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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: FDA Agrees on Primary Endpoint for Phase 3 ARDS Drug Study…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB01, EB02, and EB05, EDSA is valued at $6.00/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 (05/17/23)	$0.85
Valuation	**$6.00**

OUTLOOK

On May 11, 2023, Edesa Biotech, Inc. (EDSA) announced financial results for the second quarter of fiscal year 2023 that ended March 31, 2023 and provided a business update. Edesa recently announced that the FDA has agreed on the primary endpoint and population for a Phase 3 study evaluating EB05 as a therapy for hospitalized patients with acute respiratory distress syndrome (ARDS) hospitalized with SARS-CoV-2 infections. The primary endpoint will be the mortality rate at 28 days, with key secondary endpoints of the number of ventilator free days at 28 days and mortality at 60 days.

In addition, the company reported favorable preliminary topline results from a Phase 2b trial of EB01 as a monotherapy for moderate-to-severe chronic allergic contact dermatitis (ACD).

SUMMARY DATA

52-Week High	**$2.63**
52-Week Low	**$0.80**
One-Year Return (%)	**-56.41**
Beta	**0.43**
Average Daily Volume (sh)	**102,588**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$18**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**27**
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 A	0.0 A	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	-$0.13 A	-$0.12 A	-$0.25 E	-$0.27 E	-$0.78 E
2024					-$0.70 E
2025					-$0.67 E

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WHAT'S NEW

Business Update

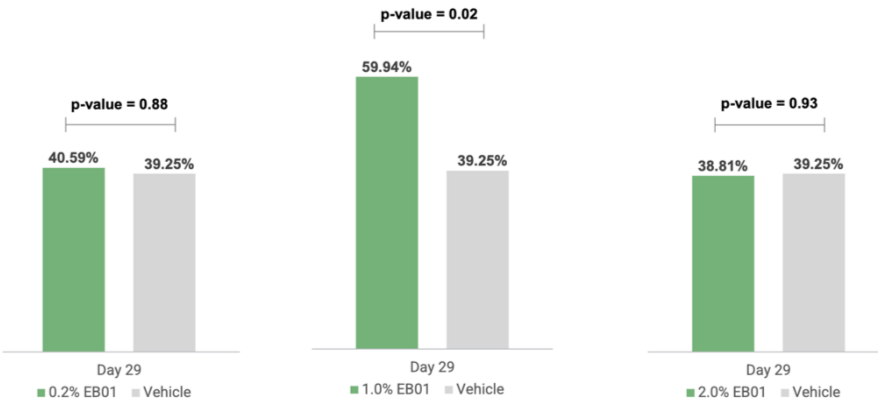
Edesa and FDA Agree on Primary Endpoint for Phase 3 ARDS Trial

In March 2023, Edesa Biotech, Inc. (EDSA) announced that the U.S. Food and Drug Administration (FDA) has agreed on the primary endpoint and population for a Phase 3 clinical trial evaluating EB05 as a therapy for hospitalized patients with acute respiratory distress syndrome (ARDS) due to SARS-CoV-2 infection. The protocol for the Phase 3 trial calls for Edesa to evaluate a single cohort of severely ill patients on invasive mechanical ventilation both with and without additional organ support such as extracorporeal membrane oxygenation (ECMO). Approximately 600 patients will be enrolled with a primary endpoint of mortality rate at 28 days. Key secondary endpoints include ventilator free data at 28 days and mortality rate at 60 days. Recruitment has initiated in the U.S., and with clinical sites now open in both the U.S. and Canada the company has discontinued enrollment at secondary sites in Poland and Colombia. Last year, Canadian regulators approved a similar Phase 3 protocol in COVID-19-induced ARDS among two separate cohorts of patients and the company is currently evaluating bringing both the U.S. and Canadian protocol in line with each other. In April 2023, Edesa announced that the World Health Organization and the U.S. Adopted Name (USAN) Council adopted the international nonproprietary name 'paridiprubart' for EB05.

In September 2022, Edesa announced final results from the Phase 2 portion of its ongoing Phase 2/3 clinical trial of EB05. At the 28-day timepoint, patients treated with EB05 in addition to standard of care (SOC) had a mortality rate of 7.7% compared to 40% for patients treated with placebo and SOC (*P*=0.04). Using the Cox's Proportional Hazard Model, this survival benefit translated to an 84.0% reduction in the risk of dying for patients treated with EB05 plus SOC compared to placebo plus SOC at 28 days. Additional efficacy signals were observed in the proportion of patients who were alive and without the need for oxygen support at Day 28 in severe COVID-19 patients at WCSS level ≥5 (99% of patients had ARDS at baseline) along with the proportion of patients who achieved at least a 2-point improvement on the WCSS.

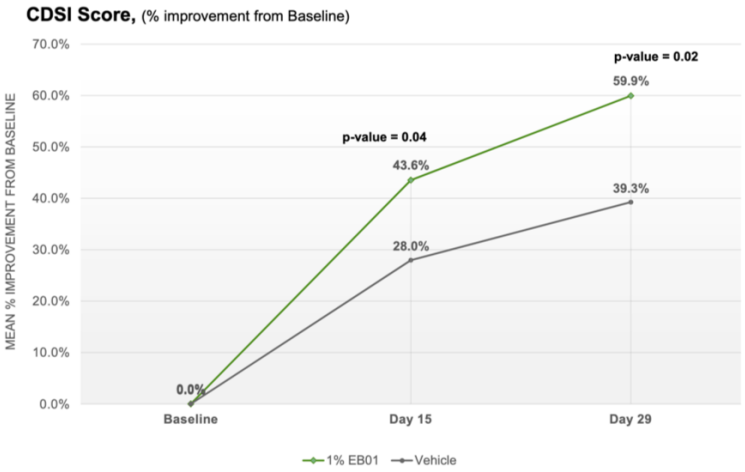
Favorable Results for EB01 Presented at AAD Meeting

In March 2023, Edesa presented data from the Phase 2b clinical trial of EB01 as a treatment for chronic moderate-to-severe Allergic Contact Dermatitis (ACD). 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). Similar results were seen for the ISGA secondary endpoint, with 53% of 1.0% EB01-treated subjects achieving 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).



Source: Edesa Biotech, Inc.

As the following figure shows, the effect was observed as early as 15 days (44% for 1.0% EB01 compared to 28% for placebo; *P*=0.04) and continued at follow up (64% for 1.0% EB01 compared to 44% for placebo; *P*=0.04).



Source: Edesa Biotech, Inc.

While the 2.0% and 0.2% EB01 creams did not reach statistical significance, it was likely due to too little active ingredient in the 0.2% EB01 cream and formulation issues with the 2.0% cream, as it is known that the active ingredient begins to aggregate at concentrations at and above 2.0%. 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.

Financial Update

On May 11, 2022, Edesa announced financial results for the second quarter of fiscal year 2023 that ended March 31, 2023. There were no revenues reported for the second quarter of fiscal year 2023. R&D expenses in the second quarter of fiscal year 2023 were $1.5 million, compared to $3.0 million for the second quarter of fiscal year 2022. The decrease was primarily due to decreases in costs associated with ongoing clinical studies and manufacturing of investigational drugs. G&A expenses totaled $1.0 million for the second quarter of fiscal year 2023 compared to $1.5 million for the second quarter of fiscal year 2022. The decrease was primarily due to a decrease in personnel expenses and non-cash, stock-based compensation.

As of March 31, 2023, Edesa had approximately $7.5 million in cash and cash equivalents. Subsequent to the end of the second quarter of fiscal year 2023, Edesa raised gross proceeds of approximately $0.6 million under the company's at-the-market offering program. We estimate that the company has sufficient capital to fund operations through the end of calendar 2023. As of May 10, 2023, Edesa had approximately 20.6 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 28.8 million.

Conclusion

We're glad to see that the FDA has agreed to the Phase 3 protocol and that patient recruitment has commence in the U.S. We look forward to updates from the company as the trial progresses. With the slowdown in COVID cases and a planned Phase 3 enrollment of 600 patients, we have pushed back our estimated approval date for EB05. In addition, due to the decrease in the company's share price we have increased the number of estimated shares to be issued for the next financing. Our valuation now stands at $6 per share.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2022 A	Q1FY23 A	Q2FY23 A	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	$1.4	$1.5	$3.7	$3.9	$10.4	$15.0	$17.0
General & Administrative	$5.0	$1.0	$1.0	$1.5	$1.7	$5.2	$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)	($2.4)	($2.4)	($5.2)	($5.6)	($15.6)	($21.0)	($23.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.8	$0.0	$0.1	$0.0	$0.0	$0.1	$0.0	$0.0
Pre-Tax Income	($17.5)	($2.4)	($2.3)	($5.2)	($5.6)	($15.5)	($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)**	**($2.4)**	**($2.3)**	**($5.2)**	**($5.6)**	**($15.5)**	**($21.0)**	**($23.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.05)**	**($0.13)**	**($0.12)**	**($0.25)**	**($0.27)**	**($0.78)**	**($0.70)**	**($0.67)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	16.7	18.4	20.0	20.6	20.7	19.9	30.0	35.0

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

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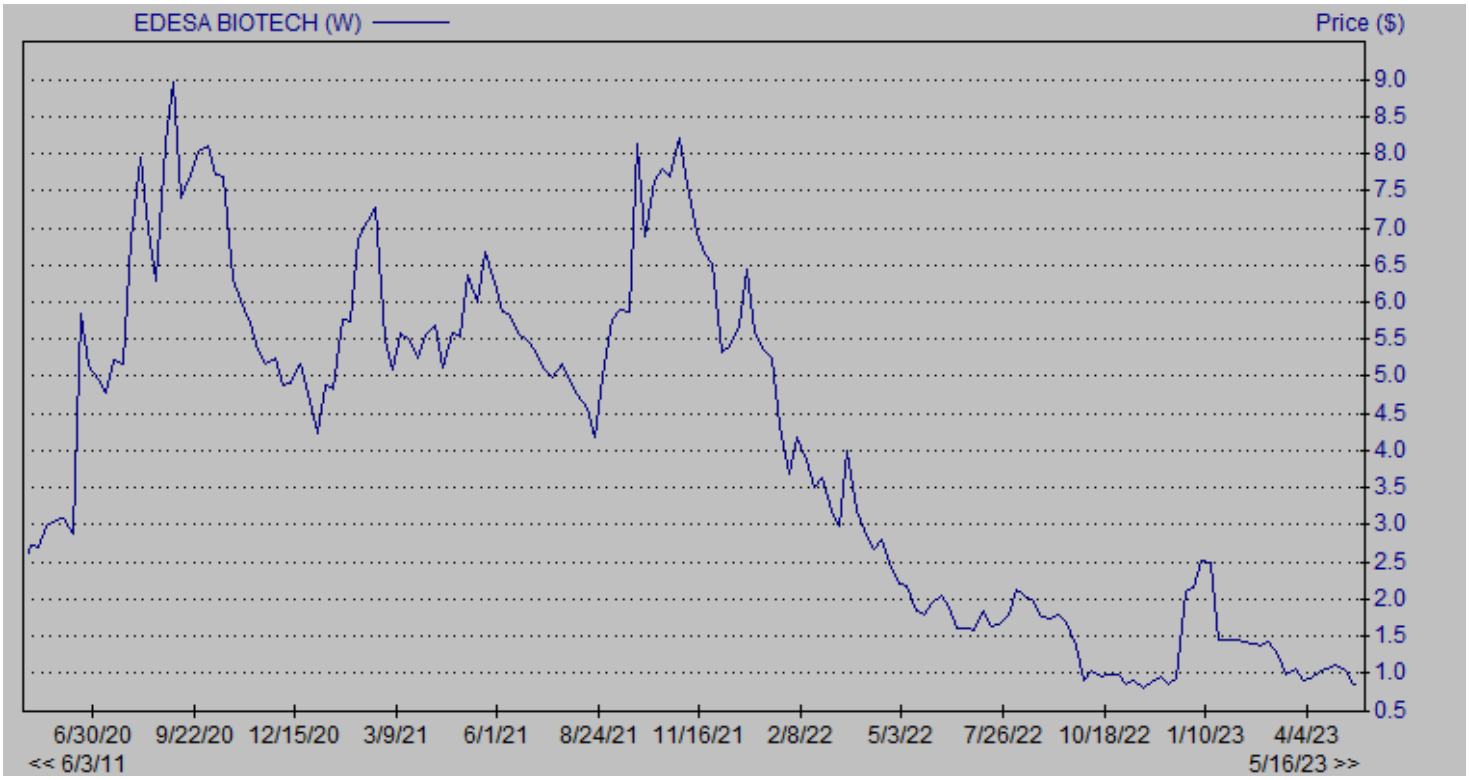
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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