



## ESSA Pharma Provides Business Update and Announces Fourth Quarter and Year Ended September 30, 2016 Financial Results

**Houston, Texas and Vancouver, Canada, December 14, 2016** - ESSA Pharma Inc. ("ESSA" or the "Company") (NASDAQ: EPIX, TSX: EPI), a clinical stage pharmaceutical company focused on developing novel therapies for prostate cancer, today reported financial results for the year ended September 30, 2016 and progress on its clinical development program.

### **2016 Business Highlights**

#### **Clinical Development**

"We continue to advance our lead clinical product candidate, EPI-506, in our Phase 1/2 clinical trial in men with metastatic castrate-resistant prostate cancer ("mCRPC"). This drug, which we believe works in a novel manner to inhibit androgen-driven pathways in prostate cancer, is being tested initially in men who have progressed after therapy with current generation anti-androgens," said David R. Parkinson, MD, President and Chief Executive Officer. "We are encouraged by the fact that the drug has been shown to be well-tolerated with a predictable pharmacokinetic profile to-date. We look forward to reporting the clinical results from the study following establishment of a Phase 2 dose."

The clinical trial continues to enroll patients in both the United States and Canada. Dose escalations have been informed by assessments of patients safety and a pharmacokinetic assessment of drug exposure.

- The study drug has been well tolerated in the clinical trial with a favorable safety profile to date.
- Patients are currently being dosed in the fifth cohort of the clinical trial. Initial dose selection in the clinical trial was estimated using allometric scaling from animal studies. Pharmacokinetic data from the clinical trial revealed lower study drug exposures than initially projected. As a result, more aggressive dose escalations were required.
- Pharmacokinetic assessments indicate dose-proportional exposure of study drug across all cohorts. The Company believes that the current dosing cohort may achieve study drug exposures similar to exposures associated with the minimally efficacious dose seen in prostate tumor animal models.
- ESSA hopes to establish a Phase 2 dose during calendar Q1 2017 and to commence the Phase 2 portion of the clinical trial thereafter.
- The Company has received regulatory clearance from the UK and French authorities to begin the Phase 2 portion of the clinical trial, pending review of the Phase 1 data.

**About the clinical trial:** The Company initiated the Phase 1/2 clinical trial of EPI-506 in late 2015. The clinical trial is designed to demonstrate the safety, tolerability, maximum tolerated-dose, pharmacokinetics and efficacy of EPI-506 in the treatment of prostate cancer patients who have failed treatments using abiraterone or enzalutamide or both, the current standard-of-care drugs in mCRPC.

The Phase 1 portion of the clinical trial is an open-label, adaptive 3 + 3 design, dose-escalation study. Enrolled patients may be allowed to escalate to a subsequent dose cohort after their initial 12 weeks. In addition to clinical, radiological and biochemical assessments including prostate specific antigen measurements, patients are being characterized biologically with respect to characteristics known to be associated with resistance to currently used anti-androgens. These assessments include expression of androgen receptor ("AR") splice variants in circulating tumor cells, assessment of AR copy number, and mutations in circulating free DNA. The Phase 1 portion of the clinical trial is being conducted in 5 institutions in the United States and Canada.

The Phase 2 portion of the clinical trial will begin following the establishment of a Phase 2 dose and will be conducted in the United States, Canada, the UK, and France, in patients with prostate cancer resistant to the newer generation anti-androgens. It is a single-arm, open-label study, with a primary



endpoint of number of patients demonstrating a 50% decline in prostate specific antigen ("PSA"), as well as radiographic progression.

Additional data about the study can be found at [ClinicalTrials.gov](http://ClinicalTrials.gov).

**Recent Scientific Publications Regarding EPI- Compounds:** In 2016, several important publications were published concerning the biochemical and biological effects of the EPI- series of compounds, adding to our understanding of their mechanism of action. Published studies have described how the EPI compounds specifically bind to the Tau5 region of the androgen receptor N-terminal domain, thereby uniquely and selectively inhibiting AR-driven gene transcription, and forming the basis for active inhibition of the AR pathway in men with castrate-resistant prostate cancer, even in the setting of resistance to currently-used anti-androgens. Further details regarding the publications discussed herein can be found on the Company's website.

### **2016 Year Financial Highlights**

Amounts disclosed herein, unless specified otherwise, are expressed in United States dollars and in accordance with International Financial Reporting Standards ("IFRS"). References to "\$" are to United States dollars and references to "C\$" are to Canadian dollars.

- **Receipt of \$3.8 million from the Cancer Prevention and Research Institute of Texas.** The approval of the Investigational New Drug ("IND") application in September 2015 triggered the receipt of an additional \$3.8 million of funding from the Cancer Prevention and Research Institute of Texas ("CPRIT"). Under ESSA's agreement with CPRIT, a total of \$12.0 million of grant funding (repayable out of potential product revenues) will be made available to the Company, of which \$2.8 million had previously been received.
- **Closed \$20.0 million in Private Placements.** On January 14, 2016 the Company completed a private placement for aggregate gross proceeds of approximately \$15.0 million led by Clarus Lifesciences (the "January 2016 Financing"; see news release dated January 14, 2016). On March 21, 2016, the Company closed a private placement to Eventide Funds for gross proceeds of \$5.0 million (the "March 2016 Financing"; see news release dated March 21, 2016).
- **Receipt of \$10.0 million term loan from Silicon Valley Bank.** On November 18, 2016, the Company entered into a term loan agreement with Silicon Valley Bank, pursuant to which the Company has drawn down \$8.0 million, with an option for an additional \$2.0 million by April 30, 2017, conditional on positive data from the ongoing Phase 1 clinical trial and receipt of the \$5.4 million balance of the grant from CPRIT.

### **Summary Financial Results**

- **Net Income (Loss).** ESSA recorded a net loss of \$13.1 million (\$0.49 per common share) for the year ended September 30, 2016, compared to a net loss of \$9.7 million (\$0.53 per common share) for the year ended September 30, 2015. The net loss for the fourth quarter of 2016 was \$4.2 million compared to a net income of \$0.5 million for the fourth quarter of 2015.
- **Research and Development ("R&D") expenditures.** R&D expenditures for the year were \$13.6 million compared to \$5.0 million, net of grants (\$10.4 million gross), for the year ended September 30, 2015. For the fourth quarter ended September 30, 2016, R&D expenditures were \$3.9 million compared to a recovery of \$0.8 million, net of grants (\$3.1 million gross), for the fourth quarter ended September 30, 2015. Increases in R&D expenditures for the full year and fourth quarter were primarily related to manufacturing and clinical costs as the Company continues its clinical development of EPI-506. In the quarter ended December 31, 2015, the Company commenced enrolling patients into its Phase 1/2 clinical trial. The composition of R&D costs has therefore evolved from preclinical and IND application work in the year ended September 30, 2015 to



include clinical, manufacturing and additional staff salaries in the year ended September 30, 2016.

- **General and administration ("G&A") expenditures.** G&A for the year ended September 30, 2016 were \$5.6 million compared to \$5.3 million for the year ended September 30, 2015. The increase was primarily due to increased activity as a public corporate entity, and additional general and administrative expenditures to support the clinical development of EPI-506. For the fourth quarter ended September 30, 2016, G&A was \$1.2 million compared to \$2.2 million for the fourth quarter ended September 30, 2015. The decrease for the fourth quarter was primarily due to decreased professional, regulatory, and listing fees, which in the prior quarter were incurred in relation to the Company's initial listings on the NASDAQ and TSX.

### ***Liquidity and Outstanding Share Capital***

Working capital as at September 30, 2016 was \$6.4 million. In November 2016, the Company secured a \$10.0 million term loan (see news release dated November 21, 2016). Management believes, assuming completion of the Phase 1 clinical trial in the first quarter of calendar 2017, that the term loan, together with the Company's existing capital, will provide the Company with sufficient funds to (i) complete EPI-506's Phase 1 clinical trial, (ii) trigger a \$5.4 million grant under the CPRIT program at completion of the Phase 1 clinical trial and (iii) commence EPI-506's Phase 2 portion of the clinical trial. The Phase 1 portion is anticipated to complete in the first quarter of calendar 2017, depending on the enrollment rate and number of dose escalation steps. Management continues to consider sources of additional financing which would assure continuation of the Company's operations and research programs.

As of September 30, 2016, the Company had 29,096,889 common shares issued and outstanding, 4,062,519 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of C\$2.76 per common share, and 7,099,541 common shares issuable upon the exercise of outstanding warrants at a weighted-average exercise price of \$3.28 per common share.

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### **About ESSA Pharma Inc.**

ESSA Pharma is a clinical-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. EPI-506 acts by disrupting the AR signaling pathway, which is the primary pathway that drives prostate cancer growth. 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.



## 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 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 (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 tumor growth when current therapies are no longer effective.

## Forward-Looking Statement Disclaimer

*Certain statements in this news release contain forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995 and/or Canadian securities laws that may not be based on historical fact, including without limitation, statements containing the words "believe", "may", "plan", "will", "estimate", "continue", "anticipate", "intend", "expect" and similar expressions. Forward-looking statements in this news release include, but are not limited to, statements regarding the Phase 1 clinical trial, including the drug exposures of the current dosing cohort, the anticipated results and the completion thereof, the Phase 2 clinical trial, including details and anticipated timing thereof, and the expected location and number of Phase 2 clinical trial centres, the sufficiency of ESSA's funds to execute the Phase 1 portion of the Phase 1/2 clinical trial and possible future financings by ESSA.*

*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 the accuracy of ESSA's financial projections and the Phase 1 portion of the Phase 1/2 clinical trial proceeding as expected.*

*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, 2016 under the heading "Risk Factors", a copy of which is available on ESSA's profile on the SEDAR website at [www.sedar.com](http://www.sedar.com), ESSA's profile on EDGAR at [www.sec.gov](http://www.sec.gov), 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.*

## **ESSA PHARMA INC.**

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

Unaudited (Amounts in thousands)

As at September 30,

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	2016		2015	
Cash	\$	8,985	\$	1,579
Prepaid and other assets		<u>1,417</u>		<u>5,961</u>
<b>Total assets</b>	<b>\$</b>	<b>10,402</b>	<b>\$</b>	<b>7,540</b>
Current liabilities		3,630		2,091
Derivative liability		7,309		993
Shareholders' equity (deficiency)		<u>(537)</u>		<u>4,456</u>
<b>Total liabilities and shareholders' equity (deficiency)</b>	<b>\$</b>	<b>10,402</b>	<b>\$</b>	<b>7,540</b>

### ESSA PHARMA INC.

#### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

Amounts in thousands, except share and per share data

	Three months ended		Year ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
<b>OPERATING EXPENSES</b>				
Research and development	\$ 3,952	\$ (792)	\$ 13,060	\$ 4,976
Financing costs	-	31	938	94
General and administration	<u>1,237</u>	<u>2,178</u>	<u>5,644</u>	<u>5,259</u>
Total operating expenses	<u>(5,189)</u>	<u>(1,417)</u>	<u>(19,642)</u>	<u>(10,329)</u>
Gain (loss) on derivative liability	1,041	1,124	6,574	(908)
Other items	<u>2</u>	<u>781</u>	<u>79</u>	<u>1,560</u>
Net income (loss) for the year before taxes	(4,146)	488	(12,989)	(9,677)
Income tax expense	<u>(91)</u>	<u>-</u>	<u>(151)</u>	<u>-</u>
<b>Net income (loss) for the year</b>	<b>\$ (4,237)</b>	<b>\$ 488</b>	<b>\$ (13,140)</b>	<b>\$ (9,677)</b>
Basic and diluted loss per common share	\$ (0.15)	\$ 0.03	\$ (0.49)	\$ (0.53)
Weighted average number of common shares outstanding	26,903,834	18,353,018	26,903,834	18,353,018