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Essa Pharma Inc

(EPIX-NASDAQ)

EPIX: *New Preclinical Data for EPI-7386 Presented at ESMO 2019…*

Based on our probability adjusted DCF model that takes into account potential future revenues from EPI-7386, EPIX is valued at $6/share. This model is highly dependent upon continued clinical success of EPI-7386 and will be adjusted accordingly based upon future clinical results.

Current Price (10/11/19)	$3.11
Valuation	**$6.00**

OUTLOOK

On September 28, 2019, ESSA Pharma Inc. (EPIX) announced new preclinical data on its lead drug candidate was presented at the European Society of Medical Oncology (ESMO) 2019 Congress. The poster presentation described the activity of EPI-7386 in multiple cellular models, including those that are driven by full length androgen receptor (AR) and AR-V7 splice variants. The drug exhibited a wide therapeutic index based on the broad dose response and high plasma exposures seen in the animal models using a new suspension formulation. An IND filing is expected in the first quarter of 2020 with a Phase 1 study initiating shortly thereafter.

SUMMARY DATA

52-Week High	**$4.09**
52-Week Low	**$1.46**
One-Year Return (%)	**-5.09**
Beta	**1.90**
Average Daily Volume (sh)	**21,170**
Shares Outstanding (mil)	**15**
Market Capitalization ($mil)	**$46**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**69**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**-4.5**
P/E using 2021 Estimate	**-5.8**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 A	0 A	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2018	-$1.40 A	-$0.83 A	-$0.50 A	-$0.39 A	-$2.55 A
2019	-$0.42 A	-$0.54 A	-$0.52 A	-$0.18 E	-$1.33 E
2020					-$0.48 E
2021					-$0.53 E

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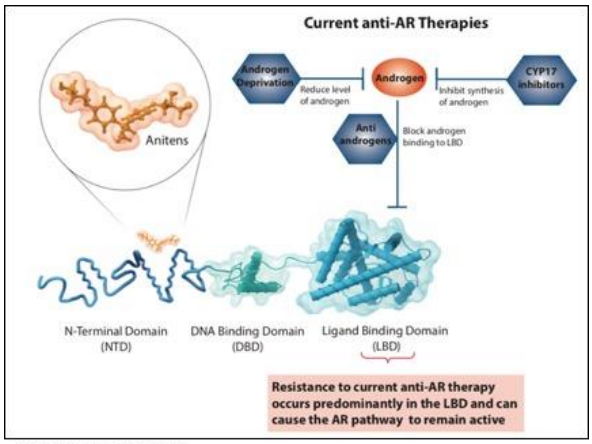
WHAT'S NEW

Business Update

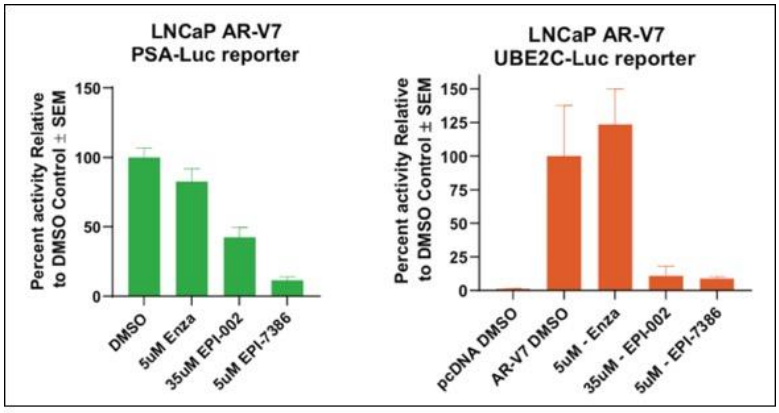
New Preclinical Data for EPI-7386 Presented at ESMO

On September 28, 2019, ESSA Pharma Inc. (EPIX) announced new preclinical data was presented at the European Society of Medical Oncology (ESMO) 2019 Congress. ESSA Pharma is developing a novel class of compounds, known as 'anitens', to treat prostate cancer in patients that are progressing on standard of care therapy. Anitens target the androgen receptor (AR), which is the main signaling mechanism driving the growth of prostate tumors, through binding of the N-terminal domain (NTD), which is unique compared to other available anti-androgen therapies. The company has completed a Phase 1 trial with a first-generation aniten compound, EPI-506, that confirmed the safety and tolerability of this class of compounds. However, due to its short half-life and other negative pharmaceutical properties, the development of EPI-506 was discontinued while research continued on the development of next-generation anitens. This work led to the discovery of EPI-7386, a next-generation aniten that has a number of advantages compared to first-generation anitens. The following graphic shows where anitens bind on the AR compared to currently available anti-AR therapies, which fully differentiates them from other prostate cancer therapies that target the AR.



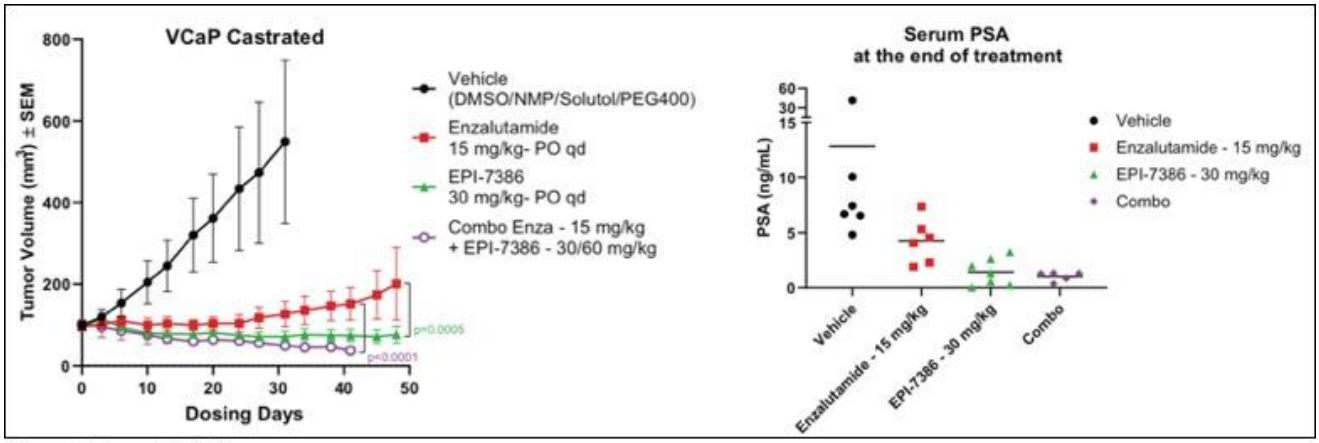
Source: Moigne *et al.*, 2019

The following figures show the activity and selectivity of anitens in two AR-V7 models. AR V7 is a splice variant of AR that lacks the LBD and is correlated with poor survival, progression, and resistance to anti-androgen therapy. LNCaP cells were transfected with a PSA-luciferase reporter gene, which can be activated by both AR WT and AR-V7 (although it is predominantly driven by AR-V7 in this model), or a UBE2C-luciferase reporter gene, which can be activated only by AR-V7. The cells were then treated with DMSO control, enzalutamide, EPI-002 (a first generation aniten), or EPI-7386. The results show that EPI-7386 inhibits AR activity in both assays. In contrast, enzalutamide did not show activity in either assay (the slight decrease in reporter gene activity in the PSA-luciferase assay was not statistically significant).



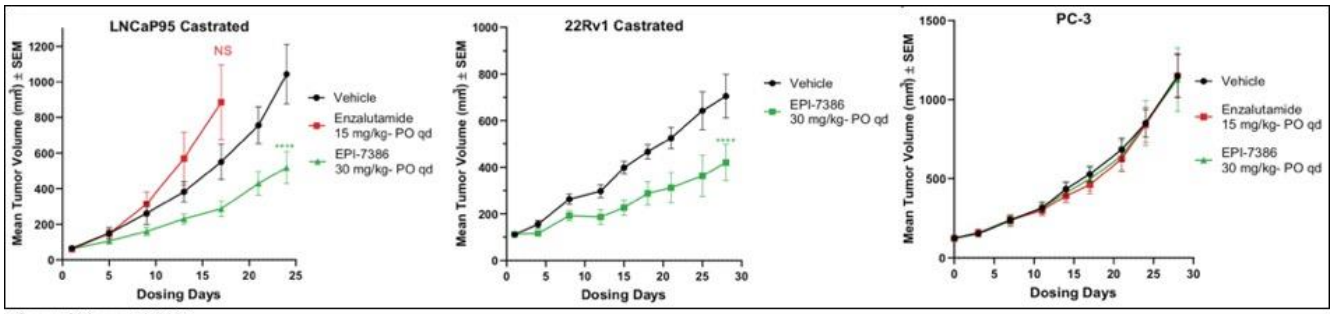
Source: Moigne *et al.*, 2019

The VCaP model of prostate cancer is initially driven by AR WT but then evolves to be an AR-V7 driven cancer. Thus, enzalutamide is active during the initial treatment period but is then no longer active. In contrast, EPI-7386 shows activity against VCaP tumors throughout the entire dosing period. Interestingly, the combination of enzalutamide and EPI-7386 shows superior activity to EPI-7386 monotherapy. This is shown by the graph of tumor growth (lower left) as well as the expression of PSA, which is substantially reduced at the end of treatment (lower right).



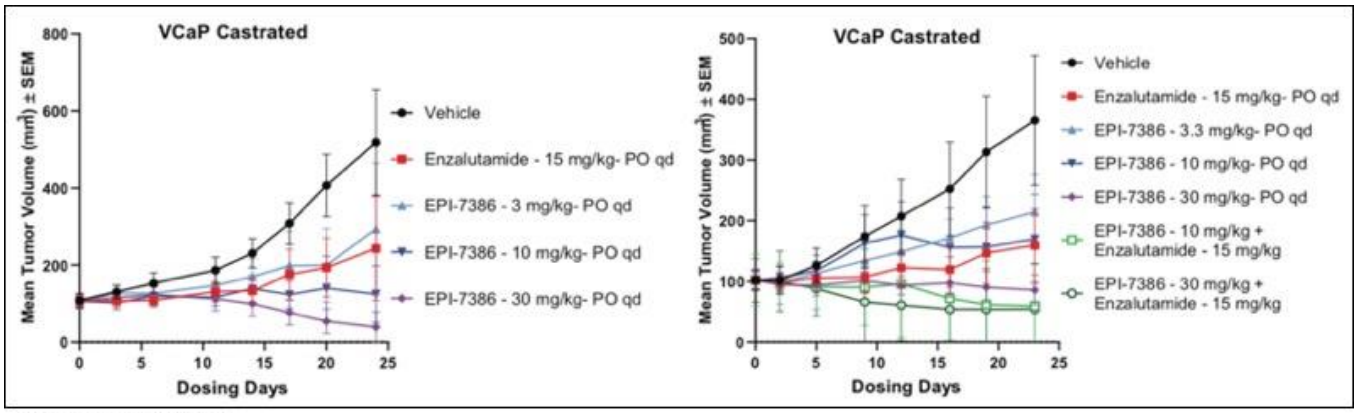
Source: Moigne *et al.*, 2019

EPI-7385 also shows activity in enzalutamide-resistant tumors in castration models such as LNCaP95 (lower left) and 22Rv1 (lower middle), while neither enzalutamide nor EPI-7836 show activity against PC-3 tumors, which express a non-functional AR.



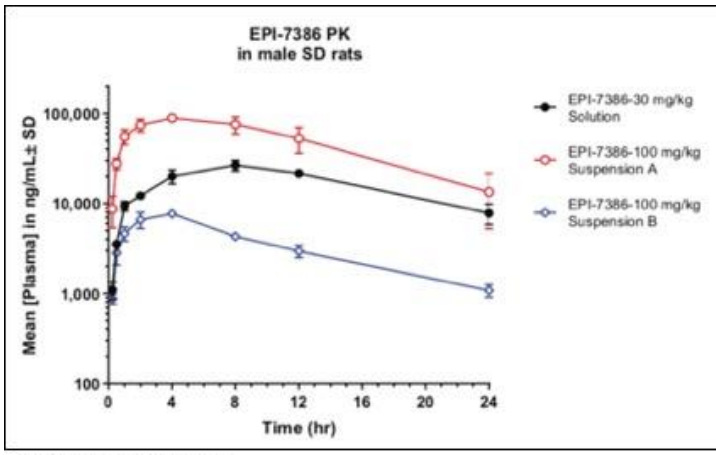
Source: Moigne *et al.*, 2019

A dose response study showed that EPI-7386 has a wide therapeutic index. The following graphs show that as a single agent, EPI-7386 shows increasing anti-tumor activity from 3 mg/kg to 30 mg/kg (left image) and also shows a dose response in combination with enzalutamide (right image).



Source: Moigne *et al.*, 2019

Lastly, the company showed that high exposure levels were attainable with EPI-7386 formulated as a suspension formulation. The following graph shows the pharmacokinetic (PK) profile for EPI-7386 following a single dose at 30 mg/kg or as a solution formulation at 100 mg/kg as two different suspension formulations, with the table listing the PK parameters.



Formulation	Dose (mg/kg)	Cmax (ng/mL)	Tmax (h)	T1/2 (h)	AUC0-last (ng*h/mL)
Solution	30	26800	9.3	7.6	399,000
Suspension A	100	89800	5.3	6.2	1,180,000
Suspension B	100	7800	3.3	8.1	82,600

Source: Moigne *et al.*, 2019

EPI-7386 Development Plan

We anticipate the company filing an IND in the first quarter of 2020 and a Phase 1 clinical trial initiating soon thereafter in patients who are resistant to second-generation anti-androgen therapies (e.g., enzalutamide). The trial will include both a dose escalation phase and a dose expansion phase. The primary objective of the dose escalation portion is to establish the safety and efficacy of EPI-7386 with the secondary objective being to determine the maximum tolerated dose and the recommended Phase 2 dose. In the dose expansion portion of the trial, the primary objective will be to further evaluate the safety, tolerability, and preliminary anti-tumor activity of the recommended Phase 2 dose. The company is also planning to initiate a combination trial with EPI-7386 and a 'lutamide' (enzalutamide, apalutamide, or darolutamide) in mCRPC patients due to the robust preclinical data showing increased activity with combination therapy. Due to the recent $36 million financing, the company has sufficient capital to conduct all three trials (the dose escalation trial, the dose expansion trial, and the combination trial).

Valuation

We value ESSA using a probability adjusted discounted cash flow model that takes into account potential future revenues for EPI-7386. We model for ESSA to partner the asset and to receive a 15% royalty on net sales.

For EPI-7386, we estimate that the company will initiate a Phase 1 trial in 2020, a Phase 3 trial in 2023, and file for approval in 2025. While the opportunity could exist for accelerated approval with exceptional results, we believe our timeframe is a bit more conservative of an estimate. For the initial indication, which is patients with mCRPC who are no longer responding to therapy, we estimate there are approximately 30,000 in the U.S. and 80,000 in the E.U. who would be eligible for treatment based on the number of deaths attributed to prostate cancer each year. While this represents a potential billion dollar opportunity on its own, we believe the much larger opportunity exists in combination therapy with earlier stage patients. We estimate there are approximately 160,000 patients who have either non-metastatic CRPC, metastatic hormone sensitive PC, or ADT-failing metastatic CRPC. When including these patients in our model we believe EPI-7386 could achieve peak sales of $4 billion worldwide. Using a 25% chance of approval along with a 13.5% discount rate leads to a net present value for EPI-7386 of $154 million. Combining the net present value of EPI-7386 with the company's current estimated cash balance and dividing by an estimated fully diluted share count of 34.1 million (excluding warrants that are priced at $42.80 and $66 per share) leads to a valuation of approximately $6 per share.

PROJECTED FINANCIALS

ESSA Pharma Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 E
EPI-7386	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$4.9	$1.3	$1.5	$2.0	$1.6	$6.3	$8.0	$10.0
Financing Costs	$0.9	$0.2	$0.2	$0.1	$0.2	$0.7	$0.8	$0.8
General & Administrative	$5.9	$1.2	$1.8	$1.2	$1.8	$6.0	$7.0	$7.3
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($11.7)	($2.7)	($3.4)	($3.3)	($3.6)	($13.0)	($15.8)	($18.1)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($11.6)	($2.7)	($3.4)	($3.3)	($3.6)	($13.0)	($15.8)	($18.1)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($11.6)**	**($2.7)**	**($3.4)**	**($3.3)**	**($3.6)**	**($13.0)**	**($15.8)**	**($18.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.55)**	**($0.43)**	**($0.54)**	**($0.52)**	**($0.18)**	**($1.33)**	**($0.48)**	**($0.53)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	4.6	6.3	6.3	6.4	20.0	9.8	33.0	34.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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