Zacks Small-Cap Research
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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: Combination Trials Upcoming with Astellas, Bayer, and Janssen…

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 (05/10/21)	$29.73
Valuation	**$40.00**

OUTLOOK

On May 6, 2021, ESSA Pharma Inc. (EPIX) announced financial results for the second quarter of fiscal year 2021 that ended March 31, 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). ESSA recently announced preliminary PK and clinical data for the initial 200 mg once-daily cohort, which included one out of four patients experiencing a PSA decline of >50% after three cycles of EPI-7386. The trial is ongoing and we anticipate another clinical update in the fourth quarter of 2021.

ESSA has also entered into three collaborations to test EPI-7386 in combination with different second-generation anti-androgen therapies. We anticipate those combination trials initiating later in 2021.

SUMMARY DATA

52-Week High	**$32.08**
52-Week Low	**$4.47**
One-Year Return (%)	**565.10**
Beta	**1.66**
Average Daily Volume (sh)	**190,703**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$1,004**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**68**
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	**-27.8**
P/E using 2021 Estimate	**-27.4**

Risk Level	**Above Avg.**
Type of Stock	**Mid-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 E	0 E	0 E
2022					0 E
2023					0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2020	-$0.22 A	-$0.45 A	-$0.24 A	-$0.17 A	-$1.04 A
2021	-$0.20 A	-$0.36 A	-$0.19 E	-$0.20 E	-$0.88 E
2022					-$0.76 E
2023					-$0.80 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. Planned dose cohorts are at 200, 400, 600, 800, and 1000 mg once daily. The company is currently dosing in the 800 mg cohort.

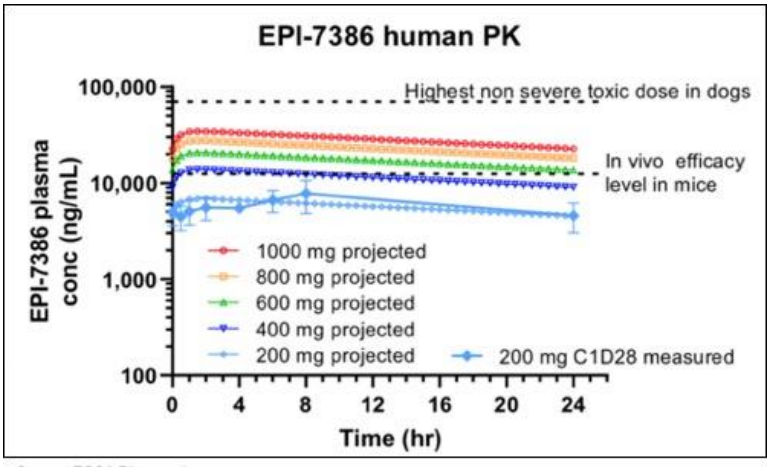
In February 2021, ESSA provided initial results for the 200 mg dose cohort. The results show that the PK parameters are right in line with what was predicted through preclinical studies. The following table shows various PK parameters measured on Day 1 and Day 28. The AUC data showing a large increase from Day 1 to Day 28 is indicative of drug accumulation with once daily dosing (steady state was reached after Day 8), and the half-life of approximately 24 hours is supportive of once daily dosing. The average AUC of approximately 147,000 is similar to what was predicted based on preclinical projections (approximately 137,000).

Measured PK parameters at 200 mg cohort

Dose (mg/day)	Day	N	t1/2 (hr)	Tmax (hr)	Cmax (ng/mL)	Clast (ng/mL)	AUC0-24 (ng•h/mL)
200	1	4	22.0	6.5	3,295	1,808	53,850
	28	3	24.8	6.7	8,020	4,593	146,833

Source: ESSA Pharma, Inc.

The following graph shows the similarity between the observed AUC data at Day 28 and what was predicted based on preclinical studies. This is very encouraging data for three reasons: 1) the drug is acting as predicted as there were no surprises with absorbance or exposure; 2) the line denoted 'In vivo efficacy level in mice' is approximately where the 600 mg dose and above are projected to be, however one of the first three patients dosed at 200 mg showed a PSA decline (discussed below); and 3) assuming the remaining doses have similar PK parameters to what was predicted, even at 1000 mg the exposure should be well below the 'highest non severe toxic dose in dogs' level.



Source: ESSA Pharma, Inc.

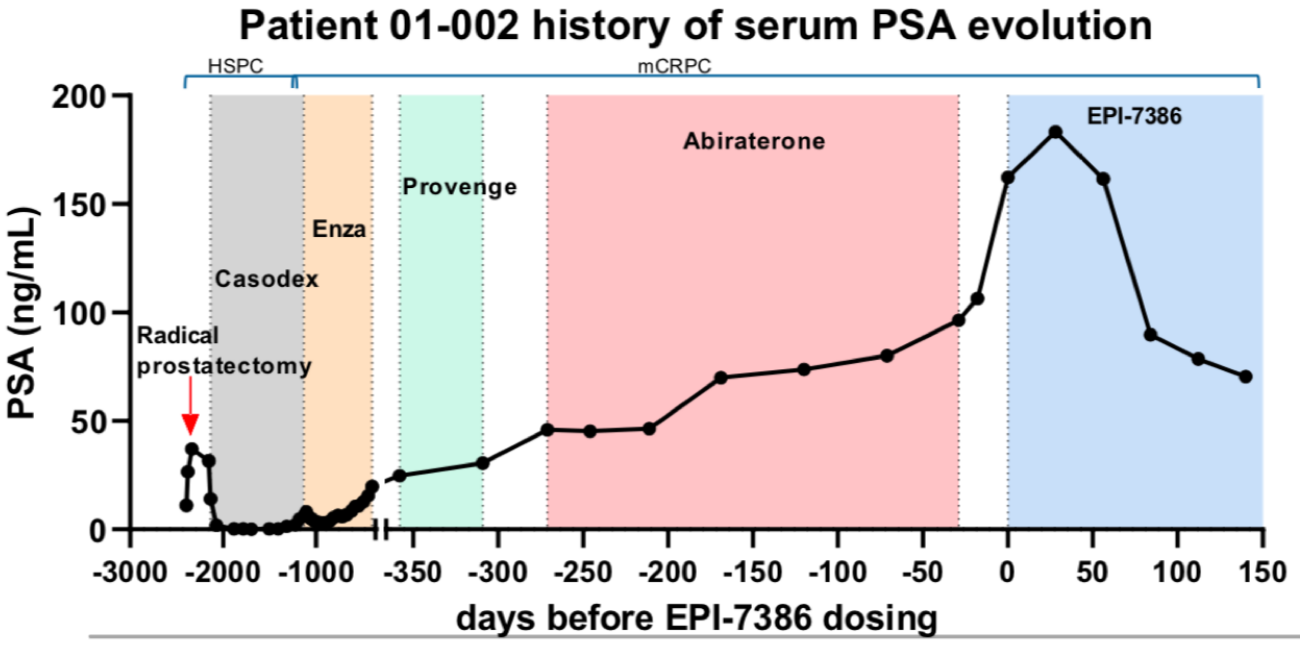
Four patients were enrolled into the 200 mg dosing cohort. One of the patients discontinued at Day 22 due to disease progression in the brain, thus three patients were evaluable for dose limiting toxicity (DLT) at Day 28. The patients had received from 2 to 7 prior lines of treatment, including two patients that had received both abiraterone

and enzalutamide, with three patients receiving prior chemotherapy. Importantly, there were no dose-limiting toxicities (DLTs) observed and no serious adverse events (SAEs). Possibly drug related adverse events are reported in the following table for the four patients from the 200 mg cohort. Importantly, all of them were Grade 1 or Grade 2, indicating they were mild to moderate. The 'hot flashes' is a potentially on-target effect of an anti-androgen therapy and the patient with neutropenia came into the study already suffering from Grade 1 neutropenia as a result of prior therapy.

Patient	Grade	AE	Comment
01-001	1	Anemia	Ongoing at time of death
01-002	2	Hot flashes	Ongoing
02-001	2	Neutropenia	Resolved
02-001	1	Hyperkalemia	Resolved
09-001	1	Weight loss	Ongoing at time of PD

Source: ESSA Pharma, Inc.

The following chart shows the serum PSA evolution for patient 01-002. Following a radical prostatectomy, the patients' PSA level had risen steadily even while being treated with enzalutamide, Provenge, and abiraterone. However, following a slight increase after beginning EPI-7386, the patient has experienced a steady decline in PSA level and that patient continues on treatment. This is very encouraging, particularly since this patients' PSA levels were not affected by other anti-androgen therapies and this dose is less than the target exposure for EPI-7386 based on preclinical models.



Source: ESSA Pharma, Inc.

In summary, the initial clinical data for EPI-7386 presented by ESSA is very encouraging as the PK parameters for the 200 mg dosing cohort aligned very well with those predicted by preclinical studies, the half-life of approximately 24 hours is compatible with once daily dosing, EPI-7386 was safe and well tolerated, and a serum PSA decrease of >50% was observed in a patient that had failed prior anti-androgen therapy. We anticipate an additional clinical update for this trial in the fourth quarter of 2021.

Multiple Collaboration Studies Being Planned

Over the past few months, ESSA has signed multiple clinical collaborations to study EPI-7386 in combination with different 'lutamide' drugs in mCRPC patients. A summary of the collaborations is provided below.

Collaborator	Combo Drug	Trial Sponsor	Patient Population
Astellas	enzalutamide	ESSA	mCRPC pts not treated by 2nd-gen anti-androgens
Bayer	daralutamide	Bayer	mCRPC pts
Janssen	a) apalutamide b) abiraterone+pred	Janssen	mCRCP pts that failed 2nd-gen anti-androgen therapy

Source: ESSA Pharma / Zacks SCR

A few observations on these collaborations:

1) Importantly, ESSA retains all rights to EPI-7386;
2) ESSA will sponsor the combination trial with enzalutamide while Bayer and Janssen will sponsor their respective trials. Sponsoring the enzalutamide trial will give ESSA more say in trial timelines, when data is announced, and choosing the exact patient population;
3) Janssen will be running up to two trials; one of which will examine EPI-7386 with apalutamide while a second trial will examine EPI-7386 with abiraterone acetate+prednisone;
4) The patient populations for each collaborative trial will be slightly different – all the trials will enroll mCRPC patients, however the trial with enzalutamide will enroll patients not yet treated with second generation anti-androgens, the trials with Janssen's drugs will enroll patients that have failed second generation anti-androgens, and there is no restriction (that we are aware of) on prior treatments for the daralutamide combination trial.

We anticipate the combination trials getting underway in the second half of 2021.

Financial Update

On May 6, 2021, ESSA announced financial results for the second quarter of fiscal year 2021 that ended March 31, 2021. The company reported a net loss of $13.0 million, or $0.36 per share, for the second quarter of fiscal year 2021 compared to a net loss of $9.4 million, or $0.45 per share, for the second quarter of fiscal year 2020. R&D expenses for the three months ending March 31, 2021 were $7.3 million compared to $4.6 million for the three months ending March 31, 2020. The increase was primarily due to increased chemistry and manufacturing of drug product along with clinical costs related to the ongoing Phase 1 clinical trial of EPI-7386. G&A expenses for the second quarter of 2021 were $4.6 million compared to $4.9 million for the second quarter of fiscal year 2020. The decrease was primarily due to decreased non-cash shared based compensation expenses.

As of March 31, 2021, ESSA had approximately $208.6 million in cash, cash equivalents, and short-term investments. This is due in part to a financing in February 2021 that resulted in gross proceeds of $150.0 million. As of May 6, 2021, the company had approximately 40.5 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 53.9 million.

Conclusion

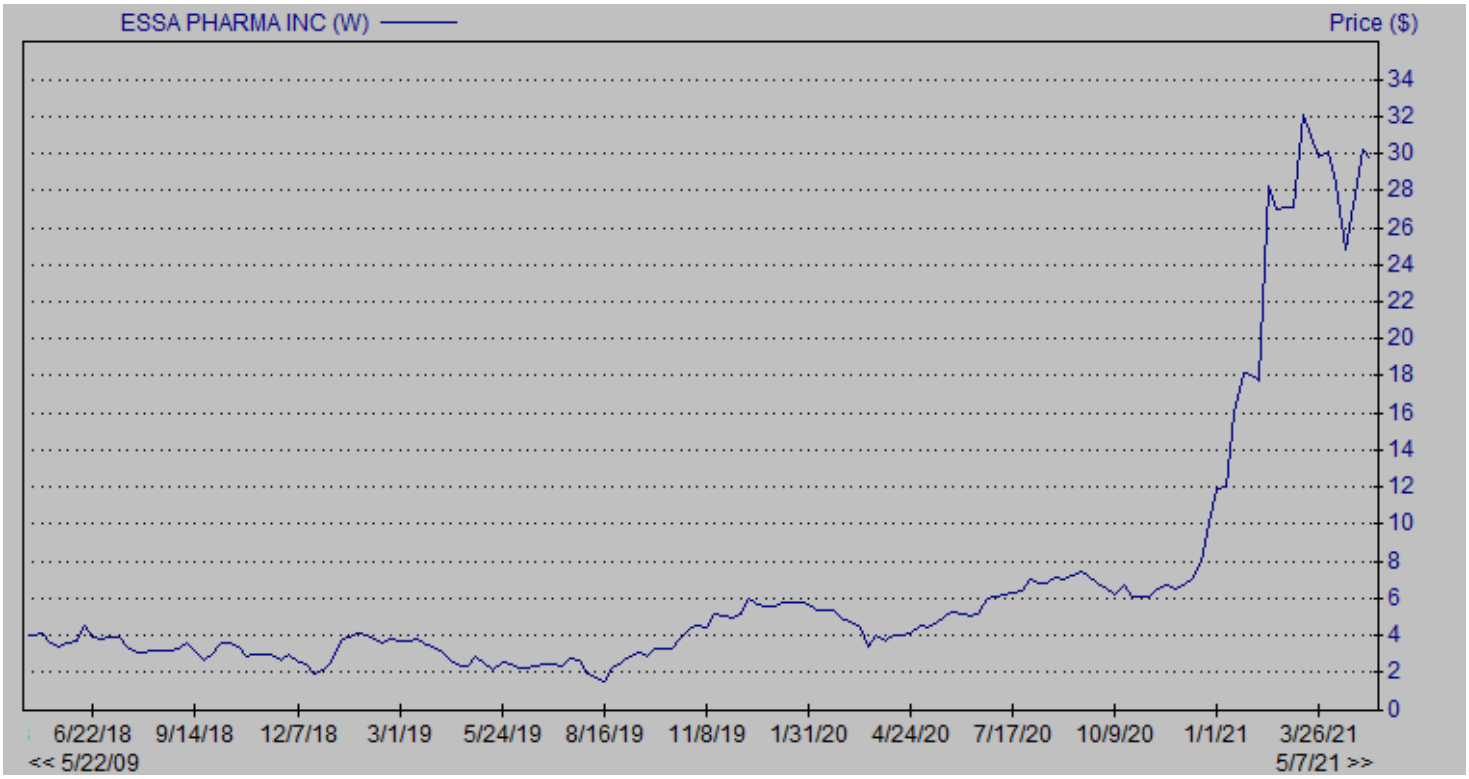
We look forward to additional updates regarding the Phase 1 trial of EPI-7386 in the fourth quarter of 2021. The early data from the trial is very encouraging and we are hopeful that additional positive responses will be seen in patients in the higher dose cohorts. The company's strategy had always included the desire to perform combination trials, thus we are glad to see the collaborations that have been put in place to allow those trials to occur. With no changes to our model our valuation remains at $40 per share and we continue to view ESSA as a top pick in our small-cap biotech coverage universe.

PROJECTED FINANCIALS

ESSA Pharma Inc.	FY2020 A	Q1FY21 A	Q2FY21 A	Q3FY21 E	Q4FY21 E	FY2021 E	FY2022 E	FY2023 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	$12.1	$4.5	$7.3	$4.7	$4.8	$21.3	$20.0	$23.0
Financing Costs	$0.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
General & Administrative	$11.4	$2.2	$4.6	$3.2	$3.3	$13.3	$13.0	$13.2
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($24.1)	($6.7)	($11.9)	($7.9)	($8.1)	($34.6)	($33.0)	($36.2)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.4	($0.1)	$1.1	$0.1	$0.1	$1.1	$0.4	$0.4
Pre-Tax Income	($23.7)	($6.6)	($13.0)	($7.8)	($8.0)	($33.4)	($32.6)	($35.8)
Income Taxes	($0.3)	$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	**($23.4)**	**($6.6)**	**($13.0)**	**($7.8)**	**($8.0)**	**($33.5)**	**($32.6)**	**($35.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.04)**	**($0.20)**	**($0.36)**	**($0.19)**	**($0.20)**	**($0.88)**	**($0.76)**	**($0.80)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	22.4	33.3	36.5	40.5	41.0	37.8	43.0	45.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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