
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): February 11, 2021

ESSA Pharma Inc.
(Exact name of registrant as specified in its charter)

British Columbia, Canada (State or other jurisdiction of incorporation)	001-37410 (Commission File Number)	47-2569713 (IRS Employer Identification No.)
Suite 720, 999 West Broadway, Vancouver, British Columbia, Canada (Address of principal executive offices)		V5Z 1K5 (Zip Code)

Registrant's telephone number, including area code: **(778) 331-0962**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Shares, no par value	EPIX	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On February 8, 2021, ESSA Pharma Inc. announced the presentation of a poster illustrating favorable initial Phase 1 clinical pharmacology data on EPI-7386 for advanced forms of prostate cancer at the 2021 ASCO Genitourinary Cancers Symposium. A copy of the related press release is attached as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 11, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ESSA PHARMA INC.

(Registrant)

Date: February 11, 2021

By: /s/ David Wood

Name: David Wood

Title: Chief Financial Officer



ESSA Pharma Presents Favorable Initial Phase 1 Clinical Pharmacology Data of EPI-7386 for Advanced Forms of Prostate Cancer at the 2021 ASCO Genitourinary Cancers Symposium

Vancouver, Canada and Houston, Texas, February 11, 2021 - 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 will present preclinical and clinical pharmacology data from ESSA’s Phase 1 clinical trial of EPI-7386 for the treatment of patients with metastatic castration-resistant prostate cancer (“mCRPC”) at the 2021 American Society of Clinical Oncology Genitourinary (“ASCO GU”) Cancers Symposium. EPI-7386, ESSA’s lead product candidate, is an investigational, highly-selective, oral, small molecule inhibitor of the androgen receptor’s N-terminal domain. ASCO GU is being held virtually from Thursday, February 11 to Saturday, February 13, 2021.

The oral poster presentation titled, “Preclinical and clinical pharmacology of EPI-7386, an androgen receptor N-terminal domain inhibitor for castration-resistant prostate cancer,” will be presented and available for viewing starting February 11 at 8:00am ET.

Data highlights compare preclinical projections of EPI-7386’s clinical pharmacokinetic parameters to the pharmacokinetic, safety and preliminary clinical data from the initial 200 mg cohort of patients enrolled in ESSA’s multi-center, open-label, ascending multiple-dose Phase 1 study of EPI-7386 to treat patients with mCRPC who have become resistant to standard of care treatments. Patients participating in this trial have progressed on two or more approved systemic therapies for mCRPC, including at least one second generation antiandrogen therapy not necessarily in the metastatic disease setting. In this initial cohort of patients receiving the 200 mg once-daily dose, EPI-7386 was well-tolerated with no SAEs observed. The results from this cohort support ESSA’s preclinical projections regarding the pharmacologic properties of EPI-7386 in patients. EPI-7386 was well-absorbed, demonstrated high exposure levels and was confirmed to have a long half life of at least 24 hours. The predicted exposures of EPI-7386 in patients were similar to our modeled projections and were still below optimal target exposures of EPI-7386 associated with anti-tumor activity in animal models. Despite the suboptimal 200 mg dose, one out of three patients who completed 12 weeks of therapy experienced a prostate specific antigen (“PSA”) decline of more than 50 percent after three cycles of EPI-7386 therapy (12 weeks) with ongoing continued PSA declines continuing through six cycles of therapy, despite previously having failed enzalutamide and abiraterone acetate. ESSA recently completed the 28-Day safety evaluation period for the 400mg dose cohort and is currently dosing patients in the 600 mg cohort.

“The results from the initial clinical data are encouraging and suggest a favorable pharmacokinetic profile of EPI-7386 in patients,” said Dr. David R. Parkinson, President and Chief Executive Officer of ESSA Pharma Inc. “Additionally, the data demonstrate proof of concept by suggesting that EPI-7386, through its novel mechanism of action of targeting the N-terminal domain, may bypass the resistant mechanisms mCRPC patients may experience on current antiandrogen therapies. While early in our clinical study, we are encouraged to have seen early signs of biological activity and declining PSA levels in a multi-refractory patient at the initial 200 mg dose. An accurate assessment of the full safety and tolerability profile as well as the potential clinical benefits to therapy with EPI-7386 will require longer observation of more patients treated at higher doses. We look forward to continuing to conduct our Phase 1 dose escalation study and anticipate providing more clinical data on the progress of the study in the second half of 2021.”

The poster is available on the ASCO GU Virtual Symposium and on the “Events & Presentations” section of the Company’s website at www.essapharma.com.

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 metastatic castration-resistant prostate cancer (“mCRPC”) whose tumors have progressed on current standard-of-care therapies. The Phase I clinical trial of EPI-7386 began in calendar Q3 of 2020 following FDA allowance of the IND and Health Canada acceptance. 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 suffering from prostate cancer. For more information, please visit www.essapharma.com and follow us on Twitter under [@ESSAPharma](https://twitter.com/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 can lead to metastatic castrate-resistant prostate cancer ("mCRPC"). The treatment of mCRPC patients has evolved rapidly over the past ten years. Despite these advances, many patients with mCRPC fail or develop resistance to existing treatments, leading to continued disease progression and limited survival rates.

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 pharmacokinetic profile of EPI-7386 in patients and the data demonstrating proof of concept by suggesting that EPI-7386 may bypass the resistant mechanisms mCRPC patients may experience on current antiandrogen therapies, the anticipated release of more clinical data on the progress of the study in the second half of 2021 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 10-K dated December 15, 2021 under the heading "Risk Factors", a copy of which is available on ESSA's profile on EDGAR at www.sec.gov, and as otherwise disclosed from time to time on ESSA's SEDAR profile www.sedar.com. 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.

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