Zacks Small-Cap Research
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ESSA Pharma Inc

(EPIX-NASDAQ)

EPIX: Combination Studies Set to Initiate…

Based on our probability adjusted DCF model that takes into account potential future revenues from EPI-7386, EPIX is valued at $40/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 (11/22/21)	$13.11
Valuation	**$40.00**

OUTLOOK

On November 18, 2021, ESSA Pharma Inc. (EPIX) announced financial results for the fourth quarter and full year for fiscal year 2021 that ended September 30, 2021 and provided a business update. The company is currently conducting a Phase 1 clinical trial of EPI-7386, its lead development candidate, in patients with metastatic castration-resistant prostate cancer (mCRPC). The company is currently dosing patients at 800 mg, dosed as 400 mg BID. ESSA remains on track to establish a recommended Phase 2 dose in the first half of 2022 and then initiate a combination therapy trial soon thereafter with enzalutamide. In addition, we anticipate a clinical readout of the monotherapy trial in the first half of 2022.

SUMMARY DATA

52-Week High	**$34.28**
52-Week Low	**$6.36**
One-Year Return (%)	**95.67**
Beta	**1.58**
Average Daily Volume (sh)	**301,953**
Shares Outstanding (mil)	**44**
Market Capitalization ($mil)	**$577**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**89**
Insider Ownership (%)	**8**
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	**-9.7**
P/E using 2021 Estimate	**-10.3**

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

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2021	0 A	0 A	0 A	0 A	0 A
2022	0 E	0 E	0 E	0 E	0 E
2023					0 E
2024					0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2021	-$0.20 A	-$0.36 A	-$0.21 A	-$0.24 A	-$0.96 A
2022	-$0.21 E	-$0.22 E	-$0.23 E	-$0.24 E	-$0.91 E
2023					-$0.96 E
2024					-$1.06 E

WHAT'S NEW

Business Update

Update on Phase 1 Trial of EPI-7386

ESSA Pharma Inc. (EPIX) is currently conducting a Phase 1 clinical trial of EPI-7386 in patients with metastatic castration-resistant prostate cancer (mCRPC) who had progressed on two or more systemic therapies, including at least one second generation anti-androgen therapy (NCT04421222). It is a multi-center, open label, ascending multiple dose trial with the primary objective being to evaluate the safety and tolerability of EPI-7386. Secondary objectives include determining the maximum tolerated dose of EPI-7386, defining the recommended Phase 2 dose of EPI-7386, evaluating the pharmacokinetics (PK) of EPI-7386, and assessing any potential drug-drug interactions. The company is currently dosing patients in the 800 mg cohorts using a twice daily (BID) dosing schedule to enhance drug exposures and has also filed an amendment to the clinical trial protocol to focus monotherapy on earlier stage patients that are less heavily pre-treated. We anticipate a clinical readout during the first half of 2022.

In addition to the monotherapy study, there are still three combination therapy trials that are set to begin in the fourth quarter of 2021 and early 2022. ESSA will be conducting a trial of EPI-7386 in combination with enzalutamide, with an expected initiation once the recommended Phase 2 dose of EPI-7386 is established. The combination trials of EPI-7386 with daralutamide (in collaboration with Bayer), apalutamide (in collaboration with Janssen) and abiraterone + predinose (in collaboration with Janssen) are set to begin in late 2021 or early 2022.

In October 2021, ESSA announced a collaboration with Caris Life Sciences in which patient blood samples will be evaluated using Caris' Whole Transcriptome Sequencing (WTS) and Whole Exome Sequencing (WES) platform in order to better characterize the tumor biological profiles of patients in the ongoing monotherapy trial. This information may help to identify relevant subpopulations in the study and possibly expedite development of EPI-7386.

Preclinical Studies Confirm EPI-7386 Mechanism of Action

In October 2021, ESSA presented preclinical data characterizing the mechanism of action of EPI-7386 at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. The data includes results from multiple nuclear magnetic resonance (NMR) studies that confirm the binding region of EPI-7386 on the androgen receptor (AR) is in the N-terminal domain. In addition, cellular thermal shift assays show that EPI-7386 interacts with the full-length AR as well as the AR variant AR-V567es, which lacks the ligand binding domain (LBD) and to which both enzalutamide and daralutamide bind. This binding inhibits the expression of genes controlled by AR-V567es. Lastly, chromatin immunoprecipitation sequencing (ChIP-Seq) data show that when combined with enzalutamide, EPI-7386 completely abrogates genome-wide androgen induced AR binding.

The important takeaway from this data set is that it definitively shows that EPI-7386 binds to the N-terminal domain of the AR and that this unique mechanism of action can inhibit AR-driven gene expression, particularly when used in combination with enzalutamide. This fully supports the company's upcoming combination therapy trials with EPI-7386 and enzalutamide.

Financial Update

On November 18, 2021, ESSA announced financial results for the fourth quarter and full year for fiscal year 2021 that ended September 30, 2021. For fiscal year 2021, the company reported a net loss of $36.8 million, or $0.96 per share, compared to a net loss of $23.4 million, or $1.04 per share, for fiscal year 2020. R&D expenses for fiscal year 2021 were $24.3 million compared to $12.1 million for fiscal year 2020. The increase was primarily due to preclinical work leading to the filing of the IND for EPI-7386, increased CMC costs, and clinical costs associated with the Phase 1 clinical trial of EPI-7386. G&A expenses for fiscal year 2021 were $12.9 million compared to $11.4 million for fiscal year 2020. The increase was primarily due to increased professional fees, higher salaries and benefits, and non-cash share-based payments.

As of September 30, 2021, ESSA had approximately $194.9 million in cash, cash equivalents, and short-term investments. As of November 18, 2021, the company had approximately 44.0 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 56.1 million.

Conclusion

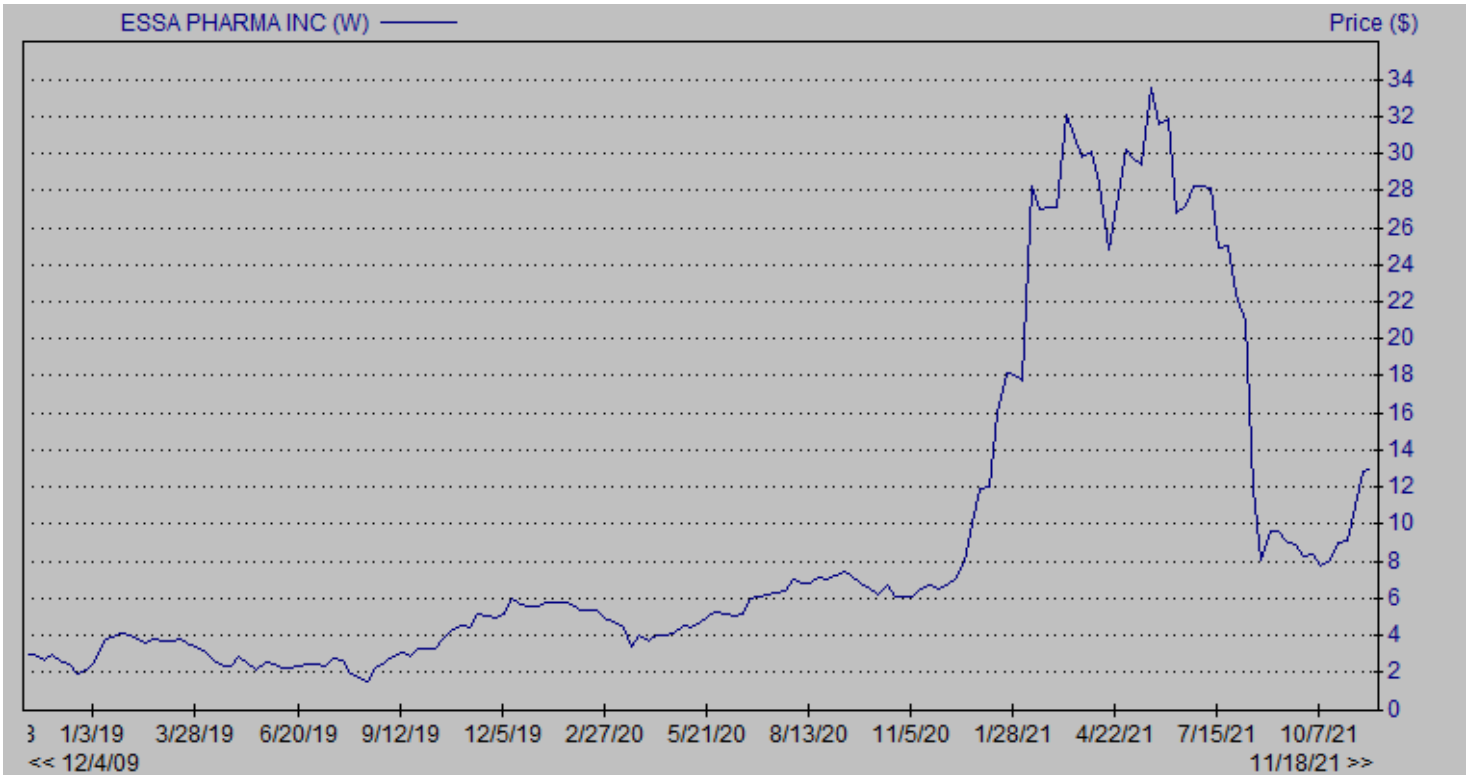
Following the sell-off after the company's previous update on the Phase 1 trial, the stock has begun to recover somewhat in the past few weeks. However, we still think there is significant upside possible and we would view the current share price as an excellent buying opportunity ahead of the next data update from the Phase 1 trial and the initiation of the combination therapy trials. With no changes to our model our valuation remains at $40 per share.

PROJECTED FINANCIALS

ESSA Pharma Inc.	FY2021 A	Q1FY21 E	Q2FY21 E	Q3FY21 E	Q4FY21 E	FY2022 E	FY2023 E	FY2024 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
Research & Development	$24.3	$6.0	$6.3	$6.8	$7.4	$26.5	$30.0	$35.0
Financing Costs	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
General & Administrative	$12.9	$3.4	$3.5	$3.6	$3.7	$14.2	$14.5	$15.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($37.2)	($9.4)	($9.8)	($10.4)	($11.1)	($40.7)	($44.5)	($50.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.4	$0.4
Pre-Tax Income	($36.8)	($9.4)	($9.8)	($10.4)	($11.1)	($40.7)	($44.1)	($49.6)
Income Taxes	($0.0)	$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	**($36.8)**	**($9.4)**	**($9.8)**	**($10.4)**	**($11.1)**	**($40.7)**	**($44.1)**	**($49.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.96)**	**($0.21)**	**($0.22)**	**($0.23)**	**($0.24)**	**($0.91)**	**($0.96)**	**($1.06)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	38.5	44.0	44.5	45.0	45.5	44.8	46.0	47.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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