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ESSA Pharma Inc

(EPIX-NASDAQ)

EPIX: Advancing Multiple Clinical Trials in 2023…

Based on our probability adjusted DCF model that takes into account potential future revenues from EPI-7386 and the ANITAC program, EPIX is valued at $27/share. This model is highly dependent upon continued clinical success of EPI-7386/TPD and will be adjusted accordingly based upon future clinical results.

Current Price (12/19/22)	$2.62
Valuation	**$27.00**

OUTLOOK

On December 13, 2022, ESSA Pharma Inc. (EPIX) announced financial results for fiscal year 2022 that ended September 30, 2022 and provided a business update. Looking ahead to 2023, the company will be advancing its lead asset, EPI-7386, in clinical trials as a monotherapy as well as in combination with multiple approved antiandrogens. ESSA has selected two dose levels to advance to Phase 1b monotherapy dose expansion testing: 600 mg QD and 600 mg BID. The company has previously announced multiple collaborative studies to evaluate EPI-7386 in combination with second generation antiandrogens. A Phase 1 study of EPI-7386 in combination with enzalutamide is currently ongoing and the company has plans to initiate clinical trials to evaluate EPI-7386 in combination with apalutamide and EPI-7386 in combination with abiraterone acetate with prednisone. Lastly, an investigator-sponsored neoadjuvant study will evaluate darolutamide compared to EPI-7386 in combination with darolutamide in patients undergoing prostatectomy for high-risk localized prostate cancer.

SUMMARY DATA

52-Week High	**$14.44**
52-Week Low	**$1.50**
One-Year Return (%)	**-80.03**
Beta	**2.04**
Average Daily Volume (sh)	**312,058**
Shares Outstanding (mil)	**44**
Market Capitalization ($mil)	**$115**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**10**
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	**-2.4**
P/E using 2021 Estimate	**-1.9**

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

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 E	0 E	0 E	0 E	0 E
2024					0 E
2025					0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2022	-$0.21 A	-$0.25 A	-$0.20 A	-$0.14 A	-$0.80 A
2023	-$0.20 E	-$0.22 E	-$0.23 E	-$0.25 E	-$0.90 E
2024					-$0.98 E
2025					-$1.09 E

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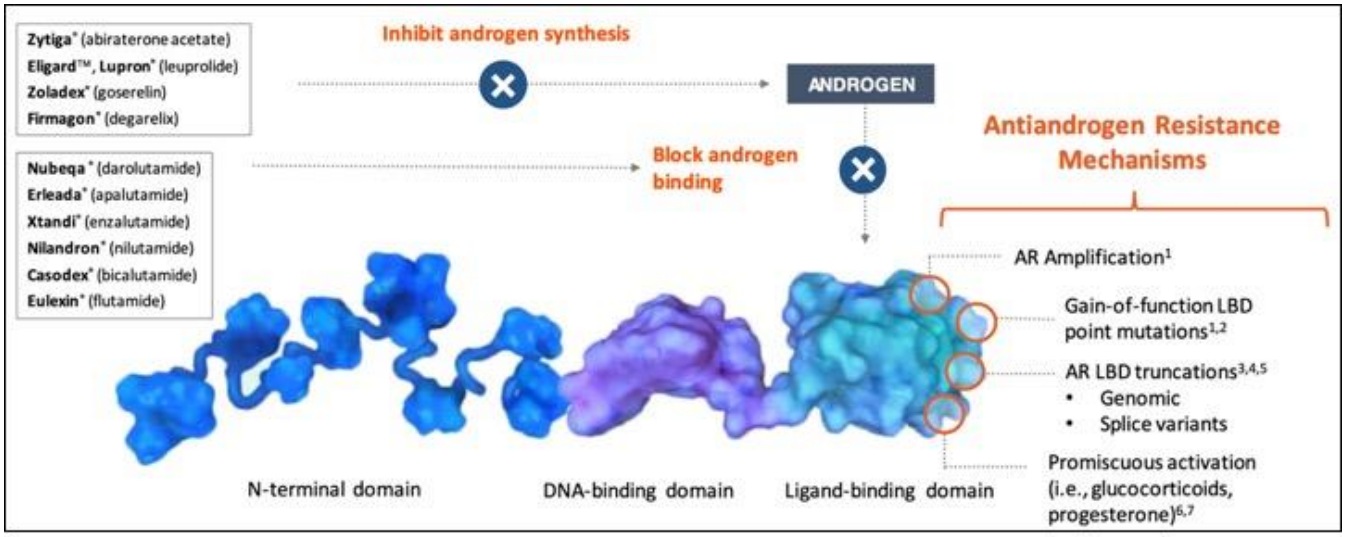
WHAT'S NEW

Business Update

Advancing Multiple Clinical Trials in 2023

ESSA Pharma Inc (EPIX) is developing EPI-7386 as a treatment for prostate cancer. It is a member of a novel class of compounds known as 'anitens', which specifically target the androgen receptor (AR). The AR is the main signaling mechanism driving the growth of prostate tumors. Anitens bind the AR at the N-terminal domain (NTD), which is unique compared to other available anti-androgen therapies that target the ligand binding domain (LBD). The following graphic shows the structure of the AR along with the various resistance mechanisms that develop to counteract therapies that target the LBD. Anitens are fully differentiated from current AR-targeted therapies through binding of the NTD.



Source: ESSA Pharma, Inc.

ESSA is testing EPI-7386 as both a monotherapy and in combination with existing second-generation antiandrogens. The company has completed enrollment of the Phase 1a monotherapy 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). Patients are currently being dosed at 1,000 mg QD and at 1,200 mg/day, administered as 600 mg dosed twice daily. One of the goals of the Phase 1a trial was to establish one or more doses to advance to the expansion Phase 1b portion of the study. Two dose levels have been selected to advance to the Phase 1b trial: 600 mg QD and 600 mg BID. In October 2022, the company presented updated clinical results for the Phase 1a trial. For a full discussion of the Phase 1a trial results please see our previous report.

The Phase 1b portion of the trial will consist of two cohorts enrolled in parallel:

- Cohort A (Dose Expansion) – The primary objective of Cohort A is to evaluate the safety, tolerability, pharmacokinetics, and preliminary anti-tumor activity (changes in tumor burden and PSA levels over time) of EPI-7386 at 600 mg BID and 600 mg QD. The patients enrolled into this cohort will be similar to the ones enrolled in the Phase 1a portion of the study except patients will not be allowed to have had prior chemotherapy.

- Cohort B (Window of Opportunity) – The primary objective of Cohort B is to assess the anti-tumor activity (measured by changes in PSA over time) of EPI-7386 administered 600 mg BID for a limited period of time (up to 12 weeks before patients start standard of care therapy) in non-metastatic CRPC (nmCRPC) patients whose disease is unperturbed by previous second generation anti-androgen therapies or chemotherapy.

Upon completion of the Phase 1 trial, ESSA will review the totality of the data to determine the design and timing of the Phase 2 clinical trial along with which patient population would be best suited for the study.

EPI-7386 is also being tested in the following combination trials:

- In February 2021, ESSA announced a collaboration with Astellas Pharma to evaluate EPI-7386 in combination with enzalutamide in patients with mCRPC. ESSA is funding and operating the trial, which consists of an initial Phase 1 dose equilibration followed by a randomized Phase 2 trial with a planned enrollment of 120 patients. The company reported initial data on the safety, tolerability, pharmacokinetics, and initial PSA responses in June 2022 and provided a clinical update in October 2022. Of the six evaluable patients treated as of the last update, five of them achieved PSA90 (a 90% decrease in PSA level from baseline) with four of those achieving it by three months, which compares very favorably to historical controls (PSA90 levels at three months of 13% to 37%). For a full summary of the update in October 2022 please see our previous report.

- In January 2021, ESSA announced a collaboration with Janssen to evaluate the combination of EPI-7386 with abiraterone acetate with prednisone along with the combination of EPI-7386 with apalutamide in mCRPC patients. According to the agreement, Janssen was to pay for and conduct a trial with EPI-7386 used in combination with Janssens antiandrogen (abiraterone acetate and apalutamide). Enrollment for the study began in March 2022 but was suspended by Janssen in October 2022 due to operational recruitment challenges. ESSA has announced its plan to revise the collaboration and to conduct a study of the combinations while Janssen will supply apalutamide and abiraterone acetate.

- In April 2021, ESSA announced a collaboration with Bayer for a clinical trial testing EPI-7386 and darolutamide in patients with mCRPC. In addition, ESSA previously announced its intention to initiate a Phase 2 investigator-sponsored neoadjuvant study to evaluate EPI-7386 in combination with darolutamide compared to darolutamide alone.

Financial Update

On December 13, 2022, ESSA announced financial results for the fourth quarter and full year for fiscal year 2022 that ended September 30, 2022. For fiscal year 2022, the company reported a net loss of $35.1 million, or $0.80 per share, compared to a net loss of $36.8 million, or $0.96 per share, for fiscal year 2021. R&D expenses for fiscal year 2022 were $24.4 million compared to $24.3 million for fiscal year 2020. While preclinical and data analysis costs increased in fiscal year 2022 compared to fiscal year 2021, these increases were offset by decreases in manufacturing costs. G&A expenses for fiscal year 2022 were $12.5 million compared to $12.9 million for fiscal year 2021. The decrease was primarily due to decreased professional fees and lower non-cash share-based payments.

As of September 30, 2022, ESSA had approximately $167.2 million in cash, cash equivalents, and short-term investments. We estimate this is sufficient to fund operations at least through 2025. As of November 18, 2021, the company had approximately 44.1 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 55.2 million.

Conclusion

We look forward to updates in 2023 on the multiple trials in which EPI-7386 is being tested, including the Phase 1b portion of the monotherapy trial and the combination trials with enzalutamide, Janssen's antiandrogens, and darolutamide. The early results for EPI-7386 have been very encouraging, particularly the PSA90 data for EPI-7386 in combination with enzalutamide, and we look forward to updated trial results throughout 2023. After advancing our DCF model ahead by a year, our valuation now stands at $27 per share.

PROJECTED FINANCIALS

ESSA Pharma Inc.	FY2022 A	Q1FY23 E	Q2FY23 E	Q3FY23 E	Q4FY23 E	FY2023 E	FY2024 E	FY2025 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	$24.4	$6.0	$6.5	$7.0	$7.5	$27.0	$30.0	$35.0
Financing Costs	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
General & Administrative	$12.5	$3.0	$3.1	$3.2	$3.3	$12.6	$14.0	$15.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($37.0)	($9.0)	($9.6)	($10.2)	($10.8)	($39.6)	($44.0)	($50.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$1.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($35.2)	($9.0)	($9.6)	($10.2)	($10.8)	($39.6)	($44.0)	($50.0)
Income Taxes	($0.1)	$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	**($35.1)**	**($9.0)**	**($9.6)**	**($10.2)**	**($10.8)**	**($39.6)**	**($44.0)**	**($50.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.80)**	**($0.20)**	**($0.22)**	**($0.23)**	**($0.25)**	**($0.90)**	**($0.98)**	**($1.09)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	44.0	44.1	44.1	44.1	44.1	44.1	45.0	46.0

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

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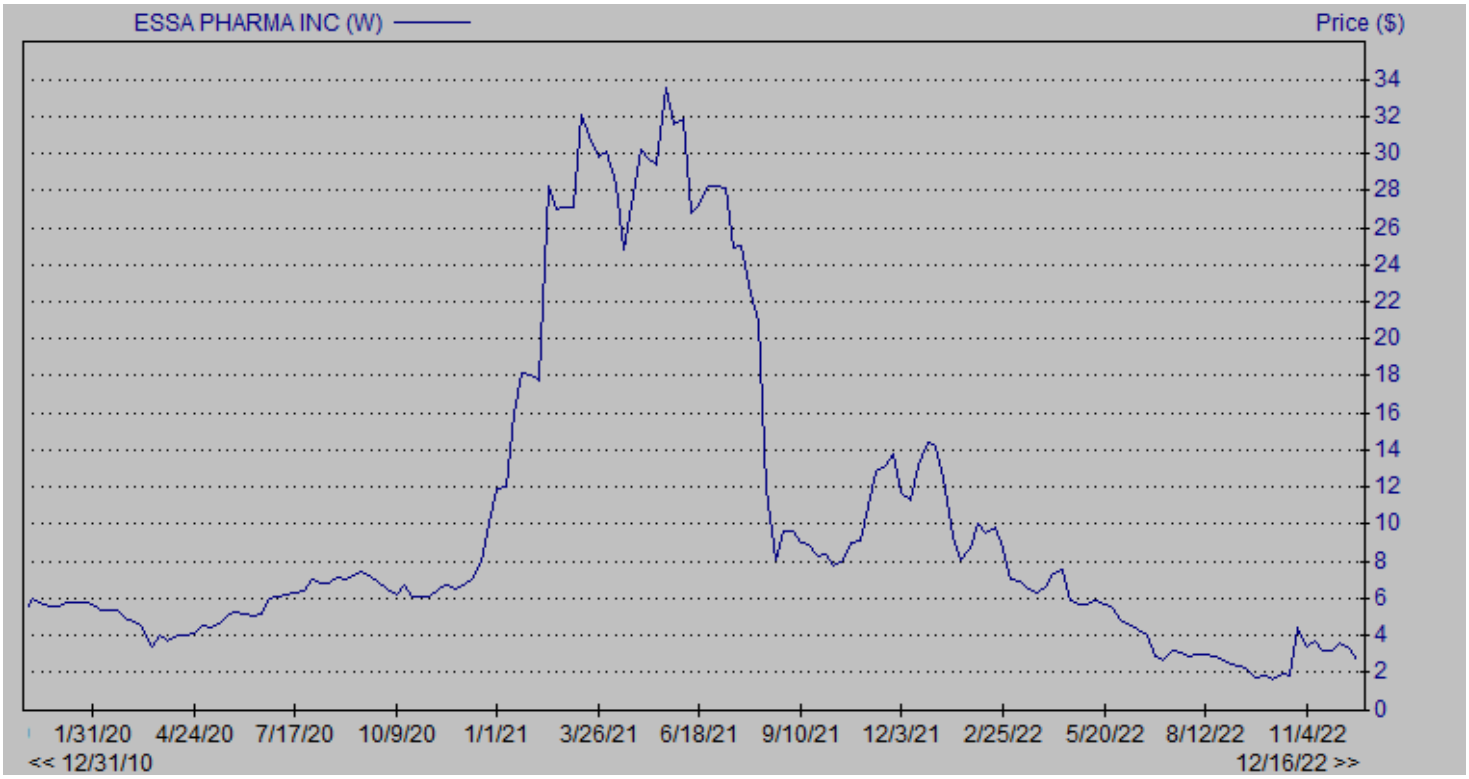
HISTORICAL STOCK PRICE



Source: Zacks SCR

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