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Essa Pharma Inc

(EPIX-NASDAQ)

EPIX: *Phase 1 Clinical Trial for EPI-7386 to Initiate in 1Q20…*

Based on our probability adjusted DCF model that takes into account potential future revenues from EPI-7386, EPIX is valued at $8.00/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 (12/30/19)	$5.58
Valuation	**$8.00**

OUTLOOK

Essa Pharma Inc. (EPIX) is a biopharmaceutical company developing therapies for treatment-resistant prostate cancer. The company is focused on compounds that inhibit activation of the androgen receptor (AR) through binding of the N-terminal domain (NTD), which is a unique mechanism of action compared to currently available prostate cancer treatments that target the AR. The company has selected EPI-7386 as its lead development candidate and we anticipate an IND being filed in the first quarter of 2020 such that a clinical trial in prostate cancer patients whose tumors are progressing on the latest anti-androgen therapy can be initiated. We also anticipate a combination study of EPI-7386 with currently available anti-androgen therapies in earlier lines of therapy. ESSA had approximately $53.3 million in cash and cash equivalents as of Sep. 30, 2019, which we estimate is sufficient to complete Phase 1 testing of EPI-7386.

SUMMARY DATA

52-Week High	**$6.00**
52-Week Low	**$1.46**
One-Year Return (%)	**164.46**
Beta	**1.99**
Average Daily Volume (sh)	**48,037**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$117**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**83**
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	**-7.7**
P/E using 2021 Estimate	**-8.0**

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)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 E	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	-$0.17 E	-$0.17 E	-$0.17 E	-$0.17 E	-$0.68 E
2021					-$0.55 E
2022					-$0.56 E

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WHAT'S NEW

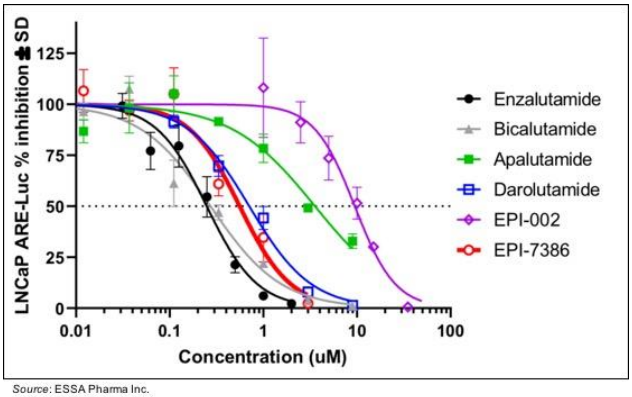
Business Update

ESSA Pharma Inc. (EPIX) is a biopharmaceutical company developing treatments for prostate cancer that is no longer responding to current therapies. The company is developing a series of compounds ('anitens') that disrupt the androgen receptor (AR) signaling pathway through a unique mechanism of action that targets the N-terminal domain (NTD) of the AR, as opposed to the ligand-binding domain (LBD) of the AR that is targeted by all other AR-directed prostate cancer treatments. The company has selected a lead preclinical aniten (EPI-7386) to advance to clinical trials, and we anticipate an IND being filed in the first quarter of 2020 such that a Phase 1 clinical trial can initiate shortly thereafter.

The company had previously tested a first-generation aniten compound, EPI-002, in a Phase 1 clinical trial in patients with mCRPC that were progressing after abiraterone or enzalutamide with serially rising PSAs (NCT02606123). While EPI-002 was shown to be safe and well tolerated, the compound exhibited a short half-life and minimal therapeutic exposure that led to suboptimal results. Therefore, ESSA embarked on a new discovery effort to develop next-generation antien's.

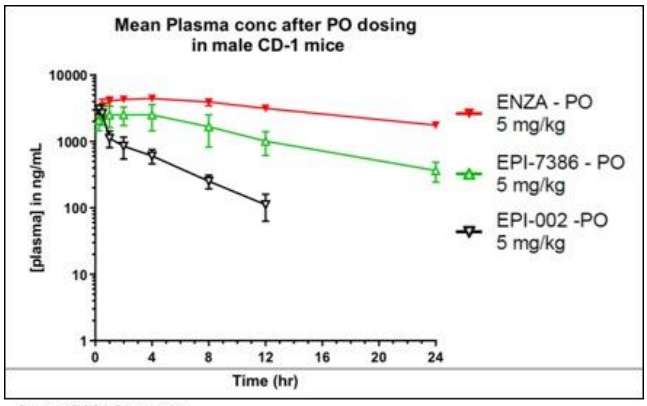
Following the synthesis of >300 compounds the company selected EPI-7386 as the lead IND candidate due to it possessing a number of positive attributes compared to EPI-002, including:

- **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.



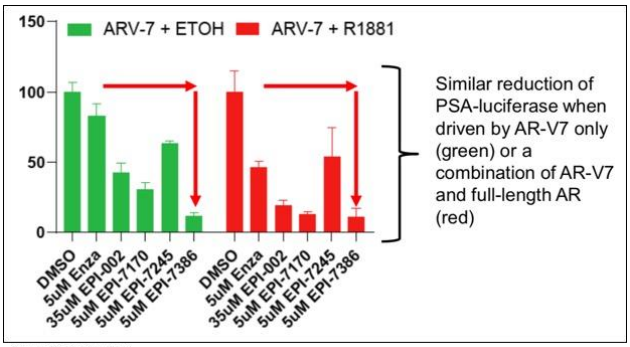
Source: ESSA Pharma Inc.

- **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.



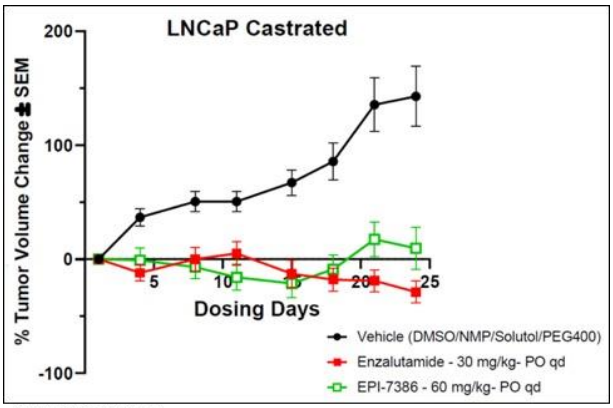
Source: ESSA Pharma Inc.

- **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 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.



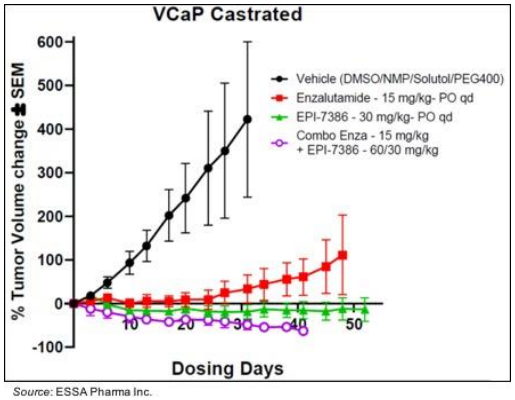
Source: ESSA Pharma Inc.

- **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.

Looking to Initiate Phase 1 Clinical Trial of EPI-7386 in 1Q20

We anticipate the company filing an IND for EPI-7386 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. We estimate that the company is fully financed to conduct all three trials (the dose escalation trial, the dose expansion trial, and the combination trial).

Financial Update

On December 19, 2019, ESSA announced financial results for fiscal year 2019 that ended September 30, 2019. The company reported a net loss of $10.4 million, or $1.24 per share, for the year ending September 30, 2019, compared to a net loss of $11.6 million, or $2.55 per share, for the year ending September 30, 2018. R&D expenses for fiscal year 2019 were $6.7 million compared to $4.9 million for fiscal year 2018. The increase in expenses was primarily related to preparation of the IND application for EPI-7386. G&A expenses for fiscal year 2019 were $5.5 million compared to $5.9 million for fiscal year 2018. The decrease was primarily due to a reduction in share-based compensation, rent expense, and professional fees.

As of September 30, 2019, ESSA had approximately $53.3 million in cash and cash equivalents, which includes the capital from the acquisition of Realm Therapeutics in July 2019 and the $36 million financing in August 2019. We estimate that the company has sufficient capital to fund operations for the next couple of years.

As of September 30, 2019, ESSA had approximately 20.8 million shares outstanding, and when factoring in the 12.2 million reasonably priced warrants and the 5.3 million stock options a fully diluted share count of approximately 38.3 million.

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% discount rate leads to a net present value for EPI-7386 of $263 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 38.3 million leads to a valuation of approximately $8.00 per share.

PROJECTED FINANCIALS

ESSA Pharma Inc.	FY2019 A	Q1FY20 E	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	$2.0	$2.0	$2.0	$2.0	$8.0	$10.0	$12.0
Financing Costs	$0.6	$0.2	$0.2	$0.2	$0.2	$0.6	$0.6	$0.6
General & Administrative	$5.5	$1.4	$1.4	$1.4	$1.4	$5.6	$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)	($3.6)	($3.6)	($3.6)	($3.6)	($14.2)	($16.6)	($19.6)
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)	($3.6)	($3.6)	($3.5)	($3.5)	($14.2)	($16.6)	($19.6)
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	**($10.4)**	**($3.6)**	**($3.6)**	**($3.6)**	**($3.6)**	**($14.2)**	**($16.6)**	**($19.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.24)**	**($0.17)**	**($0.17)**	**($0.17)**	**($0.17)**	**($0.68)**	**($0.55)**	**($0.56)**
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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