$ 6,273	\$ 2,237	\$ 24,259	\$ 12,146
Financing costs	4	117	22	618
General and administration	<u>2,942</u>	<u>2,200</u>	<u>12,885</u>	<u>11,374</u>
Total operating expenses	<u>(9,219)</u>	<u>(4,554)</u>	<u>(37,166)</u>	<u>(24,138)</u>
Gain (loss) on derivative liability	577	(51)	107	(111)
Other items	<u>121</u>	<u>37</u>	<u>219</u>	<u>515</u>
Net loss before taxes	(8,521)	(4,568)	(36,840)	(23,734)
Income tax expense	<u>-</u>	<u>15</u>	<u>35</u>	<u>(289)</u>
Net loss for the period	\$ (8,521)	\$ (4,553)	\$ (36,805)	\$ (23,445)
Basic and diluted loss per common share	\$ (0.20)	\$ (0.17)	\$ (0.96)	\$ (1.04)
Weighted average number of common shares outstanding	42,044,664	27,333,800	38,480,378	22,443,893



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