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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: 1.0% EB01 Cream Achieves Primary Endpoint in Phase 2b Trial…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB01, EB02, and EB05, EDSA is valued at $10.00/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 (01/18/23)	$1.46
Valuation	**$10.00**

OUTLOOK

On January 17, 2023, Edesa Biotech, Inc. (EDSA) announced topline results for the Phase 2b clinical trial of EB01 as a monotherapy for moderate-to-severe Allergic Contact Dermatitis (ACD). Approximately 200 patients were enrolled and treated for 28 days with either EB01 (2.0%, 1.0%, or 0.2%) or a placebo cream. 1.0% EB01 cream demonstrated statistical significance for the primary endpoint, which measured the mean percent improvement in symptoms from baseline at Day 29 on the Contact Dermatitis Severity Index (CDSI). Patients treated with 1.0% EB01 showed a 60% average improvement in symptoms from baseline on Day 29 on the CDSI compared to 39% treated with placebo (*P*=0.02). The other two concentrations of EB01 did not demonstrate statistical significance. The company will be requesting an 'End-of-Phase 2' meeting with the FDA following full analysis of the trial results, which should be complete by mid-year.

SUMMARY DAT

52-Week High	**$5.26**
52-Week Low	**$0.80**
One-Year Return (%)	**-70.02**
Beta	**0.58**
Average Daily Volume (sh)	**1,083,079**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$28**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
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 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2022	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2023	0.0 E	0.0 E	0.0 E	0.0 E	0.0 E
2024					0.0 E
2025					0.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2022	-$0.33 A	-$0.33 A	-$0.37 A	-$0.12 A	-$1.05 A
2023	-$0.21 E	-$0.24 E	-$0.22 E	-$0.23 E	-$0.90 E
2024					-$0.70 E
2025					-$0.67 E

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WHAT'S NEW

Business Update

1.0% EB01 Cream Achieves Primary Endpoint in Phase 2b Trial

On January 17, 2023, Edesa Biotech, Inc. (EDSA) announced topline results for the Phase 2b clinical trial of EB01 as a treatment for chronic moderate-to-severe Allergic Contact Dermatitis (ACD). The double blind, placebo controlled trial evaluated three different formulations of EB01 cream (2.0%, 1.0%, or 0.2%) compared to a placebo cream. Approximately 200 subjects were enrolled into the trial, which had a primary efficacy outcome of the mean percent improvement in symptoms from baseline at Day 29 on the Contact Dermatitis Severity Index (CDSI). A key secondary outcome was the success rate of subjects achieving a score of 'clear' or 'almost clear' with at least a 2-point improvement from baseline at Day 29 on the Investigator's Static Global Assessment (ISGA) scale.

The results showed that 1.0% EB01 cream demonstrated a statistically significant improvement over placebo. For the primary endpoint, subjects treated with 1.0% EB01 cream had a 60% average improvement in symptoms from baseline at Day 29 on the CDSI compared to 39% for placebo-treated subjects (*P*=0.02). The effect was observed as early as 15 days (44% for 1.0% EB01 compared to 29% for placebo; *P*=0.05) and continued at follow up (64% for 1.0% EB01 compared to 44% for placebo; *P*=0.04). For the ISGA secondary endpoint, 53% of 1.0% EB01-treated subjects achieved a score of 'clear' or 'almost clear' with at least a 2-point improvement from baseline after treatment at Day 29 compared to only 29% of placebo-treated subjects (*P*=0.04). These results are summarized in the tables below.

Percent Reduction in Contact Dermatitis Severity Index (CDSI)*

	Treatment Group	
Outcome	Placebo Vehicle (n= 84)	EB01 1.0% Cream (n=19)
Percent Change in CDSI from Baseline at Day 29		
Mean (± SD)	-39.25 (34.49)	-59.94(32.20)
95% CI for Mean	(-46.73,-31.76)	(-75.46,-44.42)
Median (IQR)	-38.75	-66.67
P-Value		0.02

Achievement of Endpoint for Investigator's Static Global Assessment (ISGA)**

	Treatment Group		
Outcome	Placebo Vehicle (n= 84)	EB01 1.0% Cream (n=19)	P-Value
≥2 grade reduction to clear or almost clear in ISGA from baseline at Day 29, % (n)	28.6% (24)	52.6% (10)	0.04

Source: Edesa Biotech, Inc.

The 2.0% and 0.2% EB01 creams did not achieve the primary or secondary endpoints. We were not surprised to see that the 0.2% EB01 cream did not reach statistical significance on the primary endpoint. The FDA had asked Edesa to conduct a dose-ranging study, with one of the stated objectives being to find the lowest effective dose. We believe this has been accomplished by showing that the 1.0% EB01 cream achieved the primary endpoint. However, the 2.0% EB01 cream not reaching statistical significance was surprising, as that concentration had shown efficacy in previous studies. In speaking to management about the results of the Phase 2b study we learned that concentrations above 2.0% led to aggregate formation. While batches of the

2.0% cream had previously been formulated and showed efficacy in a prior study, we believe it is conceivable that at 2.0% concentration there may have been issues with aggregation, which could have led to the lack of efficacy. The results were likely confusing for investors as well, as most would assume that if the drug was active at a 1.0% concentration then a 2.0% concentration should have been as well. However, knowing that during formulation development the drug substance was challenging to formulate at high concentrations in a cream should allay any fears of a dose response issue with the drug and the company would have likely had to move forward with the 1.0% cream even if the 2.0% cream had reached the primary endpoint. We are confident that the results seen with the 1.0% cream can be replicated in a Phase 3 program.

In regards to safety, all of the strengths were well tolerated with very few serious adverse events in the study. In particular, the 0.2% and 1.0% concentrations were both very well tolerated with no adverse events reported for the 1.0% cream and only one adverse event reported for the 0.2% cream. This is in contrast to the 2.0% cream, in which 37% of patients reported an adverse event (none serious), compared to 25% of patients receiving placebo cream reporting an adverse event. These results are summarized in the table below.

Summary of Incidents of Treatment Emergent Adverse Events***

	Treatment Group							
	Placebo/Vehicle (n= 84)		EB01 2.0% Cream (n=81)		EB01 1.0% Cream (n=19)		EB01 0.2% Cream (n=19)	
Parameter	Number of Events	Subjects (%)	Number of Events	Subjects (%)	Number of Events	Subjects (%)	Number of Events	Subjects (%)
Overall	35	21(25%)	53	30(37%)	0	0(0%)	1	1(5%)
Severity, n (%)								
Mild	23	15(18%)	35	21(26%)	0	0(0%)	1	1(5%)
Moderate	7	6(7%)	15	5(19%)	0	0(0%)	0	0(0%)
Severe	5	2(2%)	3	3(4%)	0	0(0%)	0	0(0%)
Seriousness, n (%)								
No	34	21(25%)	53	30(37%)	0	0(0%)	1	1(5%)
Yes	1	1(1%)	0	0(0%)	0	0(0%)	0	0(0%)

Source: Edesa Biotech, Inc.

The company will continue to analyze the full data set, which we expect to be completed by mid-year. Afterwards, Edesa will request an 'end-of-Phase 2' meeting with the FDA to map out a Phase 3 program. We anticipate two Phase 3 trials, each with approximately 500 patients testing 1.0% EB01 cream compared to placebo. Edesa may look to enter into a partnership before embarking on the Phase 3 program, however the company is also prepared to advance the drug on its own.

Conclusion

We're pleased with the results of the Phase 2b trial of EB01. We think that investors not being aware of potential reasons why the 1.0% cream was effective and the 2.0% cream was not may have contributed to the sell-off in the stock following release of the data. Formulation issues are a likely explanation for the lack of efficacy for the 2.0% cream, which would preclude any type of dose response concerns for the active ingredient. The company now knows the lowest active concentration for EB01 and is prepared to advance it into Phase 3 testing, where we are confident it will be successful. We are maintaining our $10 valuation.

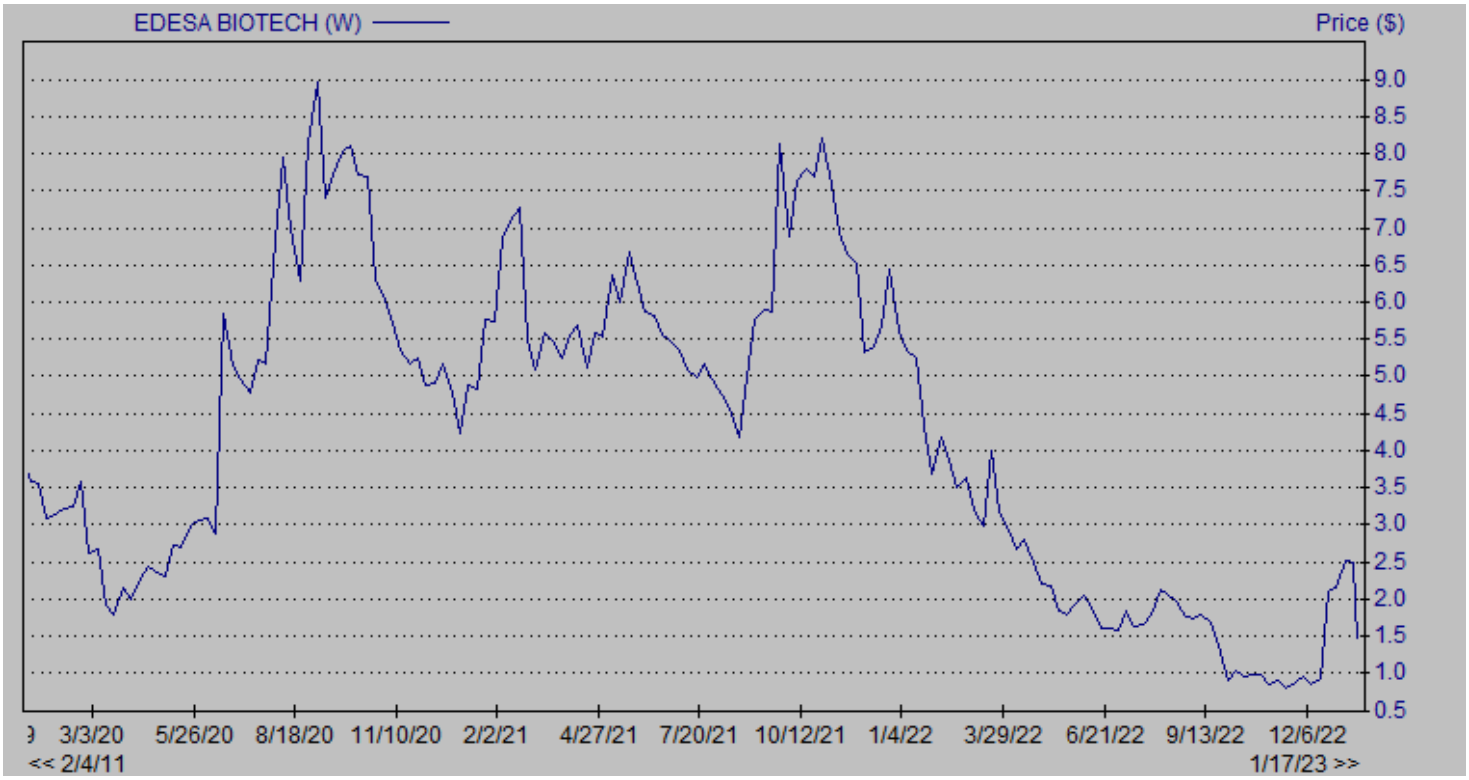
PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2022 A	Q1FY23 E	Q2FY23 E	Q3FY23 E	Q4FY23 E	FY2023 E	FY2024 E	FY2025 E
EB01	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
EB05	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$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	$13.3	$3.0	$3.4	$3.7	$3.9	$14.0	$15.0	$17.0
General & Administrative	$5.0	$1.1	$1.3	$1.5	$1.7	$5.6	$6.0	$6.5
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($18.4)	($4.1)	($4.7)	($5.2)	($5.6)	($19.6)	($21.0)	($23.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($17.5)	($4.1)	($4.7)	($5.2)	($5.6)	($19.6)	($21.0)	($23.5)
Income Taxes	$0.0	$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	**($17.5)**	**($4.1)**	**($4.7)**	**($5.2)**	**($5.6)**	**($19.6)**	**($21.0)**	**($23.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.05)**	**($0.21)**	**($0.24)**	**($0.22)**	**($0.23)**	**($0.90)**	**($0.70)**	**($0.67)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	16.7	19.5	19.5	24.0	24.5	21.9	30.0	35.0

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

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