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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Statistically Significant Mortality Reduction in Phase 2 ARDS Trial…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB01, EB02, and EB05, EDSA is valued at $15.00/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 (10/04/22)	$0.92
Valuation	**$15.00**

OUTLOOK

On September 30, 2022, Edesa Biotech, Inc. (EDSA) announced final results from the Phase 2 portion of the ongoing Phase 2/3 clinical trial evaluating EB05 for the treatment of COVID-19 induced acute respiratory distress syndrome (ARDS). The company had previously reported topline results from the trial, in which the data safety monitoring board (DSMB) had requested to unblind certain trial data due to an efficacy signal for 28-day mortality. The final Phase 2 clinical trial results showed a 28-day mortality rate of 7.7% for patients in the EB05 plus standard of care (SOC) arm compared to 40% in the placebo plus SOC arm in critically severe patients on ECMO therapy or Invasive Mechanical Ventilation (IMV) plus organ support with ARDS at baseline (*P*=0.04). The final Phase 2 trial report has been submitted to the FDA as part of the agency's review of the Phase 3 clinical trial protocol design and statistical plan.

SUMMARY DATA

52-Week High	**$8.65**
52-Week Low	**$0.92**
One-Year Return (%)	**-86.65**
Beta	**1.15**
Average Daily Volume (sh)	**411,877**
Shares Outstanding (mil)	**15**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**30**
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	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2021	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2022	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2023					0.0 E
2024					0.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2020	-$0.26 A	-$0.19 A	-$0.36 A	-$0.28 A	-$1.10 A
2021	-$0.33 A	-$0.33 A	-$0.37 A	-$0.43 E	-$1.47 E
2022					-$1.42 E
2023					-$1.34 E

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WHAT'S NEW

Business Update

Statistically Significant Mortality Reduction in Phase 2 ARDS Trial

On September 30, 2022, Edesa Biotech, Inc. (EDSA) announced final results from the Phase 2 portion of its ongoing Phase 2/3 clinical trial evaluating EB05, the company's monoclonal antibody therapy that targets toll-like receptor 4 (TLR4), as a treatment for hospitalized patients with or at risk of developing COVID-19 induced acute respiratory distress syndrome (ARDS). The company had previously reported initial topline data from the trial in September 2021, at which time the data safety monitoring board (DSMB) had requested to unblind certain data due to an efficacy signal seen with 28-day mortality. The data reported today is from Edesa's Clinical Study Report (CSR) on the full, validated Phase 2 dataset.

The following table shows the mortality rates from the Phase 2 trial for critically ill patients (defined as Level 7 on the World Health Organization's COVID-19 Severity Scale [WCSS]). 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.

Mortality Rates - Critically Ill Patients (WCSS Level 7)

	Treatment Group				
	EB05 (n=13)		Placebo (n=20)		
Timepoint	Number of Deaths	Mortality Rate	Number of Deaths	Mortality Rate	P-Value
28-Day	1	7.7%	8	40.0%	0.04
60-Day	3	23.1%	12	60.0%	0.20

Source: Edesa Biotech, Inc.

In addition to the statistically significant mortality reduction in critically ill patients, additional efficacy signals were observed in the full Phase 2 dataset.

While not achieving statistical significance, clinically meaningful differences in the proportion of patients who were alive and without the need for oxygen support at Day 28 were observed in severe COVID-19 patients at WCSS level ≥5 (99% of patients had ARDS at baseline). The primary endpoint was achieved by 45.8% in the EB05 plus SOC arm compared to 36.1% in the placebo plus SOC arm (*P*=0.16). An additional positive efficacy signal was also seen in the proportion of patients who achieved at least a 2-point improvement on the WCSS, with 46.7% of patients in the EB05 plus SOC arm achieving that outcome compared to 36.1% in the placebo plus SOC arm (*P*=0.12). There were no clinically meaningful differences detected for COVID-19 patients at WCSS level ≤ 4, likely due to the baseline severity score being too close to the endpoint (WCSS ≤ 3).

	Treatment Group				
	EB05 (n=107)		Placebo (n=97)		
Endpoint[1]	Number Reaching Primary Endpoint	Rate	Number Reaching Primary Endpoint	Rate	P-Value
Patients Alive without Need for Oxygen Support at Day 28	49	45.8%	35	36.1%	0.16
Patients who Achieved at Least a 2-Point Improvement on the WCSS	50	46.7%	35	36.1%	0.12

Note 1: mLOCF imputed for Day 28.

Source: Edesa Biotech, Inc.

Importantly, a single dose of EB05 was generally well-tolerated. Serious adverse events from 352 patients showed similar results between the two treatment groups and the incidence of treatment-emergent adverse events (TEAEs) and serious TEAEs were comparable between the treatment groups.

Edesa has submitted the Phase 2 CSR as was requested by the FDA as part of the review of the company's Phase 3 clinical protocol design and statistical plan. Recruitment for the Phase 3 study is already underway in Canada, Colombia, and Poland. The first cohort of patients being enrolled in the Phase 3 study are critically ill COVID-19 patients that are receiving extracorporeal membrane oxygenation (ECMO) and/or invasive mechanical ventilation plus organ support (Level 7 on the WCSS). The second cohort will consist of hospitalized COVID-19 patients on invasive mechanical ventilation alone (Level 6 on the WCSS). The primary endpoint for the Level 7 cohort will be 28-day mortality. The primary endpoint for the Level 6 cohort will be the number of ventilator-free days at Day 28.

Conclusion

The final results from the Phase 2 portion of the Phase 2/3 clinical trial of EB05 in hospitalized COVID-19 patients with or at risk of developing ARDS are very exciting and support its continued development in this patient population. Now that the FDA has the final Phase 2 CSR, we are hopeful that the company will be able to begin enrolling patients in the U.S. as soon as the agency agrees with the study design and statistical plan. In addition to the trial of EB05, enrollment in the Phase 2b trial of EB01 is complete and we look forward to results from that trial, which we anticipate by the end of calendar 2022. With no changes to our model our valuation remains at $15 per share.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2021 A	Q1FY22 A	Q2FY22 A	Q3FY22 A	Q4FY22 E	FY2022 E	FY2023 E	FY2024 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	$17.9	$4.0	$3.0	$4.5	$5.0	$16.5	$19.0	$20.0
General & Administrative	$5.7	$1.2	$1.5	$1.2	$1.7	$5.7	$6.5	$6.7
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($23.7)	($5.2)	($4.6)	($5.8)	($6.7)	($22.2)	($25.5)	($26.7)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$10.3	$0.8	$0.0	$0.0	$0.0	$0.8	$0.0	$0.0
Pre-Tax Income	($13.3)	($4.3)	($4.6)	($5.8)	($6.7)	($21.4)	($25.5)	($26.7)
Income Taxes	$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	**($13.3)**	**($4.3)**	**($4.6)**	**($5.8)**	**($6.7)**	**($21.4)**	**($25.5)**	**($26.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.10)**	**($0.33)**	**($0.33)**	**($0.37)**	**($0.43)**	**($1.47)**	**($1.42)**	**($1.34)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	12.1	13.4	13.9	15.5	15.6	14.6	18.0	20.0

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

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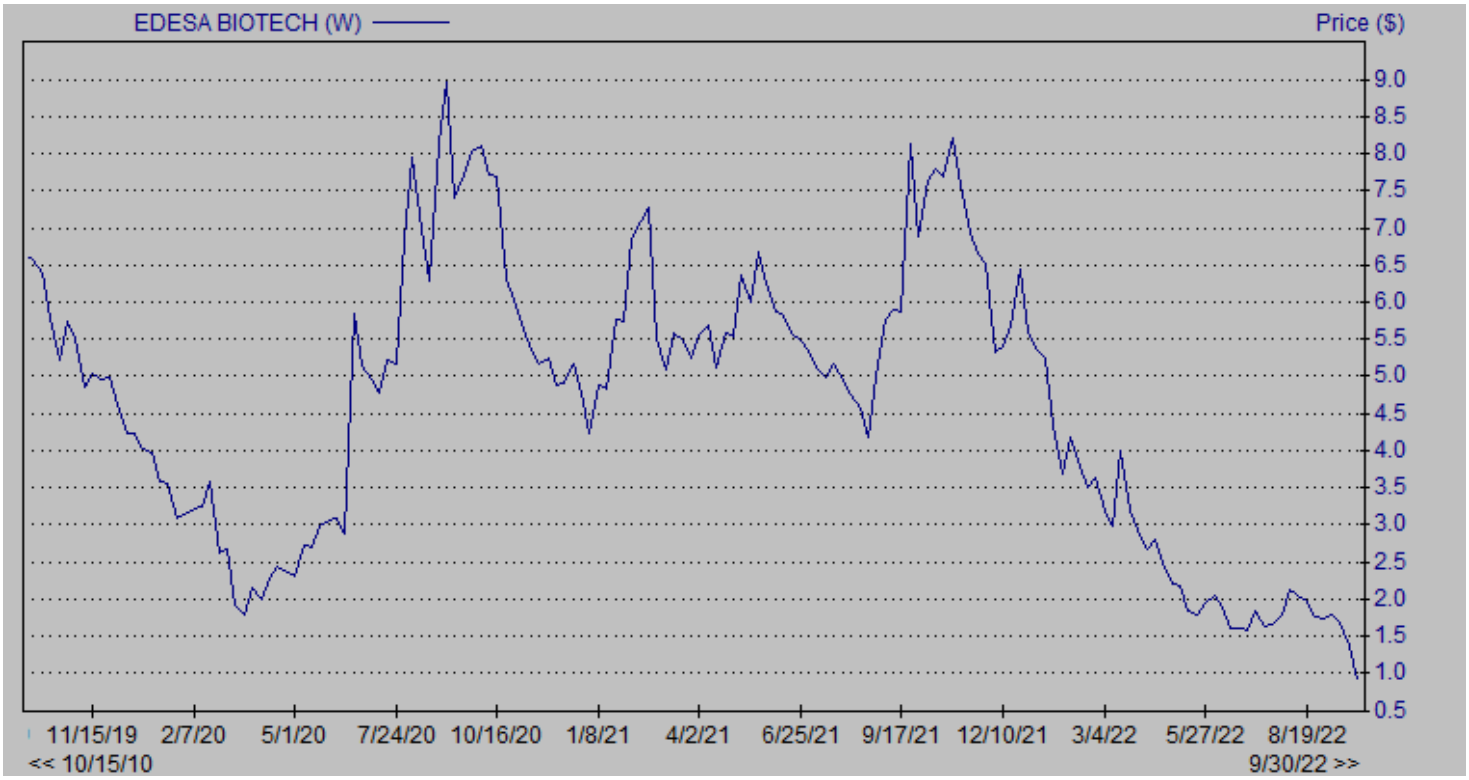
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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