# ESSA Pharma Provides Corporate Update and Reports Financial Results for Fiscal Third Quarter Ended June 30, 2022

**South San Francisco, California and Vancouver, Canada, August 4, 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 third quarter ended June 30, 2022. All references to "\$" in this release refer to United States dollars, unless otherwise indicated.

"It is a busy and important time for ESSA as we advance our lead candidate for the treatment of prostate cancer, EPI-7386, into the dose expansion phase of the single agent trial, dose the second cohort of patients in the Company-sponsored combination trial with enzalutamide, and plan to initiate additional trials of EPI-7386 in earlier-line patients," stated David Parkinson, M.D., President and CEO of ESSA. "During this past quarter, we were pleased to report clinical results from the Phase 1a dose escalation study demonstrating that EPI-7386 was safe and well-tolerated at all dose levels tested and that tumor volume decreases were observed in a subgroup of patients with measurable disease who were on therapy for more than 12 weeks. We also shared preliminary results from the first cohort of patients in our Phase 1/2 combination trial with enzalutamide."

## **Clinical Highlights**

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

- In June 2022, ESSA reported clinical results from the Phase 1a dose escalation study of EPI-7386 in patients with metastatic castration-resistant prostate cancer ("mCRPC") resistant to current standard-of-care therapies. The initial data demonstrate that EPI-7386 was well-tolerated, exhibited a favorable pharmacokinetic profile, and demonstrated initial anti-tumor activity in heavily pretreated patients. EPI-7386 was safe and well-tolerated at all dose levels and schedules tested, with no dose-limiting toxicities.
- The Phase 1b expansion study is expected to begin in the third quarter of calendar 2022; the trial
  is expected to enroll two dose cohorts as well as an additional cohort of patients with non-metastatic
  castration-resistant prostate cancer ("nmCRPC") who have not yet been treated with a secondgeneration antiandrogen in a 12-week window of opportunity study.

#### **EPI-7386 Clinical Collaborations**

- The Company has completed dosing of the first cohort of patients and is currently enrolling the second cohort of patients in the Company-sponsored Phase 1/2 study of EPI-7386 in combination with Astellas Pharma Inc.'s and Pfizer Inc.'s enzalutamide in patients with mCRPC who have not been treated with second-generation antiandrogens. In June 2022, the Company reported preliminary results from the first cohort suggesting that the drugs can be combined safely and result in active drug levels of both EPI-7386 and enzalutamide.
- Janssen Research and Development LLC continues to enroll patients in the Phase 1/2 trial of EPI-7386 in combination with apalutamide or abiraterone acetate plus prednisone in earlier line mCRPC patients.
- The Bayer-led Phase 1/2 trial will evaluate EPI-7386 in combination with darolutamide in earlier line mCRPC patients.
- The Company expects to initiate a Phase 2 investigator-sponsored neoadjuvant study to evaluate darolutamide compared to EPI-7386 + darolutamide in patients undergoing prostatectomy for highrisk localized prostate cancer by year-end.

### Summary Financial Results

- **Net Loss**. ESSA recorded a net loss of \$8.8 million (\$0.20 loss per common share based on 44,059,700 weighted average common shares outstanding) for the quarter ended June 30, 2022, compared to 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. For the quarter ended June 30, 2022, this included non-cash share-based payments of \$1.6 million compared to \$2.8 million for the comparable period in 2021, recognized for stock options granted and vesting.
- Research and Development ("R&D") expenditures. R&D expenditures for the quarter ended June 30, 2022 were \$6.4 million compared to \$6.2 million for the quarter ended June 30, 2021 and included non-cash costs related to share-based payments (\$872,531 for the quarter ended June 30, 2022 compared to \$1.2 million for the quarter ended June 30, 2021). The increase in R&D expenditures for the fiscal quarter ended June 30, 2022 was primarily related to preclinical and clinical data analysis associated with the Phase 1a clinical study.
- General and administration ("G&A") expenditures. G&A expenditures for the quarter ended June 30, 2022 were \$2.9 million compared to \$3.1 million for the quarter ended June 30, 2021 and included non-cash costs related to share-based payments of \$718,469 for the quarter ended June 30, 2022 compared to \$1.5 million for the comparable period in 2021. The decreased expenditure is the result of decreased professional fees from collaboration contracts in the prior period and decreased non-cash share-based payments.

### Liquidity and Outstanding Share Capital

At June 30, 2022, the Company had available cash reserves and short-term investments of \$174.6 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 2024.

As of June 30, 2022, the Company had 44,073,076 common shares issued and outstanding.

In addition, as of June 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 7,852,061 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$5.15 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 CRPC and mCRPC whose tumors have progressed on current standard-of-care therapies. The Phase 1 clinical trial of EPI-7386 began in calendar Q3 of 2020 following FDA allowance of ESSA's Investigational New Drug application and Health Canada acceptance. The Phase 1b component of the study comprises two cohorts enrolling in parallel. Cohort A - a dose expansion study of EPI-7386 to evaluate the safety, tolerability, pharmacokinetic, and preliminary anti-tumor activity and Cohort B – a window of opportunity study with clinical endpoints to assess the anti-tumor activity in nmCRPC patients unperturbed by previous second generation anti-androgen therapies or chemotherapy. EPI-7386 is also being studied in earlier line mCRPC patients in Phase 1/2 trials in combination with enzalutamide, apalutamide and abiraterone acetate with prednisone. 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 <a href="www.essapharma.com">www.essapharma.com</a> and follow us on Twitter under <a href="@ESSAPharma">@ESSAPharma</a>.

#### 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 the initial clinical data, including the favorable pharmaceutical properties of EPI-7386, the expected commencement and timing of the Phase 1b study, the nature of the Phase 1/2 trial, the potential clinical benefit of EPI-7386 in combination with approved second-generation antiandrogens 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, 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 4, 2022 under the heading "Risk Factors", a copy of which is available on ESSA's profile on EDGAR at <a href="www.sec.gov">www.sec.gov</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.**

# CONDENSED CONSOLIDATED INTERIM BALANCE SHEETS

(Unaudited)

Amounts in thousands of United States dollars

	June 30, 2022	Se	ptember 30, 2021
Cash and cash equivalents Prepaids and other assets	\$ 67,868 107,793	\$	137,825 60,341
Total assets	\$ 175,661	\$	198,166
Current liabilities Long-term debt Derivative liability Shareholders' deficiency	 4,034 111 - 171,516		3,930 210 20 194,006
Total liabilities and shareholders' equity	\$ 175,661	\$	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

		ee months ended	d ended		Nine months ended		Nine months ended	
	Jun	e 30, 2022	Jun	e 30, 2021	Ju	ine 30, 2022	Ju	ıne 30, 2021
OPERATING EXPENSES								
Research and development Financing costs	\$	6,395	\$	6,232 17	\$	20,064 11	\$	17,986 18
General and administration	_	2,896	_	3,118	_	9,77 <u>5</u>	_	9,942
Total operating expenses		(9,294)	_	(9,367)	_	(29,850)	_	(27,946)
Gain (loss) on derivative liability Other items	_	2 419		569 46	_	20 1,005		(470) 136
Net loss before taxes Income tax recovery	_	(8,873) 46	_	(8,752)		(28,825) 46		(28,280) <u>34</u>
Net loss and comprehensive loss for the period	\$	(8,827)	\$	(8,752)	\$	(28,779)	\$	(28,246)
Basic and diluted loss per	<b>c</b>	(0.00)	Φ	(0.04)	Φ.	(0.05)	Φ.	(0.70)
common share	\$	(0.20)	\$	(0.21)	\$	(0.65)	\$	(0.76)
Weighted average number of common shares outstanding		44,059,700		41,018,024		44,026,502		36,937,014

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