

ESSA Pharma Provides Corporate Update and Reports Financial Results for Fiscal Third Quarter Ended June 30, 2021

Houston, Texas and Vancouver, Canada, August 16, 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 third quarter ended June 30, 2021. All references to “\$” in this release refer to United States dollars, unless otherwise indicated.

“During this quarter, the Company continued to focus on the execution of the Phase 1a clinical program of EPI-7386 as a monotherapy in patients with late-stage metastatic castration-resistant prostate cancer (“mCRPC”) whose tumors have progressed on multiple current standard-of-care therapies, including antiandrogens,” said Dr. David R. Parkinson, M.D., President and Chief Executive Officer of ESSA Pharma Inc. “In this heavily pretreated cohort of patients, EPI-7386 continues to be safe, well-tolerated, with generally good drug exposures, and adverse-events typical of those associated with antiandrogen therapy. Patients are currently being dosed at 600 mg, 800 mg, and 1,000 mg QD, with each of these dose levels being cleared as safe and tolerable. Given the favorable tolerability of the drug and the wide therapeutic window seen in preclinical studies, we plan to enroll additional higher dose cohorts using a twice daily (BID) dosing schedule to further enhance patient drug exposures. In addition, we are planning to file a protocol amendment to focus further monotherapy development in less heavily pretreated patients in whom we believe the androgen receptor pathway continues to be the primary driver of tumor growth. Our goal is to establish a recommended Phase 2 dose (“RP2D”) for monotherapy during the first half of 2022 and commence the expansion Phase 1b study soon thereafter in earlier, less heavily pretreated and more biologically characterized patients. We look forward to presenting a clinical readout of the Phase 1a monotherapy trial in the first half of 2022.”

Dr. Parkinson continued, “In parallel, our development of EPI-7386 in combination with current antiandrogens in mCRPC patients remains on track. The ESSA-managed clinical trial collaboration with Astellas (enzalutamide) will begin in the fourth quarter of 2021. The EPI-7386 combination studies with other antiandrogens that were announced earlier this year are on track and are anticipated to begin in late 2021 or early 2022. Lastly, using nuclear magnetic resonance studies, we have achieved our long-term preclinical goal of demonstrating definitive evidence that EPI-7386 binds to the N-terminal domain of the androgen receptor and look forward to presenting these results at an upcoming scientific conference this year. As a result of the successful financing earlier this year, our cash and short-term investments of over \$202 million provide us a cash runway into 2024 and fully fund the current development programs.”

Recent Clinical and Corporate Highlights

- 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 metastatic castration-resistant prostate cancer (“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 American Association of Cancer Research (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 androgen receptor (“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.

Summary Financial Results

- **Net Loss.** ESSA recorded a net loss of \$8.8 million (\$0.21 loss per common share based on 41,018,024 weighted average common shares outstanding) for the quarter ended June 30, 2021, compared to a net loss of \$4.9 million (\$0.24 loss per common share based on 20,824,568 weighted average common shares outstanding) for the quarter ended June 30, 2020. For the period ended June 30, 2021, this included non-cash share-based payments of \$2.8 million compared to \$1.5 million for the prior year, recognized for stock options granted and vesting.
- **Research and Development (“R&D”) expenditures.** R&D expenditures for the quarter ended June 30, 2021 were \$6.2 million compared to \$2.7 million for the quarter ended June 30, 2020 and includes non-cash costs related to share-based payments (\$1.2 million for period ended June 30, 2021 compared to \$382,941 for period ended June 30, 2020). The increase in R&D expenditures for the third quarter were primarily related to preclinical research with work directed to the completion of the IND filing in March 2020 and chemistry and manufacturing costs in preparation for the Phase 1 study.
- **General and administration (“G&A”) expenditures.** G&A expenditures for the quarter ended June 30, 2021 were \$3.1 million compared to \$2.2 million for the quarter ended June 30, 2020 and include non-cash costs related to share-based payments of \$1.5 million for the period ended June 30, 2021 compared to \$1.1 million for the period ended June 30, 2020. The increase in the third quarter is the result of increased share-based payments related to the expense recognized in relation to the grant and vesting of these equity instruments.

Liquidity and Outstanding Share Capital

At June 30, 2021, the Company had available cash reserves and short-term investments of \$202,263,003 reflecting the gross proceeds of the February 2021 financing of \$150.0 million and July 2020 financing of \$48.9 million, less operating expenses in the intervening period.

As of June 30, 2021, the Company had 41,854,916 common shares issued and outstanding.

In addition, as of June 30, 2021 there were 5,359,750 common shares issuable upon the exercise of warrants and broker warrants. This includes 5,045,000 prefunded warrants at an exercise price of \$0.0001, and 314,750 warrants at a weighted average exercise price of \$49.69. There are 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 recommended Phase 2 dose 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.

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 Quarterly Report on Form 10-Q dated August 16, 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.
CONDENSED CONSOLIDATED INTERIM BALANCE SHEETS
(Unaudited)
Amounts in thousands of United States dollars

	June 30, 2021	September 30, 2020
Cash and cash equivalents	\$ 145,194	\$ 56,321
Prepays and other assets	<u>58,330</u>	<u>24,254</u>
Total assets	\$ 203,524	\$ 80,575
Current liabilities	3,008	1,204
Long-term liability	220	-
Derivative liability	598	127
Shareholders' deficiency	<u>199,698</u>	<u>79,244</u>
Total liabilities and shareholders' equity	\$ 203,524	\$ 80,575

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, 2021	Three months ended June 30, 2020	Nine months ended June 30, 2021	Nine months ended June 30, 2020
OPERATING EXPENSES				
Research and development	\$ 6,232	\$ 2,704	\$ 17,986	\$ 9,909
Financing costs	17	197	18	501
General and administration	<u>3,118</u>	<u>2,171</u>	<u>9,942</u>	<u>9,174</u>
Total operating expenses	(9,367)	(5,072)	(27,946)	(19,584)
Gain (loss) on derivative liability	(569)	(36)	(470)	(60)
Other items	<u>46</u>	<u>183</u>	<u>136</u>	<u>478</u>
Net loss before taxes	(8,752)	(4,925)	(28,280)	(19,166)
Income tax recovery	<u>-</u>	<u>-</u>	<u>35</u>	<u>274</u>
Net loss and comprehensive loss for the period	\$ (8,752)	\$ (4,925)	\$ (28,245)	\$ (18,892)
Basic and diluted loss per common share	\$ (0.21)	\$ (0.24)	\$ (0.76)	\$ (0.91)
Weighted average number of common shares outstanding	41,018,024	20,824,568	36,937,014	20,802,026



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