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Essa Pharma Inc

(EPIX-NASDAQ)

EPIX: *EPI-7386 IND Filed…*

Based on our probability adjusted DCF model that takes into account potential future revenues from EPI-7386, EPIX is valued at $9.50/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 (04/02/20)	$4.00
Valuation	**$9.50**

OUTLOOK

On March 31, 2020, Essa Pharma Inc. (EPIX) announced it had filed an Investigational New Drug (IND) application with the FDA for EPI-7386, the company's lead clinical candidate. The company is planning to initiate a Phase 1 clinical trial of EPI-7386 in patients with metastatic castration-resistant prostate cancer (mCRPC). Approximately 18 patients will be enrolled in a standard 3+3 trial design with an additional 10 patients enrolled in the dose expansion cohort. The company had approximately $45.9 million in cash as of Dec. 31, 2019, which is enough to fund operations through September 2022, thus the company has sufficient capital to fund operations through the Phase 1 dose-escalation study, the expansion phase, and a combination study of EPI-7386 with antiandrogen therapy in earlier stage CRPC patients.

SUMMARY DATA

52-Week High	**$6.00**
52-Week Low	**$1.46**
One-Year Return (%)	**16.21**
Beta	**1.76**
Average Daily Volume (sh)	**35,111**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$79**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**67**
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	**-4.9**
P/E using 2021 Estimate	**-5.0**

Risk Level	**Average**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 E	0 E	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2019	-$0.42 A	-$0.54 A	-$0.52 A	-$0.07 A	-$1.24 A
2020	-$0.22 A	-$0.17 E	-$0.17 E	-$0.17 E	-$0.72 E
2021					-$0.55 E
2022					-$0.56 E

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WHAT'S NEW

Business Update

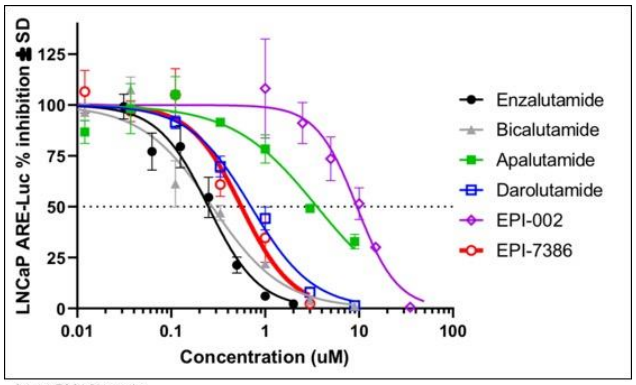
IND for EPI-7386 Filed

On March 31, 2020, ESSA Pharma Inc. (EPIX) announced that it submitted an Investigation New Drug (IND) application for EPI-7386, the company's lead clinical candidate. The company is planning to conduct a Phase 1 clinical trial of EPI-7386 in patients with metastatic castration-resistant prostate cancer (mCRPC). There will be approximately 18 patients enrolled into the trial with a standard 3+3 trial design. An additional 10 patients are expected to be enrolled in the dose expansion cohort. 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. Based on previously presented PK and toxicity data (see here), we believe the company will be able to initiate with a high dose that may be close to the relevant exposure range and thus the Phase 2 dose could be identified relatively quickly.

EPI-7386 is a second-generation 'aniten' compound that binds to the N-terminal domain (NTD) of the androgen receptor (AR). This is in contrast to all other anti-androgen prostate cancer compounds that bind to the androgen receptor (AR) through the ligand binding domain (LBD). Unfortunately, all current anti-androgen therapies are prone to resistance mechanisms that arise through targeting of the LBD. Due to its unique mechanism of action, EPI-7386 is unlikely to succumb to the same resistance mechanisms as currently available anti-androgen therapies.

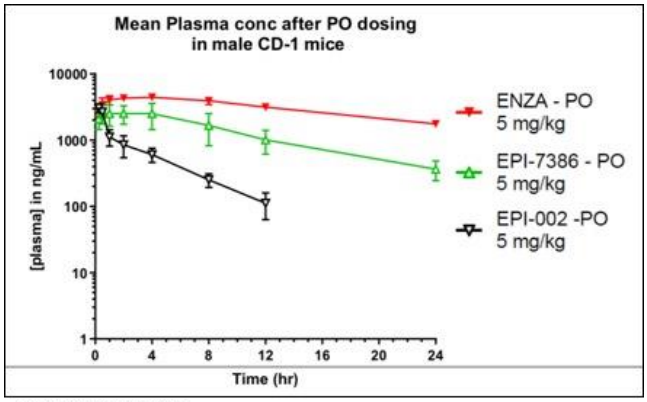
ESSA had originally developed EPI-002 (and its prodrug EPI-506), a first-generation aniten compound that did not have the proper pharmcodynamic or efficacy profile to take further into development. EPI-7386 has a number of very promising attributes, particularly in comparison to EPI-002, including:

- **Increased potency**: the following chart shows a cellular inhibition assay in which various AR antagonists were tested along with EPI-002 and EPI-7386. The results show that EPI-7386 has a similar IC50 value compared with enzalutamide, bicalutamide, and darolutamide while EPI-002 had an IC50 value 20X higher than EPI-7386.



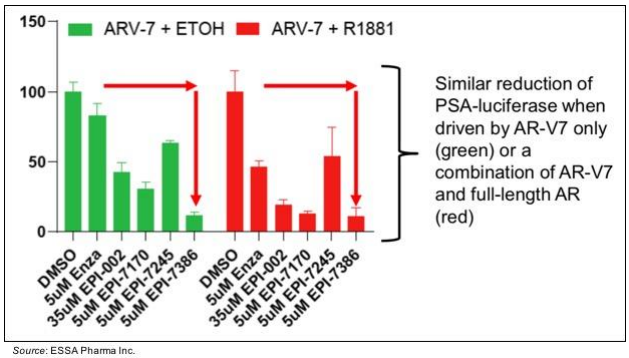
Source: ESSA Pharma Inc.

- **Reduced *in vitro* metabolism**: EPI-7386 exhibits *in vitro* hepatocyte stability that is approximately 10X greater than EPI-002 based on half-life and similar to what is seen with enzalutamide. In addition, the following graph shows that the PK profile in mice for EPI-7386 is similar to enzalutamide while EPI-002 showed a rapid reduction in plasma concentration over 12 hours.



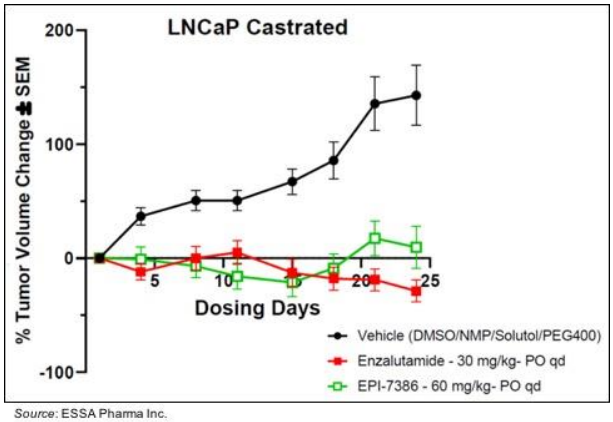
Source: ESSA Pharma Inc.

- **Activity against AR-V7 in *in vitro* models**: The following chart shows the results of an AR activity assay in which PSA is coupled to a luciferase reporter and tested against enzalutamide, EPI-002, and next-generation aniten compounds including EPI-7386. The assay was performed using the AR splice variant AR-V7, which shows androgen-independent activity (green bars), and activity using a combination of AR-V7 and full-length AR (R1881). The results show that EPI-7386 inhibits the activity of both full-length AR and the AR-V7 splice variant. This is in contrast to enzalutamide, which only shows activity against the full-length AR (red bars) but not against AR-V7, where activity is similar to that seen with only vehicle (DMSO) present.



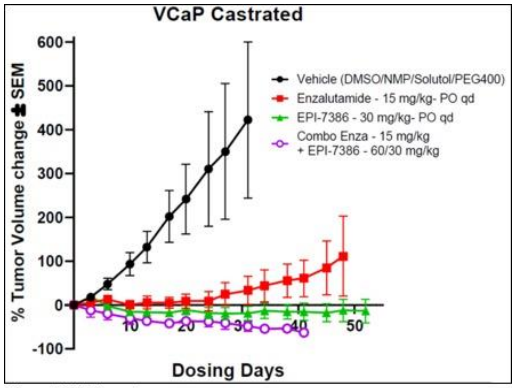
Source: ESSA Pharma Inc.

- **Similar activity to enzalutamide in LNCaP xenograft models**: The following graph shows the activity of both EPI-7386 and enzalutamide in an LNCaP xenograft model, which is driven by a full-length AR. Both drugs similarly inhibit the growth of the tumor in that model.



Source: ESSA Pharma Inc.

- **Enhanced activity in VCaP xenograft model**: The VCaP model is initially driven by full-length AR but is then followed by AR-V7-driven growth. The following graph shows that EPI-7386 shows significant and sustained antitumor activity in this model, while enzalutamide treated tumors show resistance to treatment after day 24. Interestingly, the combination of EPI-7386 and enzalutamide shows even greater activity than either drug on its own.



Source: ESSA Pharma Inc.

Conclusion

We are glad to see that ESSA is continuing to hit the timelines regarding submission of the IND for EPI-7386 and we look forward to the initiation of the Phase 1 trial. The company indicated that the current coronavirus epidemic has not had a material impact on operations, however the company is using mitigation strategies to deal with clinical trial sites that may be impacted by the ongoing COVID-19 situation. We anticipate the trial getting underway in the second quarter of 2020 and hope to have an update on the trial in the second half of 2020. With $45.9 million in cash and cash equivalents as of Dec. 31, 2019, the company is funded to conduct the Phase 1 dose-ranging study, an expansion cohort of that study, and a combination trial of EPI-7386 and currently utilized antiandrogens in patients with earlier stage mCRPC. Our current valuation is $9.50 per share.

PROJECTED FINANCIALS

ESSA Pharma Inc.	FY2019 A	Q1FY20 A	Q2FY20 E	Q3FY20 E	Q4FY20 E	FY2020 E	FY2021 E	FY2022 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	$6.7	$2.6	$2.0	$2.0	$2.0	$8.6	$10.0	$12.0
Financing Costs	$0.6	$0.2	$0.0	$0.0	$0.0	$0.2	$0.0	$0.0
General & Administrative	$5.5	$2.1	$1.4	$1.4	$1.4	$6.3	$6.0	$7.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($12.8)	($4.9)	($3.4)	($3.4)	($3.4)	($15.1)	($16.0)	($19.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$2.4	($0.0)	$0.0	$0.0	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($10.4)	($4.9)	($3.4)	($3.4)	($3.4)	($15.2)	($16.0)	($19.0)
Income Taxes	$0.0	($0.3)	$0.0	$0.0	$0.0	($0.2)	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($10.4)**	**($4.6)**	**($3.4)**	**($3.4)**	**($3.4)**	**($14.9)**	**($16.0)**	**($19.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.24)**	**($0.22)**	**($0.16)**	**($0.16)**	**($0.16)**	**($0.72)**	**($0.53)**	**($0.54)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	8.4	20.8	20.8	20.8	20.8	20.8	30.0	35.0

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

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