Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

May 12, 2020
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Essa Pharma Inc

(EPIX-NASDAQ)

EPIX: FDA Gives OK to Initiate Phase 1 Trial of EPI-7386…

Based on our probability adjusted DCF model that takes into account potential future revenues from EPI-7386, EPIX is valued at $10.50/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 (05/12/20)	$4.70
Valuation	**$10.50**

OUTLOOK

On May 7, 2020, ESSA Pharma Inc. (EPIX) announced financial results for the second quarter of 2020 and provided a business update. After filing the IND for EPI-7386 on March 31, 2020, the company received allowance from the FDA to conduct the Phase 1 clinical trial. The company is currently working to get clinical sites opened in the U.S. and Canada. We estimate approximately 18 patients with metastatic castration-resistant prostate cancer (mCRPC) that is no longer responding to anti-androgen treatment will be enrolled in the dose escalation trial. An additional 10 patients will then be tested in the dose expansion cohort. We estimate the trial taking nine to 12 months to complete.

SUMMARY DATA

52-Week High	**$6.00**
52-Week Low	**$1.46**
One-Year Return (%)	**95.83**
Beta	**1.65**
Average Daily Volume (sh)	**23,056**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$98**
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	**-4.1**
P/E using 2021 Estimate	**-5.4**

Risk Level	**Below Avg.**
Type of Stock	**Small-Blend**
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 A	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	-$0.45 A	-$0.16 E	-$0.16 E	-$1.03 E
2021					-$0.53 E
2022					-$0.54 E

© Copyright 2019, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

IND Cleared to Start Phase 1 Clinical Trial of EPI-7386

On March 31, 2020, ESSA Pharma Inc. (EPIX) announced that the company filed an Investigational New Drug (IND) application with the US FDA and on April 30, 2020, the company received clearance from the FDA to initiate a Phase 1 clinical trial of EPI-7386 for the treatment of metastatic castration-resistant prostate cancer (mCRPC).

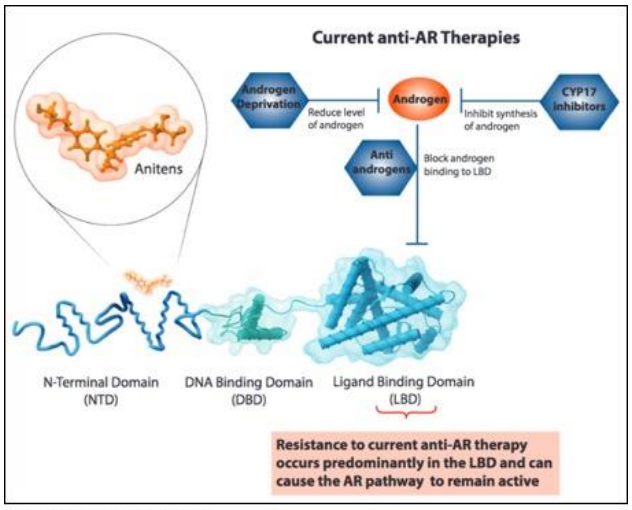
We anticipate the Phase 1 clinical trial enrolling approximately 18 patients who are resistant to second-generation anti-androgens therapies (e.g., enzalutamide) to evaluate the safety, pharmacokinetics, and maximum-tolerated dose of the compound in multiple-dose escalations. It will encompass a standard 3+3 trial design (three patients enrolled per dose cohort) with an estimated 10 patients being 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. 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).

Background on EPI-7386

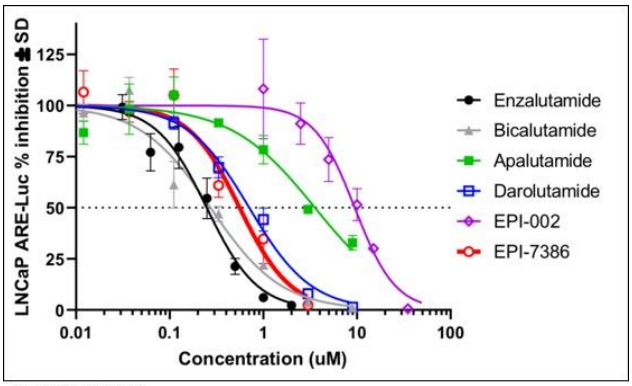
EPI-7386 is a next-generation 'aniten' compound that disrupts the androgen receptor (AR) signaling pathway through a unique mechanism of action that targets the N-terminal domain (NTD) of the AR, which is in contrast to the ligand-binding domain (LBD) of the AR that is targeted by all other AR-directed prostate cancer treatments. The following graphic, from a poster presented at the 2020 ASCO GU conference, shows where anitens bind on the AR compared to currently available anti-AR therapies, which fully differentiates anitens from other prostate cancer therapies that target the AR.



Source: Le Moigne *et al.*, 2020

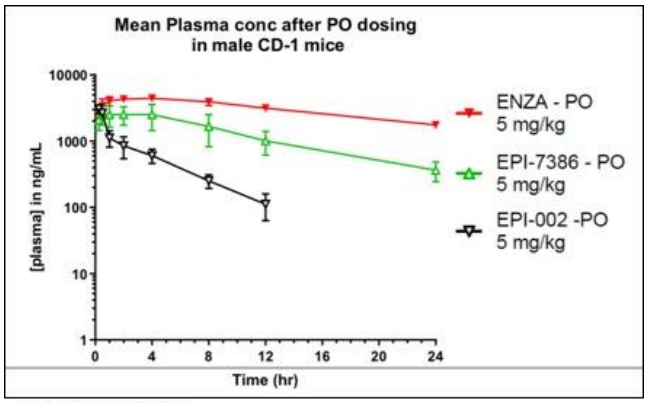
ESSA had previously tested a first-generation aniten compound, EPI-002, in a Phase 1 clinical trial in patients with mCRPC that were progressing after abiraterone or enzalutamide with serially rising PSAs (NCT02606123). While EPI-002 was shown to be safe and well tolerated, the compound exhibited a short half-life and minimal therapeutic exposure that led to suboptimal results. Therefore, ESSA embarked on a new discovery effort that ultimately led to EPI-7386, which has 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.



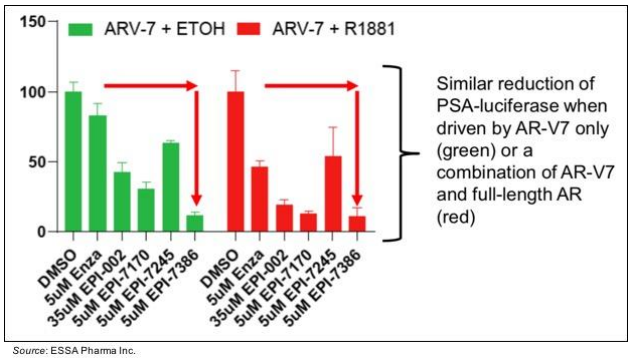
Source: ESSA Pharma Inc.

- **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.



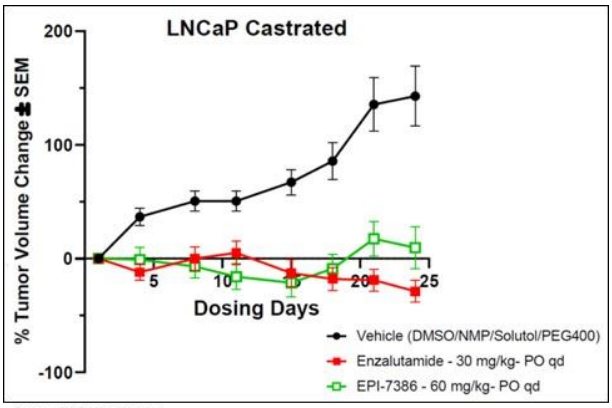
Source: ESSA Pharma Inc.

- **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.



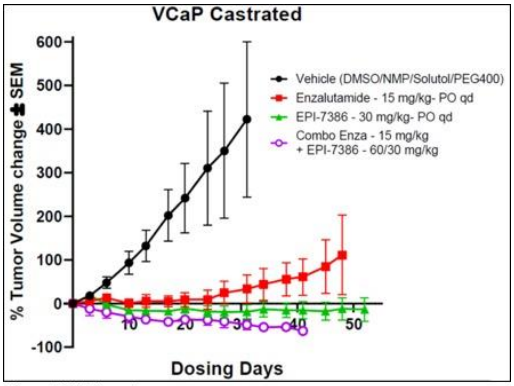
Source: ESSA Pharma Inc.

- **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.

Financial Update

On May 7, 2020, ESSA Pharma announced financial results for the second quarter of fiscal year 2020 that ended Mar. 31, 2020. The company reported a net loss of $9.4 million, or $0.45 per share, for the second quarter of fiscal year 2020 compared to a net loss of $3.4 million, or $0.54 per share, for the second quarter of fiscal year 2019. R&D expenses for the three months ending Mar. 31, 2020 were $4.6 million compared to $1.5 million for the three months ending Mar. 31, 2019. The increase was primarily due to preparing the IND application for EPI-7386, preparatory clinical costs, manufacturing costs, and non-cash share-based payments. G&A expenses for the three months ending Mar. 31, 2020 were $4.9 million compared to $1.8 million for the three months ending Mar. 31, 2019. The increase was primarily due to non-cash share-based payments.

As of Mar. 31, 2020, ESSA Pharma had approximately $39.9 million of cash and cash equivalents. During the second quarter of fiscal year 2020 the company entered into an Open Market Sales Agreement with Jeffries LLC, in which ESSA may sell up to $35 million in common stock in 'at-the-market' transactions. As of Mar. 31, 2020, ESSA had approximately 20.8 million shares outstanding and when factoring in stock options and warrants the fully diluted share count of 38.2 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 anti-androgen 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 35% chance of approval along with a 13% discount rate leads to a net present value for EPI-7386 of $316 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 38.2 million leads to a valuation of approximately $10.50 per share.

PROJECTED FINANCIALS

ESSA Pharma Inc.	FY2019 A	Q1FY20 A	Q2FY20 A	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	$4.6	$2.0	$2.0	$11.2	$10.0	$12.0
Financing Costs	$0.6	$0.2	$0.1	$0.0	$0.0	$0.3	$0.0	$0.0
General & Administrative	$5.5	$2.1	$4.9	$1.4	$1.4	$9.8	$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)	($9.6)	($3.4)	($3.4)	($21.3)	($16.0)	($19.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$2.4	($0.0)	($0.2)	$0.0	$0.0	($0.2)	$0.0	$0.0
Pre-Tax Income	($10.4)	($4.9)	($9.4)	($3.4)	($3.4)	($21.6)	($16.0)	($19.0)
Income Taxes	$0.0	($0.3)	$0.0	$0.0	$0.0	($0.3)	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($10.4)**	**($4.6)**	**($9.4)**	**($3.4)**	**($3.4)**	**($21.3)**	**($16.0)**	**($19.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.24)**	**($0.22)**	**($0.45)**	**($0.16)**	**($0.16)**	**($1.03)**	**($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*

© Copyright 2019, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2019, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.