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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: Unwarranted Selloff Following Phase 1 Trial Update…

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 (08/24/21)	$8.66
Valuation	**$40.00**

OUTLOOK

On August 16, 2021, ESSA Pharma Inc. (EPIX) announced financial results for the third quarter of fiscal year 2021 that ended June 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 600 mg, 800 mg, and 1000 mg, with all doses cleared as safe and tolerable. Following a discussion with management we learned that a significant percentage of the patients treated thus far had neuroendocrine differentiation, which is a very difficult patient population to treat and is not responsive to anti-androgen receptor (AR) therapy. ESSA will continue evaluating higher doses in very late stage patients, however the company will also begin testing monotherapy treatment in less heavily pretreated patients where tumor growth is more likely to be AR-driven. With these changes, we now anticipate a clinical data readout in the first half of 2022.

SUMMARY DATA

52-Week High	**$34.28**
52-Week Low	**$5.47**
One-Year Return (%)	**19.94**
Beta	**1.65**
Average Daily Volume (sh)	**1,185,371**
Shares Outstanding (mil)	**40**
Market Capitalization ($mil)	**$350**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**77**
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	**-7.2**
P/E using 2021 Estimate	**-6.2**

Risk Level	**Above 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)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 A	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	-$0.21 A	-$0.18 E	-$0.89 E
2022					-$0.71 E
2023					-$0.75 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 600, 800, and 1000 mg cohorts and thus far the drug has been safe and well tolerated in all dosing cohorts. ESSA will be enrolling additional patients in higher dose cohorts using a twice daily (BID) dosing schedule to enhance drug exposures and also filing an amendment to the clinical trial protocol to focus monotherapy on earlier stage patients that are less heavily pre-treated.

Following the trial update (and in the week leading up to the announcement) the stock sold off a tremendous amount, possibly due to the fact that the company did not provide any updated clinical data, although we don't necessarily believe that the lack of a data update should be viewed negatively. However, following a discussion with management we were able to gain a clearer understanding of exactly what the company is seeing in the trial, and we believe the selloff was unwarranted:

1) The initial patients that were enrolled in the study had been very heavily pre-treated, with a median seven prior therapies (range of 3-14). Thus, the patients entering the study are very sick.
2) 7/12 of the patients tested positive for neuroendocrine differentiation factors, thus indicating their cancers have progressed to a neuroendocrine phenotype (NEPC). In primary prostate cancers, neuroendocrine phenotypes make up approximately 1% of patients, however in mCRPC the percentage increases to approximately 25-30% and are associated with a very poor prognosis (Santoni *et al*., 2014). In addition, NEPC growth is not androgen receptor (AR) driven, but is instead driven by alternative signaling pathways such as PI3K and Myc (Dardenne *et al*., 2016). EPI-7386 targets the AR signaling pathway, thus it is much more difficult to achieve a clinical response in a patient whose cancer is being driven by an alternative signaling pathway.
3) EPI-7386 is safe and well tolerated at the doses tested thus far. The company is going to determine if responses are possible in this very heavily pre-treated, late stage cohort by increasing the dose while at the same time spreading that dose out (BID dosing) to maximize the drug exposure.
4) The company is also going to amend the clinical trial protocol so that they can begin enrolling patients that are less heavily pre-treated, which should lead to a higher percentage of patients having AR-driven mCRPC.
5) Given that additional dosing cohorts are going to be added, the goal now is to have a recommended Phase 2 dose in 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 in the fourth quarter of 2021. The combination trials of EPI-7386 with daralutamide (in collaboration with Bayer) and apalutamide/abiraterone + predinose (in collaboration with Janssen) are set to begin in late 2021 or early 2022.

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

Additional details regarding the combination trials:

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) All the trials will enroll mCRPC patients; the trial with enzalutamide will enroll patients not yet treated with second generation anti-androgens, while the trials with Janssen's and Bayer's drugs will enroll earlier mCRPC patients, however the exact patient populations for those trials is still being finalized.

Financial Update

On August 16, 2021, ESSA announced financial results for the third quarter of fiscal year 2021 that ended June 30, 2021. The company reported a net loss of $8.8 million, or $0.21 per share, for the third quarter of fiscal year 2021 compared to a net loss of $4.9 million, or $0.24 per share, for the third quarter of fiscal year 2020. R&D expenses for the three months ending June 30, 2021 were $6.2 million compared to $2.7 million for the three months ending June 30, 2020. The increase was primarily due to preclinical research and chemistry and manufacturing costs. G&A expenses for the third quarter of 2021 were $3.1 million compared to $2.2 million for the third quarter of fiscal year 2020. The increase was primarily due to increased non-cash shared based compensation expenses.

As of June 30, 2021, ESSA had approximately $202.3 million in cash, cash equivalents, and short-term investments. As of August 16, 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 company's update on the Phase 1 trial, ESSA's stock reacted very unfavorably. However, the weakness in the stock actually began the week before the company's press release when a shareholder sold a significant number of shares, however we are unsure of who it was or the reason behind the sale. Regardless, that set off a chain reaction of heavy pressure on the stock throughout the week that culminated in the significant drop following the release of the company's recent update. The move down in the stock is unfortunate because we believe investors are misinterpreting what is happening in the Phase 1 trial. The company previously disclosed that a patient originally enrolled in the 200 mg cohort showed a decrease in PSA level of >50%, and as of the previous update for that patient in June 2021 his PSA continued to decline beyond PSA50 and he had dose escalated while remaining on study. In addition, that patient only had four prior systemic therapies following a radical prostatectomy, thus it may give an indication of how patients who are less heavily pre-treated could respond to EPI-7386.

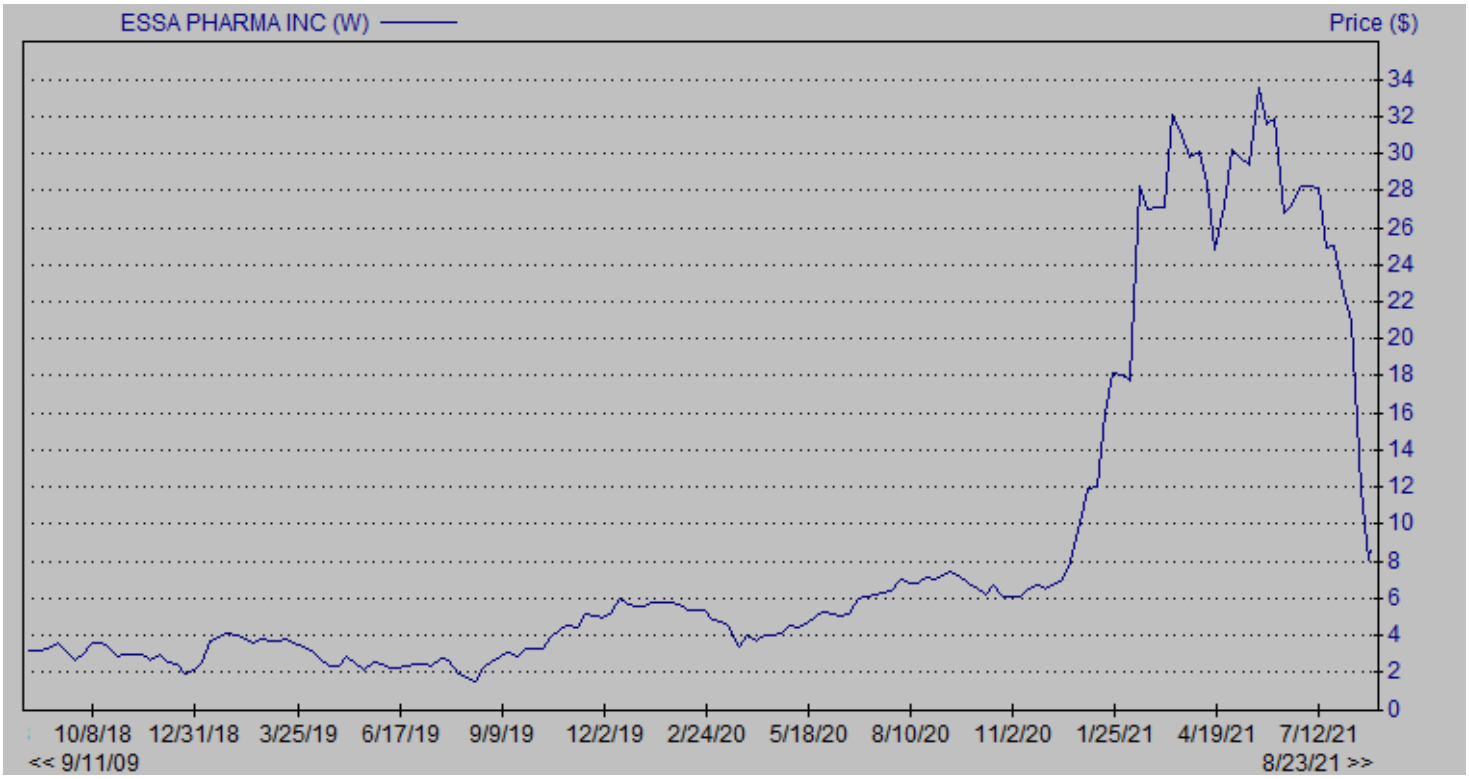
Investors are understandably nervous given the lack of efficacy thus far, however this is still just a dose-ranging Phase 1 study and with a significant percentage of the patients thus far likely having NEPC it is not surprising that more positive responses haven't been seen. We believe that once the company moves into a less heavily pre-treated population with a majority of patients having AR-driven disease then signs of clinical efficacy will increase. We have not made any changes to our model, thus our valuation remains at $40 per share.

PROJECTED FINANCIALS

ESSA Pharma Inc.	FY2020 A	Q1FY21 A	Q2FY21 A	Q3FY21 A	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	$6.2	$4.8	$22.8	$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	$3.1	$3.3	$13.2	$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)	($9.4)	($8.1)	($36.0)	($33.0)	($36.2)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.4	($0.1)	$1.1	$0.6	$0.1	$1.7	$0.4	$0.4
Pre-Tax Income	($23.7)	($6.6)	($13.0)	($8.8)	($8.0)	($34.4)	($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)**	**($8.8)**	**($8.0)**	**($34.4)**	**($32.6)**	**($35.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.04)**	**($0.20)**	**($0.36)**	**($0.21)**	**($0.18)**	**($0.89)**	**($0.71)**	**($0.75)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	22.4	33.3	36.5	41.0	44.0	38.7	46.0	48.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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