Zacks Small-Cap Research
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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Positive Interim Efficacy Analysis for EB01 Phase 2b Trial in Allergic Contact Dermatitis…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB01, EB02, and EB05, EDSA is valued at $16.00/share. This model is highly dependent upon continued clinical success of the company's pipeline and will be adjusted accordingly based on future clinical results.

Current Price (06/04/21)	$5.99
Valuation	**$16.00**

OUTLOOK

On June 3, 2021, Edesa Biotech, Inc. (EDSA) announced positive interim results for the Phase 2b trial of EB01 in allergic contact dermatitis (ACD). The Data Safety Monitoring Board (DSMB) performed a blinded analysis of the data and reported a 1.7-fold difference between the treatment groups for the primary efficacy endpoint (the mean percent change from baseline on the Contact Dermatitis Severity Index [CDSI] at day 29) as well as a 1.8-fold difference between the treatment groups in the proportion of patients achieving success on the Investigator's Static Global Assessment [ISGA], a key secondary endpoint. The study will now proceed to enrolling the second cohort of patients. As of June 2, 2021, 66 total patients have been randomized into the study and we estimate another approximately 100 patients will be enrolled before the final data analysis.

SUMMARY DATA

52-Week High	**$9.45**
52-Week Low	**$2.87**
One-Year Return (%)	**86.03**
Beta	**0.64**
Average Daily Volume (sh)	**164,840**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$79**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**45**
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 2019 Estimate	**-6.5**
P/E using 2020 Estimate	**-3.3**

Risk Level	**Above Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2020	0.1 A	0.1 A	0.1 A	0.1 A	0.4 A
2021	0.0 A	0.0 A	0.0 E	0.0 E	0.0 E
2022					0.0 E
2023					0.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2020	-$0.15 A	-$0.17 A	-$0.19 A	-$0.22 A	-$0.74 A
2021	-$0.26 A	-$0.19 A	-$0.18 E	-$0.20 E	-$0.83 E
2022					-$0.66 E
2023					-$0.65 E

WHAT'S NEW

Business Update

Positive Interim Analysis for EB01 in Phase 2b Trial

On June 3, 2021, Edesa Biotech, Inc. (EDSA) announced positive interim results for EB01 in the Phase 2b clinical trial in patients with allergic contact dermatitis (ACD). The initial study cohort consisted of 46 subjects randomized 1:1 to receive treatment with either EB01 2.0% cream or placebo and 36 (n=18 EB01; n=18 placebo) completed the study follow-up and were used in the interim analysis.

The study's Data Safety Monitoring Board (DSMB) performed a blinded analysis of the data and reported an approximately 1.7-fold difference between treatment groups for the primary efficacy endpoint, the mean percent change from baseline on the Contact Dermatitis Severity Index (CDSI). CDSI uses physician's visual assessment of dryness, scaling, redness, pruritis, and fissures, with each scored from 0 (none) to 3 (severe).

In addition, the DSMB reported an approximately 1.8-fold difference between the treatment groups in the Investigator's Static Global Assessment (ISGA), a key secondary efficacy endpoint. The ISGA uses a five-point rating scale: 0 – clear, 1 – almost clear, 2 – mild, 3 – moderate, 4 – severe disease. Success on the ISGA is defined as a two-point reduction from baseline and a final ISGA score of 0 or 1. The ISGA is commonly used for FDA-regulated registration trials in dermatitis.

For both the CDSI and ISGA, double-digit absolute differences were seen between the treatment groups and no serious treatment-related adverse events were reported for either treatment group.

Now that the interim analysis is complete, Edesa will focus on enrolling the second cohort of patients into the Phase 2b trial. We estimate that approximately 120 patients will be enrolled in the second cohort and the company reported that as of June 2, 2021 a total of 66 patients (including the first cohort) have been randomized into the study, thus leaving approximately 100 more patients to enroll before the final data analysis can be completed. The company is focused on getting those patients enrolled as expeditiously as possible, which may include opening additional centers in the study.

ACD Market Opportunity

ACD is a very common condition, with some studies suggesting a prevalence as high as 20% of the general population (Alinaghi *et al*., 2019). If one member of a family develops ACD then others in the same family have a higher prevalence of developing the condition, which would suggest a genetic predisposition, although environmental exposure most likely contributes as well. Women tend to develop ACD more than men, although this is likely due to a higher prevalence of wearing jewelry, which increases contact with nickel, a known trigger of ACD.

We estimate there are approximately 2.5 million individuals in the U.S. that suffer from ACD and that approximately 1.0 million suffer from the condition chronically. However, given how difficult it is to distinguish ACD from irritant contact dermatitis (ICD) we may be underestimating the potential number of patients. In addition, we are unaware of any FDA-approved therapies for ACD.

Conclusion

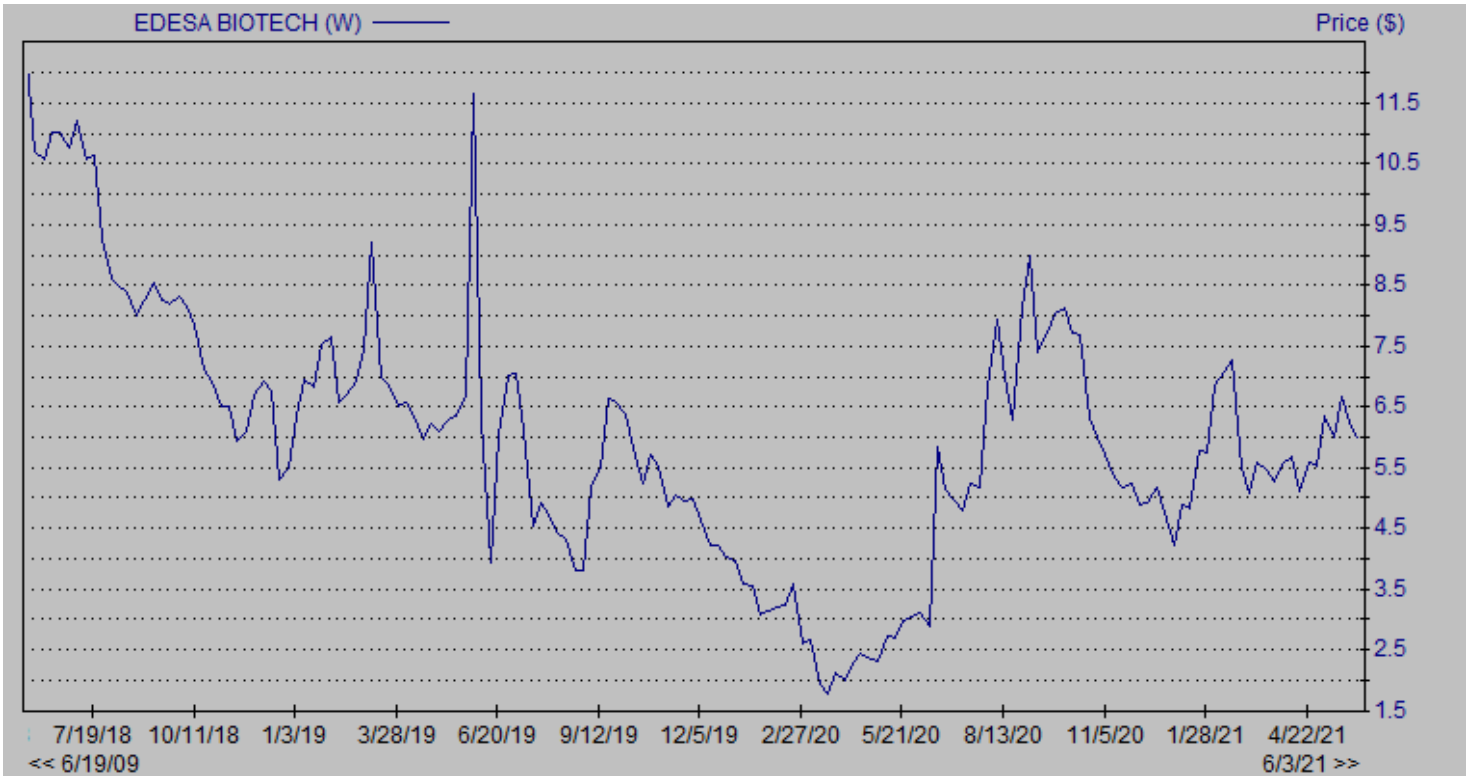
We are very encouraged by the positive interim analysis for EB01 in the Phase 2b trial in patients with ACD. Particularly intriguing is the data showing a 1.8-fold separation between the treatment groups in the ISGA, which is an outcome measure commonly used for dermatitis registration trials. Edesa did not have any previous data on ISGA outcomes with EB01 so this data could prove very valuable in helping to design a Phase 3 program. Of course, the data is still blinded so we aren't certain that EB01 is having a treatment effect, however given the previous positive data from earlier trials we believe it is reasonable to assume that the treatment group exhibiting greater efficacy is being administered EB01. We look forward to additional updates from the company regarding patient enrollment in the trial and when the topline data could be available. We had modeled for a positive outcome from the interim analysis thus with no change to our model our valuation remains at $16 per share.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2020 A	Q1FY21 A	Q2FY21 A	Q3FY21 E	Q4FY21 E	FY2021 E	FY2022 E	FY2023 E
EB01	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
EB02	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.3**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Cost of Sales	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$3.3	$1.4	$8.0	$1.4	$1.6	$12.4	$6.0	$7.0
General & Administrative	$3.4	$1.2	$1.5	$1.0	$1.1	$4.9	$4.5	$4.7
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($6.4)	($2.6)	($9.5)	($2.4)	($2.7)	($17.2)	($10.5)	($11.7)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	($0.0)	$7.3	$0.0	$0.0	$7.2	$0.0	$0.0
Pre-Tax Income	($6.4)	($2.6)	($2.3)	($2.4)	($2.7)	($10.0)	($10.5)	($11.7)
Income Taxes	$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	**($6.4)**	**($2.6)**	**($2.3)**	**($2.4)**	**($2.7)**	**($10.0)**	**($10.5)**	**($11.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.74)**	**($0.26)**	**($0.19)**	**($0.18)**	**($0.20)**	**($0.83)**	**($0.66)**	**($0.65)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	8.6	10.3	11.6	13.0	13.5	12.1	16.0	18.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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