# ESSA Pharma Provides Corporate Update and Reports Financial Results for Fiscal First Quarter Ended December 31, 2022

Completion of Phase 1 EPI-7386 combination study with enzalutamide expected in 1H2023 followed by initiation of the randomized Phase 2 study

Phase 1b EPI-7386 monotherapy expansion study in mCRPC patients ongoing

**South San Francisco, California and Vancouver, Canada, February 7, 2023 -** 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, 2022. All references to "\$" in this release refer to United States dollars, unless otherwise indicated.

"Building on our momentum and encouraging clinical results observed in 2022, we continue to advance our studies of EPI-7386, ESSA's first-in-class N-terminal domain androgen receptor inhibitor, in patients with metastatic castration-resistant prostate cancer ("mCRPC")," stated David Parkinson, MD, President and CEO of ESSA. "In the first half of 2023, we expect to complete the Phase 1 EPI-7386 combination study with Xtandi® (enzalutamide) in patients with mCRPC naïve to second generation anti-androgens and to initiate the Phase 2 randomized study in the same patient population shortly thereafter. In addition, our cash runway continues to be strong and is expected to fund our operations and clinical programs through 2025."

## Clinical and Corporate Highlights for the First Quarter Ended December 31, 2022

#### **EPI-7386 Combination Studies**

- The Company continues to enroll patients in the third cohort of the Phase 1/2 study of EPI-7386 in combination with enzalutamide in patients with mCRPC naïve to second generation antiandrogens. The Company expects to complete the Phase 1 portion of the study and establish the recommended Phase 2 combination doses (for both EPI-7386 and enzalutamide when used in combination) in the first half of 2023, followed by initiation of the Phase 2 study. The open-label, randomized Phase 2 study will assess the antitumor activity of EPI-7386 in combination with enzalutamide at the recommended phase 2 combination dose of EPI-7386 and enzalutamide versus single agent enzalutamide at the standard of care dose.
- Initial results from the first two cohorts of the Phase 1/2 study of EPI-7386 in combination with enzalutamide
  were presented at the Prostate Cancer Foundation Scientific Retreat in October 2022. Further analysis of
  these data will be presented at the 2023 American Society of Clinical Oncology Genitourinary Cancers
  Symposium ("ASCO GU"), taking place February 16-19, 2023, in San Francisco, CA and online.
- The Company continues to anticipate that enrollment of additional combination regimens of EPI-7386 with other antiandrogens in different studies will begin in 2023 in different prostate cancer patient populations.

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

- The Phase 1b dose expansion study is ongoing and evaluating two doses/schedules of single agent EPI-7386 in mCRPC patients with less than three prior lines of therapy, no visceral disease and no prior chemotherapy who have progressed on second-generation antiandrogens
- The Company is continuing to seek to enroll patients in the Window of Opportunity study in non-metastatic CRPC patients. Patients will receive 12 weeks of EPI-7386 monotherapy treatment before starting standard of care therapy.

# Summary Financial Results

• **Net Loss**. ESSA recorded a comprehensive loss of \$6.7 million for the first quarter ended December 31, 2022, compared to a comprehensive loss of \$9.1 million for the first quarter ended December 31, 2021. For

the first quarter ended December 31, 2022, this included non-cash share-based payments of \$1.6 million compared to \$2.5 million for the prior year, recognized for stock options granted and vesting. The decrease in the first quarter was primarily attributed to decreases in research and development expenditures and general and administration expenditures in addition to an increase of \$1.1 million in interest income.

- Research and Development ("R&D") expenditures. R&D expenditures for the first quarter ended December 31, 2022 were \$5.3 million compared to \$6.0 million for the first quarter ended December 31, 2021 and include non-cash costs related to share-based payments (\$791,192 for the first quarter ended 2022 compared to \$1.3 million for the first quarter ended 2021). The R&D expenditures for the year ended December 31, 2022 is the result of decreased non-cash share-based payments, legal patents and license fees and manufacturing costs related to the Phase 1 clinical trial of EPI-7386.
- **General and administration ("G&A") expenditures.** G&A expenditures for the first quarter ended December 31, 2022 were \$2.5 million compared to \$3.1 million for the first quarter ended December 31, 2021 and include non-cash costs related to share-based payments of \$772,419 for the first quarter ended 2022 compared to \$1.2 million for the first quarter ended 2021. The decrease in the first quarter is the result of decreased non-cash share-based payments and professional fees.

#### Liquidity and Outstanding Share Capital

At December 31, 2022, the Company had available cash reserves and short-term investments of \$163.1 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 2025.

As of December 31, 2022, the Company had 44,092,374 common shares issued and outstanding.

In addition, as of December 31, 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 7,922,061 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$5.13 per common share.

#### **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="www.essapharma.com">@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 completion of the Phase 1 EPI-7386 monotherapy study and the Phase 1/2 combination study, enrollment in the monotherapy and combination studies, treatments under the Phase 1b dose expansion study, the Phase 1b Window of Opportunity study and the Phase 1/2 combination study evaluating EPI-7386 with enzalutamide, the initiation of the Phase 2 study, the assessment of anti-tumor activity in the monotherapy and combination studies, the presentation of initial results in the monotherapy and combination studies, and the Company's expected cash runway into 2025.

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 December 13, 2022 under the heading "Risk Factors", a copy of which is available on ESSA's profile on EDGAR at <a href="www.sec.gov.com">www.sec.gov.com</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

	De	ecember 31, 2022	Se	eptember 30, 2022
Cash and cash equivalents Prepaids and other assets	\$	51,221 113,782	\$	57,076 112,429
Total assets	\$	165,003	\$	169,505
Current liabilities Long-term debt Shareholders' deficiency		2,935 48 162,020		2,310 76 167,119
Total liabilities and shareholders' equity	\$	165,003	\$	169,505

**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, 2022		Three months ended December 31, 2021	
OPERATING EXPENSES  Research and development Financing costs General and administration	\$	5,344 2 2,519	\$	6,020 4 3,062	
Total operating expenses		(7,865)		(9,086)	
Loss on derivative liability Other items  Net loss before taxes	_	1,124 (6,741)	_	(99) <u>87</u> (9,098)	
Income tax recovery	_	(0,741)	_	(9,098)	
Net loss and comprehensive loss for the period	\$	(6,738)	\$	(9,097)	
Basic and diluted loss per common share	\$	(0.15)	\$	(0.21)	
Weighted average number of common shares outstanding		44,073,286		43,989,773	

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