



ESSA Pharma Provides Corporate Update and Reports Financial Results for Fiscal Second Quarter Ended March 31, 2021

- Presented promising preliminary pharmacokinetic and clinical data on EPI-7386 in metastatic castration-resistant prostate cancer at 2021 AACR
 - Raised approximately \$150 million in a public offering

Houston, Texas and Vancouver, Canada, May 6, 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 second quarter ended March 31, 2021. All references to “\$” in this release refer to United States dollars, unless otherwise indicated.

“This quarter was a very productive period for ESSA. We continue to advance our lead product candidate, EPI-7386, in an ongoing Phase 1 trial in patients with metastatic castration-resistant prostate cancer who are resistant to standard-of-care treatments. We recently reported promising preliminary pharmacokinetic and clinical data from the study and expect to provide a clinical update in the fourth quarter of this calendar year,” said Dr. David R. Parkinson, M.D., President and Chief Executive Officer of ESSA Pharma. “During the quarter, we also announced clinical collaborations with Janssen and Astellas, and recently on April 28th entered into a partnership with Bayer, all focused on evaluating EPI-7386 in Phase 1/2 clinical studies in combination with their respective anti-androgen therapies.”

Dr. David R. Parkinson added, “With the completion of a successful public offering in which we raised approximately \$150 million, we are well-positioned to fund our monotherapy and collaboration studies of EPI-7386 in prostate cancer. In addition, the funding will expand and accelerate our discovery and preclinical research and development efforts to continue to build value across our overall pipeline.”

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. The clinical study is expected to start in the second half of calendar 2021.
- On April 10, 2021, the Company reported updated preclinical data on EPI-7386 at the 2021 American Association of Cancer Research (AACR) Annual Meeting demonstrating that the product candidate can inhibit in vitro androgen receptor (“AR”) splice variants including AR-v567es. The results also suggest 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.
- On February 25, 2021, the Company announced a clinical collaboration with Astellas Pharma Inc. (“Astellas”) 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. The clinical study remains on track to start in the second half of calendar 2021.
- On February 22, 2021, the Company completed an underwritten public offering for aggregate gross proceeds of \$149,999,985. The Company issued a total of 5,555,555 common shares of the Company at a public offering price of \$27.00 per share, including the underwriters’ fully exercised option to purchase an additional 724,637 shares.

- On January 13, 2021, the Company announced a clinical collaboration with Janssen Research & Development, LLC (“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 who have failed a second-generation antiandrogen therapy. 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, which are planned to start in 2021. ESSA will retain all rights to EPI-7386.

Summary Financial Results

- **Net Loss.** ESSA recorded a net loss of \$13.0 million (\$0.36 loss per common share based on 36,484,041 weighted average common shares outstanding) for the quarter ended March 31, 2021, compared to a net loss of \$9.4 million (\$0.45 loss per common share based on 20,821,956 weighted average common shares outstanding) for the quarter ended March 31, 2020. For the period ended March 31, 2021, this included non-cash share-based payments of \$2.7 million compared to \$3.6 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 March 31, 2021 were \$7.3 million compared to \$4.6 million for the quarter ended March 31, 2020 and includes non-cash costs related to share-based payments (\$791,969 for period ended March 31, 2021 compared to \$1.0 million for period ended March 31, 2020). The increase in R&D expenditures for the second quarter were primarily related to the increased expenditure on chemistry and manufacturing of the 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 quarter ended March 31, 2021 were \$4.6 million compared to \$4.9 million for the quarter ended March 31, 2020 and include non-cash costs related to share-based payments of \$1.9 million for the period ended March 31, 2021 compared to \$2.6 million for the period ended March 31, 2020. The increase in the second quarter is the result of increased share-based payments related the expense recognized in relation to the grant and vesting of these equity instruments.

Liquidity and Outstanding Share Capital

At March 31, 2021, the Company had available cash reserves and short-term investments of \$208,597,224 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 March 31, 2021, the Company had 40,417,857 common shares issued and outstanding.

In addition, as of March 31, 2021 there were 6,728,398 common shares issuable upon the exercise of warrants and broker warrants. This includes 6,370,000 prefunded warrants at an exercise price of \$0.0001, and 358,398 warrants at a weighted average exercise price of \$44.13. There are 6,726,642 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$4.53 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, the proceeds from the Company's \$150 million public offering to expand and accelerate the Company's discovery and preclinical research and development efforts, the potential of our clinical collaboration with Janssen to improve treatment options for patients with prostate cancer, 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 May 6, 2021 under the heading "Risk Factors", a copy of which is available on ESSA's profile on EDGAR at www.sec.gov 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*

	March 31, 2021	September 30, 2020
Cash and cash equivalents	\$ 151,562	\$ 56,321
Prepays and other assets	<u>58,439</u>	<u>24,254</u>
Total assets	<u>\$ 210,001</u>	<u>\$ 80,575</u>
Current liabilities	3,180	1,204
Long-term liability	247	-
Derivative liability	1,166	127
Shareholders' deficiency	<u>205,408</u>	<u>79,244</u>
Total liabilities and shareholders' equity	<u>\$ 210,001</u>	<u>\$ 80,575</u>

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 March 31, 2021	Three months ended March 31, 2020	Six months ended March 31, 2021	Six months ended March 31, 2020
OPERATING EXPENSES				
Research and development	\$ 7,268	\$ 4,618	\$ 11,754	\$ 7,206
Financing costs	-	88	1	304
General and administration	<u>4,615</u>	<u>4,864</u>	<u>6,824</u>	<u>7,003</u>
Total operating expenses	<u>(11,883)</u>	<u>(9,570)</u>	<u>(18,579)</u>	<u>(14,513)</u>
Gain (loss) on derivative liability	(1,128)	33	(1,039)	(24)
Other items	<u>47</u>	<u>187</u>	<u>90</u>	<u>295</u>
Net loss before taxes	(12,924)	(9,350)	(19,528)	(14,242)
Income tax recovery	<u>-</u>	<u>(4)</u>	<u>35</u>	<u>274</u>
Net loss and comprehensive loss for the period	<u>\$ (12,964)</u>	<u>\$ (9,354)</u>	<u>\$ (19,493)</u>	<u>\$ (13,968)</u>
Basic and diluted loss per common share	\$ (0.36)	\$ (0.45)	\$ (0.56)	\$ (0.67)



Weighted average number of common shares outstanding	36,484,041	20,821,956	34,896,509	20,790,817
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