

# ESSA PHARMA INC. REPORTS FINANCIAL RESULTS FOR THE FOURTH QUARTER AND YEAR ENDED SEPTEMBER 30, 2015

**Vancouver, Canada, and Houston, Texas, December 14, 2015 -** ESSA Pharma Inc. ("ESSA" or the "Company") (TSX: EPI, NASDAQ: EPIX) today reported financial results for the year ended September 30, 2015. Amounts, unless specified otherwise, are expressed in Canadian dollars and in accordance with International Financial Reporting Standards ("IFRS").

## Fourth Quarter and 2015 Year Highlights and Corporate Update

FDA Approval to Commence Clinical Development

On September 23, 2015, the U.S. Food and Drug Administration approved ESSA's Investigational New Drug ("IND") application to initiate a Phase 1/2 clinical study on its novel agent, EPI-506, for the treatment of metastatic castration-resistant prostate cancer ("CRPC") in patients who have failed current therapies.

Health Canada Approval to Commence Clinical Development

On November 5, 2015, the Health Protection Branch ("HPB") of Health Canada has issued a 'no objection letter' for the Clinical Trial Authorization ("CTA") application that ESSA has submitted. The HPB letter will allow ESSA to include Canadian sites in its Phase 1/2 clinical study.

Enrolment of First Patient in Phase 1/2 Trial

On November 24, 2015, the Company enrolled its first patient in the Phase 1/2 clinical study.

Receipt of US\$3.7m from the Cancer Prevention and Research Institute of Texas

The approval of the IND application triggered the receipt of an additional US\$3.7 million of funding from the Cancer Prevention and Research Institute of Texas ("CPRIT"). Under ESSA's agreement with CPRIT, a total of US\$12 million of grant funding (repayable out of potential product revenues) will be made available to the Company, of which US\$2.8 million had previously been received.

## Looking Forward

In its Phase 1/2 clinical trial, ESSA intends to demonstrate the safety, tolerability, maximum tolerated-dose, pharmacokinetics, and efficacy of EPI-506 in treating prostate cancer patients who have failed abiraterone or enzalutamide or both, the current standard-of-care drugs in metastatic CRPC. The trial is expected to enrol approximately 150 subjects.

## **Summary Results**

ESSA recorded a net loss of \$11.5 million (\$0.63 per common share) for the year ended September 30, 2015, compared to a net loss of \$2.0 million (\$0.13 per common share) for the year ended September 30, 2014. The net income for the fourth quarter of 2015 was \$0.1 million compared to a net loss of \$1.6 million for the fourth quarter of 2014. Recoveries from the CPRIT grant resulted in a net income for the fourth quarter of 2015 in addition to foreign exchange adjustments on the Company's U.S. dollars.

Research and Development ("R&D") expenditures for the year were \$5.9 million compared to \$0.7 million for 2014. The increase was primarily due to increased R&D activity related to preclinical work on the clinical candidate EPI-506 in support of the IND to the U.S. FDA and CTA application in Canada for the HPB. The Company recognized a recovery on R&D expenditures in the fourth quarter of 2015 of \$1.0 million compared to expenditures of \$0.5 million in the fourth quarter of 2014. The recovery in the fourth quarter of 2015 resulted from the timing of recoveries under the CPRIT grant.



General and administration expenditures for the year 2015 were \$6.5 million compared to \$1.2 million for the year 2014. General and administration expenditures for the fourth quarter of 2015 were \$2.8 million compared to \$1.0 million for the fourth quarter of 2014. The increase was primarily due to increased activity as a corporate entity as the Company successfully completed a listing on the TSX Venture Exchange in January 2015, a listing on the Nasdaq Capital Market (the "Nasdaq") in July 2015, and graduation to the TSX in July 2015.

## Liquidity and Outstanding Share Capital

Working capital as at September 30, 2015 was \$6.7 million, which included the subsequent receipt of US\$3.7 million from CPRIT following clearance of the IND with the FDA in September 2015, a significant milestone. Management has forecasted that the Company's working capital will not be sufficient to execute its planned expenditures for the coming year (see "Note 1" of the Company's consolidated financial statements). Accordingly the Company recognizes that additional funding will be required to continue operations. Management continues to seek sources of additional financing which would assure continuation of the Company's operations and research programs, however, there is no certainty that such financing will be provided or provided on favourable terms. The Company believes that it will complete one or more of these arrangements in sufficient time to continue to execute its planned expenditures without interruption.

As of September 30, 2015, the Company had 22,629,271 common shares issued and outstanding, 3,473,519 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$1.91 per share, and 282,489 common shares issuable upon the exercise of outstanding warrants at a weighted-average exercise price of \$3.52 per share.

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## About ESSA Pharma Inc.

ESSA Pharma is a development-stage pharmaceutical company focused on developing novel and proprietary therapies for the treatment of castration resistant prostate cancer ("CRPC") in patients whose disease is progressing despite treatment with current therapies. ESSA believes that its product candidate, EPI-506, can significantly expand the interval of time in which patients suffering from CRPC can benefit from hormone-based therapies. Specifically, EPI-506 acts by disrupting the androgen receptor ("AR") signaling pathway, which is the primary pathway that drives prostate cancer growth. We have shown that EPI-002, the primary metabolite of EPI-506, prevents AR activation by binding selectively to the N-terminal domain ("NTD") of the AR. A functional NTD is essential for activation of the AR. Blocking the NTD prevents activation of the AR by all of the three known mechanisms of activation. In pre-clinical studies, blocking the NTD has demonstrated the capability to overcome the known AR-dependent mechanisms of CRPC. ESSA was founded in 2009 and is headquartered in Vancouver, British Columbia, Canada.

## **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, 2012). Adenocarcinoma of the prostate is dependent on androgen for tumour progression and depleting or blocking androgen action has been a mainstay of hormonal treatment for over six decades. Although tumours are often initially sensitive to medical or surgical therapies that decrease levels of testosterone (for example, ADT), disease progression despite castrate levels of testosterone generally represents a transition to the lethal variant of the disease (mCRPC) and most patients ultimately succumb to the illness. The treatment of mCRPC patients has evolved rapidly



over the past five years; despite these advances, additional treatment options are needed to improve clinical outcomes in patients, particularly those who fail existing treatments including abiraterone or enzalutamide, or those that have contraindications to receive those drugs. Over time, patients with mCRPC generally experience continued disease progression, worsening pain, leading to substantial morbidity and limited survival rates. In both in vitro and in vivo studies, ESSA's novel approach to blocking the androgen pathway has been shown to be effective in blocking tumour growth when current therapies are no longer effective.

## Forward-Looking Statement Disclaimer

This release contains certain information which, as presented, constitutes "forward-looking information" within the meaning of 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 about the implementation of the Company's business model and strategic plans.

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) obtaining positive results of clinical trials; (ii) obtaining regulatory approvals; and (iii) 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 20-F dated December 14, 2015 under the heading "Risk Factors", a copy of which is available on ESSA's profile at the SEDAR website at <a href="https://www.sedar.com">www.sedar.com</a>, ESSA's profile on EDGAR at <a href="https://www.sec.gov">www.sec.gov</a>, and as otherwise disclosed from time to time on ESSA's SEDAR profile. 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 Canadian and United States securities laws. Readers are cautioned against attributing undue certainty to forward-looking statements.