

# ESSA Pharma Provides Corporate Update and Reports Financial Results for Fiscal Fourth Quarter and Year Ended September 30, 2019

Vancouver, Canada and Houston, Texas, December 19, 2019 - ESSA Pharma Inc. ("ESSA", or the "Company") (NASDAQ: EPIX, TSX-V: EPI), a 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 year ended September 30, 2019. All references to "\$" in this release refer to United States dollars, unless otherwise indicated.

"This past year was ESSA's most significant year of progress towards its goal of developing a novel prostate cancer therapy. Our discovery efforts led to the selection of a next generation N-terminal domain inhibitor of the androgen receptor ("aniten"), EPI-7386, that was nominated as the IND candidate. Preclinically, this potent compound exhibits a long half-life, and excellent pharmaceutical properties, while also demonstrating on-target specificity and anti-tumor activity against prostate cancer cell lines and animal models resistant to currently used anti-androgens. Preparations for an IND filing continue to advance and we remain on track to file the IND in the first quarter of 2020 with an initiation of the Phase 1 study of EPI-7386 expected in the first half of 2020," stated David Parkinson, MD, President and CEO of ESSA.

Dr. Parkinson continued, "With the \$56 million raised through the acquisition of Realm Therapeutics, plc and the subsequent private placement, the Company has sufficient funds to complete the Phase 1 monotherapy dose-escalation study and an expansion phase to that study. In addition, the Company believes it is funded to be able to conduct a combination study of EPI-7386 with currently utilized antiandrogens in prostate cancer patients with earlier stages of the disease. 2020 will be another important year as we commence clinical development of EPI-7386 as a single agent in advanced prostate cancer as well as in combination with standard of care anti-androgens in earlier lines of therapy. The Phase I clinical trial will be conducted in men whose tumors are progressing (and therefore PSA levels are rising) despite therapy with one of the latest generation anti-androgen therapies. While patients will be selected for the trial on the basis of clinical considerations, a series of biological studies will characterize their individual tumor biology. In addition, we will continue the characterization of other aniten molecules in our pre-clinical pipeline."

### Clinical and Corporate Highlights for 2019 Fiscal Year

- On March 28, 2019, the Company nominated EPI-7386 as the lead clinical candidate for the treatment of metastatic castration-resistant prostate cancer ("mCRPC")
- On July 15, 2019, the Company appointed Dr. Alessandra Cesano as Chief Medical Officer
- On July 31, 2019, the Company completed the acquisition of Realm Therapeutics, plc ("Realm"), which provided the Company with approximately \$20M in additional funds
- On August 23, 2019, the Company closed an equity financing for gross proceeds of \$36 million
- In October, the Company paid off the balance of its \$3.6M debt facility, leaving the Company with no outstanding debt
- Throughout the year, at multiple scientific conferences, the Company presented preclinical data characterizing the preclinical profile of EPI-7386 in various prostate cancer preclinical models

### Summary Financial Results

- **Net Income (Loss)**. ESSA recorded a net loss of \$10.4 million (\$1.24 loss per common share based on 8,433,441 weighted average common shares outstanding) for the year ended September 30, 2019, compared to a net loss of \$11.6 million (\$2.55 loss per common share based on 4,566,519 weighted average common shares outstanding) for the year ended September 30, 2018. The net loss for the fourth quarter ended September 30, 2019 was \$1.0 million compared to a net loss of \$2.3 million for the fourth quarter ended September 30, 2018.
- Research and Development ("R&D") expenditures. R&D expenditures for the year ended September 30, 2019 were \$6.7 million compared to \$4.9 million for the year ended September 30, 2018. For the fourth quarter ended September 30, 2019, R&D expenditures were \$2.0 million (net and gross), as compared to \$0.9 million net of grants (\$1.2 million gross) for the fourth quarter ended September 30, 2018. The increase



in R&D expenditures for the full year and fourth quarter were primarily related to ESSA's efforts in preparing an Investigational New Drug ("IND") application for its recently nominated clinical candidate, EPI-7386. Costs in the comparative period included preclinical research related to the Company's next-generation aniten compounds.

• General and administration ("G&A") expenditures. G&A expenditures for the year ended September 30, 2019 were \$5.5 million compared to \$5.9 million for the year ended September 30, 2018. For the fourth quarter ended September 30, 2018, G&A expenditures were \$1.3 million, compared to \$1.2 million for the fourth quarter ended September 30, 2018. The decrease in the full year is the result of a reduction in share-based payments, rent expense, and professional fees. The increase in the fourth quarter is a result of increased corporate activity following the acquisition of Realm, including directors fees, investor relations, and regulatory fees.

# Liquidity and Outstanding Share Capital

Cash on hand at September 30, 2019 was \$53.3 million, with working capital of \$48.7 million, reflecting the aggregate gross proceeds of the completed August 2019 financing of \$36 million, the acquisition of Realm which provided the Company with \$22.2 million in cash, less operating expenses in the intervening period.

As of September 30, 2019, the Company had 20,762,374 common shares issued and outstanding.

In addition, as of September 30, 2019 there were 12,393,092 common shares issuable upon the exercise of warrants and broker warrants. This includes 11,919,404 prefunded warrants at an exercise price of \$0.0001, and 473,688 other warrants at a weighted average exercise price of \$34.36. There are 5,314,000 common shares issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$3.19 per common share.

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## About ESSA Pharma Inc.

ESSA is a pharmaceutical company focused on developing novel and proprietary therapies for the treatment of castration-resistant prostate cancer in patients whose disease is progressing despite treatment with current therapies. ESSA's proprietary "aniten" compounds bind to the N-terminal domain of the androgen receptor ("AR"), inhibiting AR driven transcription and the AR signaling pathway in a unique manner which bypasses the drug resistance mechanisms associated with current anti-androgens. The Company is currently progressing IND-enabling studies and expects to file an IND with the U.S. Food and Drug Administration ("FDA") for EPI-7386 in the first calendar quarter of 2020. For more information, please visit www.essapharma.com or follow us on Twitter under @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 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 who 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 animal 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

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 preparation and expected timing of an IND filing with the FDA for EPI-7386, a Phase 1 study of EPI-7386, a combination study of EPI-7386 and other statements surrounding the Company's clinical evaluation of EPI-7386.

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 20-F dated December 19, 2019 under the heading "Risk Factors", a copy of which is available on ESSA's profile on the SEDAR website at www.sedar.com, ESSA's profile on EDGAR at 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.

Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.



## **ESSA PHARMA INC.**

# CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(Unaudited)

Amounts in thousands of United States dollars

		September		September
		30, 2019		30, 2018
Cash Prepaid and other assets	\$	53,323 1,451	\$	14,829 1,188
Total assets	\$	54,774	\$	16,017
Current liabilities Long-term debt Derivative liability Shareholders' deficiency	_	5,575 - 18 49,181	_	3,344 3,501 20 9,152
Total liabilities and shareholders' deficiency	\$	54,774	\$	16,017

# **ESSA PHARMA INC.**

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

Amounts in thousands of United States dollars, except share and per share data

	Т	hree months	Th	ree months				
	_	ended	_	ended		Year ended		Year ended
	Se	eptember 30,	Se	ptember 30,	Se	ptember 30,	Sep	otember 30,
		2019		2018		2019		2018
OPERATING EXPENSES								
Research and development	\$	,	\$	927	\$	6,696	\$	4,873
Financing costs		119		207		603		912
General and administration	_	1,251		1,211	_	5,473		5,929
Total operating expenses		(3,375)		(2,345)		(12,772)		(11,714)
Gain (loss) on derivative liability Gain on acquisition of Realm Other items	_	(10) 2,333 <u>52</u>		21 - 53		1 2,333 <u>35</u>		151 - (39)
Net loss before taxes Income tax expense	_	(1,000)		(2,271) (5)		(10,403) (38)		(11,602) (27 <u>)</u>
Net loss for the period	\$	(1,000)	\$	(2,276)	\$	(10,441)	\$	(11,629)
Basic and diluted loss per	\$	(0.07)	\$	(0.30)	\$	(1.24)	\$	(2.55)
common share	Φ	(0.07)	Ф	(0.39)	Ф	(1.24)	Ф	(2.55)
Weighted average number of common shares outstanding		14,665,230		5,776,098		8,433,441		4,566,519