Zacks Small-Cap Research

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ESSA Pharma Inc

(EPIX-NASDAQ)

EPIX: Deep and Sustained PSA Responses in Phase 1/2 Combination Trial of EPI-7386 and Enzalutamide…

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 (02/23/23)	$3.37
Valuation	**$27.00**

OUTLOOK

On February 13, 2023, ESSA Pharma Inc. (EPIX) announced additional data from two Phase 1 studies of EPI-7386 in patients with metastatic castration resistant prostate cancer (mCRPC) will be presented at the 2023 ASCO GU meeting. Updated data from the Phase 1/2 multicenter, open-label trial of EPI-7386 in combination with enzalutamide shows that the combination continues to be safe and well-tolerated. Five of six evaluable patients achieved PSA90 (≥90% decline in PSA) with the responses being maintained or further deepened during the study. In addition, four of six evaluable patients PSA levels reached <0.2 ng/mL, which has been correlated with positive outcomes in multiple prostate cancer trials.

SUMMARY DATA

52-Week High	**$10.02**
52-Week Low	**$1.50**
One-Year Return (%)	**-65.29**
Beta	**2.17**
Average Daily Volume (sh)	**224,717**
Shares Outstanding (mil)	**44**
Market Capitalization ($mil)	**$149**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**12**
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	**-2.8**

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 A	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	-$0.15 A	-$0.22 E	-$0.23 E	-$0.25 E	-$0.85 E
2024					-$0.98 E
2025					-$1.09 E

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WHAT'S NEW

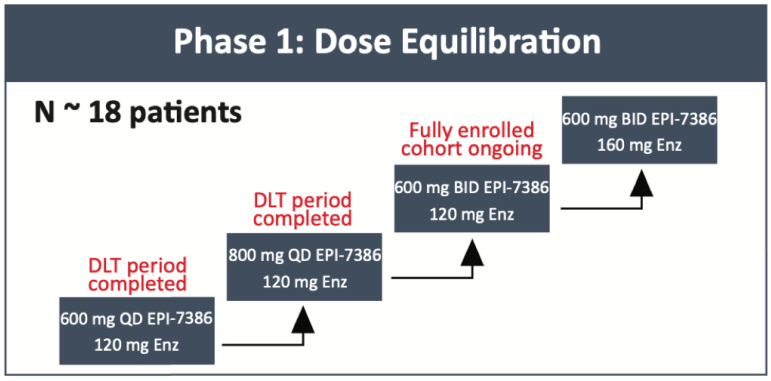
Business Update

Update on EPI-7386 Phase 1 Clinical Trials

On February 13, 2023, ESSA Pharma Inc. (EPIX) announced that updated data from two Phase 1 clinical trials of EPI-7386 in patients with metastatic castration-resistant prostate cancer (mCRPC) would be presented at the 2023 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU). Importantly, EPI-7386 continues to be safe and well-tolerated and is showing initial anti-tumor activity as both a monotherapy and in combination with enzalutamide. A copy of the posters can be found here.

Phase 1/2 Study of EPI-7386 in Combination with Enzalutamide (Enz) Compared with Enz Alone in Subjects with Metastatic Castration-Resistant Prostate Cancer (mCRPC)

This Phase 1/2 clinical trial is enrolling mCRPC patients on androgen deprivation therapy that are naïve to second-generation antiandrogens (one prior line of chemotherapy is allowed). A total of 10 patients have been enrolled in the first three dosing cohorts: three in cohort 1 (600 mg QD EPI-7386 + 120 mg Enz), four in cohort 2 (800 mg QD EPI-7386 + 120 mg Enz), and three in cohort 3 (600 mg BID EPI-7386 + 120 mg Enz). Cohort 3 has not cleared the dose-limiting toxicity (DLT) period yet, thus this update concerns the first two cohorts. As previously disclosed, EPI-7386 does not impact Enz exposure, however Enz significantly reduces EPI-7386 exposure, however EPI-7386 levels are still in an active range.



Source: Laccetti *et al.*, 2023

Of the six evaluable patients (one patient discontinued after one cycle due to a drug-drug interaction with a concomitant medication [primodone; CYP3A4 inducer] that resulted in negligible exposure to EPI-7386), five (83%) of them showed a decrease in prostate specific antigen (PSA) level > 90% (PSA90) and four of the six (67%) showed PSA < 0.2 ng/mL (undetectable). These PSA responses compare very favorably with previous studies of Enz, particularly since the other studies analyzed Enz at 160 mg in comparison to ESSA's current study that has only examined Enz at 120 mg.

PSA Responses Compares Favorably to Historical Controls where Enz was used at the full dose (160 mg)

Patient Population	Agent	Enz Dose (mg/day)	Study Type	Patient Number	Median Baseline PSA level in ng/mL (range)	PSA50 (Overall)	PSA90 (Overall)	PSA<0.2 ng/mL (Overall)	Time to PSA progression (months)	Reference
mCRPC (pre and post chemo)	EPI-7386 + ENZ	120	Dose escalation	7*	2.7 (1.8-1,209)	83%	83%	67%	ND	EPI-7386-CS-010 trial
mCRPC pre-chemo (PREVAIL)	ENZ	160	Pivotal	872	54.1 (0.1-3,182)	78%	47%	ND	11.2	Beer et al., NEJM 2014; Armstrong et al., Eu Assoc of Uro 2020
mCRPC pre-chemo (PREMISE)	ENZ	160	Observational	1171	27.7 (0.1-4,384)	76%	45%	ND	17.7	Payne et al., Int J of Cancer 2021
mCRPC post-chemo (AFFIRM)	ENZ	160	Pivotal	800	108 (0.2-11,794)	54%	25%	ND	8.3	Scher et al., NEJM 2021; Armstrong et al., Cancer 2017
mCRPC post-chemo (PREMISE)	ENZ	160	Observational	418	44.4 (0-5,162)	61%	31%	ND	9.8	Payne et al., Int J of Cancer 2021

*One Patient was non-evaluable for efficacy: discontinued after 1 cycle due to a strong CYP3A4 inducer concomitant medication which lowered EPI-7386 and Enz exposure

Source: Laccetti *et al.*, 2023

PSA response is an important prognosticator, as it was shown to be correlated with a number of positive outcomes from the PREVAIL study (Armstrong *et al*., 2019). This agrees with multiple other studies of hormone-sensitive prostate cancer (HSPC) patients that show greater PSA responses are associated with better long-term prognoses. In addition, PSA response was shown to correlated with five-year survival in the PREVAIL study:

- Armstrong *et al*., 2020: This was a long-term safety and efficacy analysis of the PREVAIL trial that evaluated 5-year survival and its correlation with various pretreatment prognostic factors and post-treatment PSA declines. The results showed that the 5-year survival rate for those with a best overall PSA decline of < 0.2 ng/mL was 71% compared to just 11% for those with no PSA decline or < 30% confirmed decline. Even for those who achieved PSA90, the 5-year survival rate was only 42%. This exemplifies the importance of achieving PSA < 0.2 ng/mL and how that can have a positive impact on long-term survival. Approximately 11% (100/872) of patients treated with Enz in PREVAIL achieved PSA < 0.2 ng/mL.

PSA responses of < 0.2 ng/mL do not appear to be commonly reported in studies of mCRPC patients, however the Phase 3 ACIS study showed that 25% of mCRPC patients treated with apalutamide plus abiraterone acetate and prednisone achieved a PSA level < 0.2 ng/mL at any time during treatment compared to 19% treated with just abiraterone acetate and prednisone (Saad *et al*., 2021).

The results seen thus far in the combination trial of EPI-7386 and Enz are very encouraging, particularly in regards to PSA response. While the number of patients analyzed thus far is small, the deep and prolonged PSA responses could indicate the potential for long-term positive treatment outcomes.

Oral EPI-7386 in Patients with Metastatic Castration-Resistant Prostate Cancer

This is updated data for the Phase 1, open label dose escalation (Part 1a) and expansion (Part 1b) trial of EPI-7386 in heavily pretreated mCRPC patients. EPI-7386 continues to be well tolerated at all dose levels and schedules. This is a very important point since ESSA's plan is to move EPI-7386 to earlier line patients in multiple combination therapy trials. In Part 1a of the trial, EPI-7386 showed preliminary signs of antitumor activity in a predefined subset of patients whose cancers continued to be driven by androgen receptor molecular alterations. Part 1b of the study is now open and is focused on pre-chemotherapy, post-second-generation antiandrogen treated mCRPC patients in one cohort (600 mg BID and 600 mg QD) and treatment-naïve non-mCRPC patients in a 'window of opportunity' proof-of-concept second cohort (600 mg BID).

Financial Update

On February 7, 2023, ESSA announced financial results for the first quarter of fiscal year 2023 that ended December 31, 2022. For the first quarter of fiscal year 2023, the company reported a net loss of $6.7 million, or $0.15 per share, compared to a net loss of $9.1 million, or $0.21 per share, for the first quarter of fiscal year 2022. R&D expenses for the first quarter of fiscal year 2023 were $5.3 million compared to $6.0 million for the first quarter of fiscal year 2022. The decrease was primarily due to decreased manufacturing costs and lower non-cash share-based payments. G&A expenses for the first quarter of fiscal year 2023 were $2.5 million compared to $3.1 million for the first quarter of fiscal year 2022. The decrease was primarily due to lower non-cash share-based payments.

As of December 31, 2022, ESSA had approximately $163.1 million in cash, cash equivalents, and short-term investments. As of February 7, 2023, 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

The updated data for the combination trial of EPI-7386 and Enz is very compelling, albeit the number of patients treated thus far is still small. However, the PSA responses compare quite favorably with prior studies of Enz, and the high percentage of patients achieving PSA < 0.2 ng/mL is particularly encouraging. We look forward to continued updates from the trial, including the initial data for the third cohort and the potential for a cohort examining a full dose of Enz (160 mg) before the Phase 2 portion of the study initiates. With no changes to our model our valuation remains at $27 per share.

PROJECTED FINANCIALS

ESSA Pharma Inc.	FY2022 A	Q1FY23 A	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	$5.3	$6.5	$7.0	$7.5	$26.3	$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	$2.5	$3.1	$3.2	$3.3	$12.1	$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)	($7.87)	($9.6)	($10.2)	($10.8)	($38.5)	($44.0)	($50.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$1.8	$1.1	$0.0	$0.0	$0.0	$1.1	$0.0	$0.0
Pre-Tax Income	($35.2)	($6.74)	($9.6)	($10.2)	($10.8)	($37.4)	($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)**	**($6.7)**	**($9.6)**	**($10.2)**	**($10.8)**	**($37.4)**	**($44.0)**	**($50.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.80)**	**($0.15)**	**($0.22)**	**($0.23)**	**($0.25)**	**($0.85)**	**($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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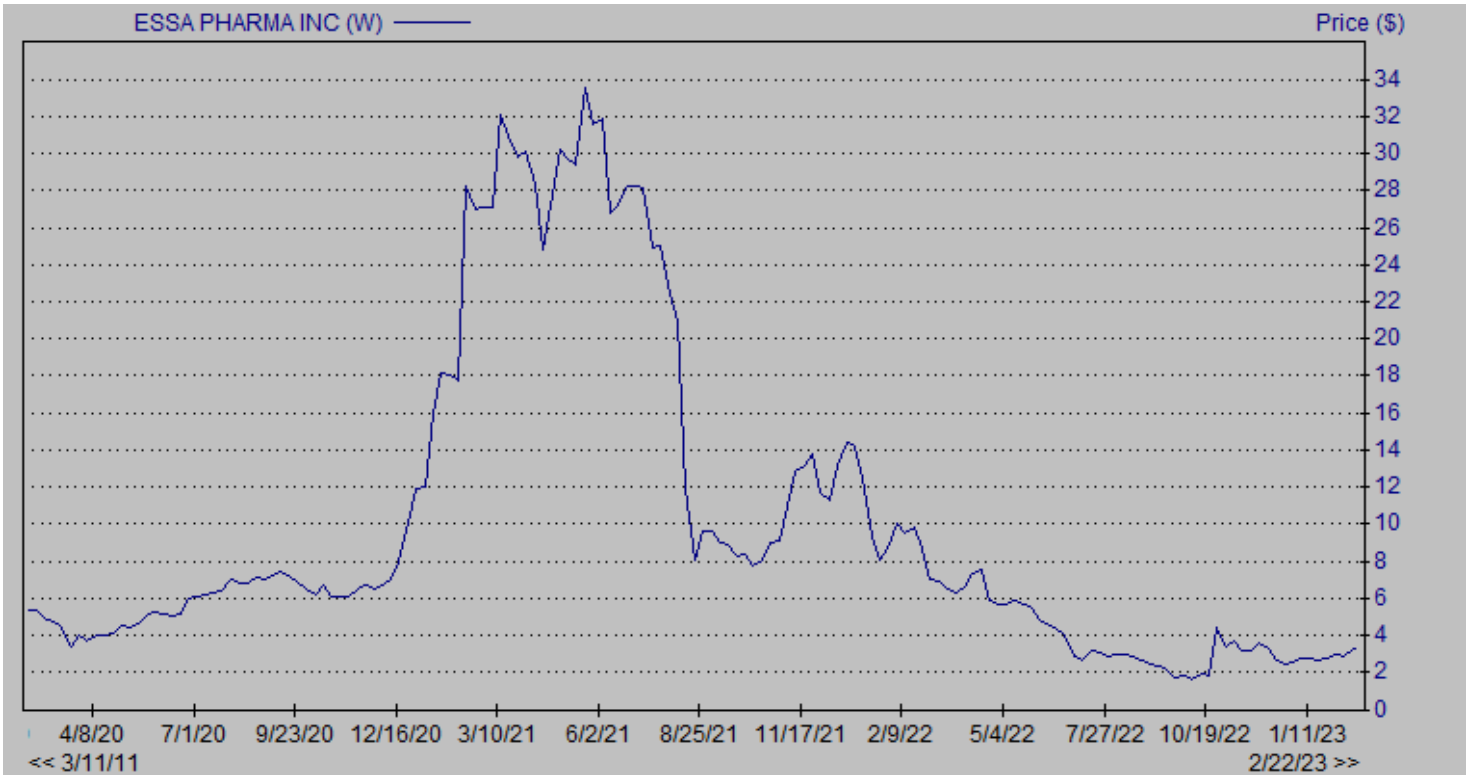
HISTORICAL STOCK PRICE



Source: Zacks SCR

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