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Edesa Biotech, Inc.

(EDSA-NASDAQ)

EDSA: EB05 Reduces Risk of Death 25% in Phase 3 ARDS Trial…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB05 and EB06, EDSA is valued at $19.00/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 (11/05/25)	$1.70
Valuation	**$19.00**

OUTLOOK

On October 28, 2025, Edesa Biotech, Inc. (EDSA) announced positive results from a Phase 3 clinical trial evaluating paridiprubart (EB05) as a treatment for Acute Respiratory Distress Syndrome (ARDS). EB05 met both the primary and secondary endpoints of the study, which included a statistically significant and clinically meaningful 25% relative risk reduction in the risk of death compared to placebo (P<0.001). Across the 275 patients that were enrolled for the Phase 2 and Phase 3 studies, EB05 was generally well-tolerated and consistent with the observed safety profile to date. The company plans to submit data to regulatory agencies to determine the next steps for the program.

SUMMARY DATA

52-Week High	**$3.30**
52-Week Low	**$1.59**
One-Year Return (%)	**-36.57**
Beta	**-0.02**
Average Daily Volume (sh)	**912,031**
Shares Outstanding (mil)	**7**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**23**
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 2025 Estimate	**N/A**
P/E using 2026 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)
2024	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2025	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2026					0.0 E
2027					0.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2024	-$0.54 A	-$0.58 A	-$0.52 A	-$0.30 A	-$1.93 A
2025	-$0.48 A	-$0.30 A	-$0.25 A	-$0.26 E	-$1.19 E
2026					-$0.56 E
2027					-$0.45 E

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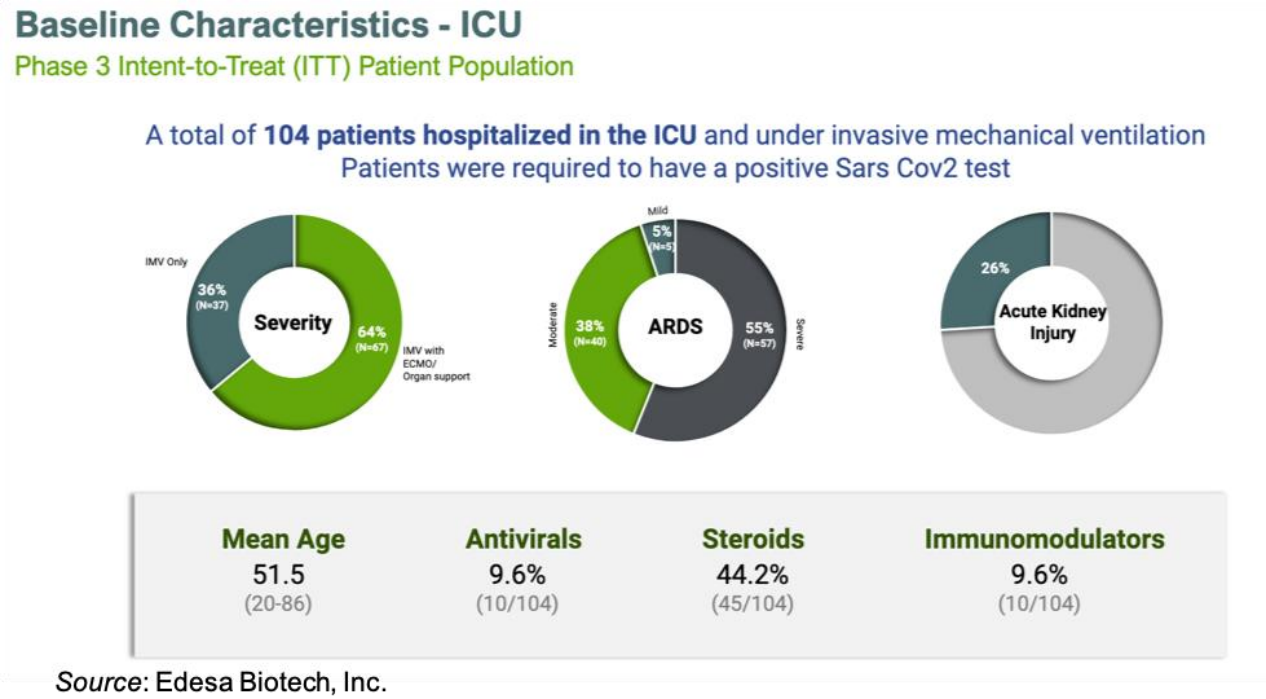
WHAT'S NEW

Business Update

Positive Phase 3 Results for EB05 in ARDS

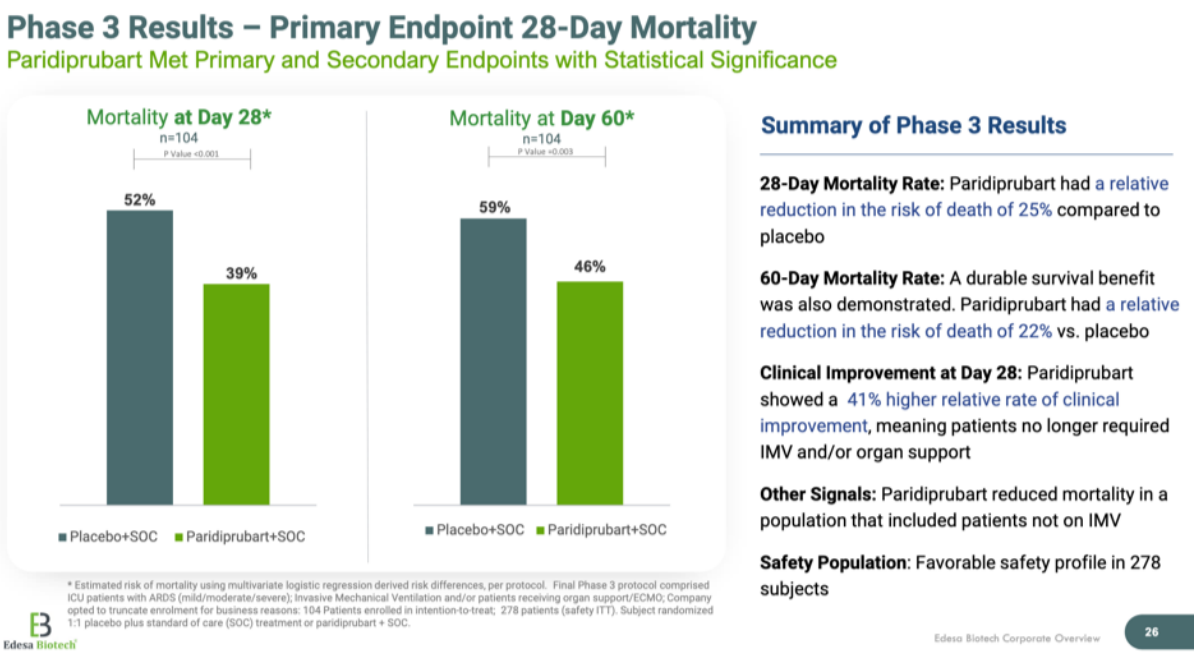
On October 28, 2025, Edesa Biotech, Inc. (EDSA) announced positive results from the Phase 3 trial evaluating paridiprubart (EB05) in the treatment of acute respiratory distress syndrome (ARDS). ARDS is caused by an exaggerated immune response that leads to an unregulated inflammatory response in the body and ultimately injury to the lungs that results in oxygen deprivation. There are a number of different causes, including virus-induced pneumonia, smoke/chemical inhalation, sepsis, and chest injury. There are approximately 600,000 ARDS-related ICU admissions every year across the seven major markets (U.S., U.K., Germany, France, Spain, Italy, Japan, and Canada). There are currently few treatment options for moderate to severe ARDS aside from supplemental oxygen and mechanical ventilation. ARDS imposes a very high burden on the healthcare system, both in terms of cost (averages >$100,000 per patient in the U.S.) and a very high mortality rate.

The Phase 3 trial of EB05 enrolled a total of 104 patients that were hospitalized in the ICU, receiving invasive mechanical ventilation (IMV), and had a positive SARS-CoV-2 test. The baseline characteristics of the intent-to-treat population is given below. The majority of patients were receiving IMV with ECMO/organ support, had severe ARDS, and over a quarter of them had acute kidney injury.



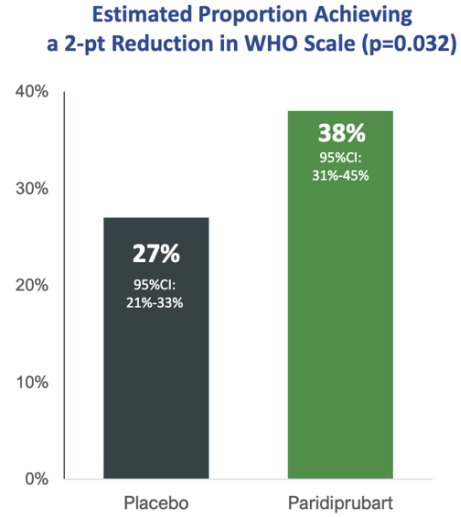
Source: Edesa Biotech, Inc.

The study met the primary endpoint by showing a statistically significant improvement in 28-day mortality for patients treated with standard of care (SOC) + EB05 compared to those receiving only SOC (P<0.001). The relative reduction in the risk of death at Day 28 was 25% for EB05-treated patients compared to placebo. Importantly, a durable survival benefit was shown as the relative reduction in the risk of death at Day 60 was 22% for EB05-treated patients compared to placebo. The results also show just how sick of a population the Phase 3 study enrolled, with over half of placebo-treated patients dying by Day 28. This underscores how important these results are for a patient population that has few effective treatment options.



Source: Edesa Biotech, Inc.

In addition to improving mortality, treatment with EB05 also led to a significant improvement on clinical improvement, which was defined as at least a 2-point reduction in the WHO 9-point ordinal scale (WHO). The following graph shows that 38% of EB05-treated patients had a ≥2-point reduction in the WHO scale compared to only 27% receiving SOC (*P*=0.032). These results indicate that not only is treatment with EB05 preventing patients from dying, but it is also helping to improve patient's quality of life, for example moving them out of the ICU and off of mechanical ventilation.



Source: Edesa Biotech, Inc.

Lastly, EB05 has exhibited a very favorable safety profile. The following table shows the safety outcomes for the 278 patients in the safety database (n=138 EB05; n=140 placebo). There were no treatment-related adverse events observed and the event profile between the two treatment groups was very similar. EB05 has been dosed in over 460 patients and healthy volunteers through its development, which supports its favorable safety profile.

Parameter	Treatment Group			
	EB05 (N=138)		Placebo (N=140)	
	N of Event	Patients (%)	N of Event	Patients (%)
Overall	51	13 (9.4%)	74	14 (10.0%)
Severity, n (%)				
Mild	21	8 (5.8%)	32	10 (7.1%)
Moderate	15	8 (5.8%)	21	8 (5.7%)
Severe	15	8 (5.8%)	21	9 (6.4%)
Seriousness, n (%)				
Persistent Disability	0	0 (0.0%)	1	1 (0.7%)
Prolongation of Hospitalization	2	1 (0.7%)	3	3 (2.1%)
Life Threatening	1	1 (0.7%)	13	8 (5.7%)
Medically Important	1	1 (0.7%)	6	4 (2.9%)
Relationship to study drug, n (%)				
Definitely	0	0 (0.0%)	1	1 (0.7%)
Possibly	0	0 (0.0%)	3	2 (1.4%)
Unlikely	12	7 (5.1%)	23	4 (2.9%)
Not related	39	10 (7.2%)	47	10 (7.1%)

Source: Edesa Biotech, Inc.

EB05 is also currently being evaluated in a $117M platform study funded by BARDA that is evaluating three novel therapeutics for ARDS (no necessity for a SARS-CoV-2 positive test). The company is supplying EB05 through manufacturing scale-up that is supported by the Government of Canada's Strategic Innovation Fund, thus no company resources are being utilized for that study.

Conclusion

The results for EB05 from the Phase 3 trial in ARDS are an exciting advancement in the treatment for that patient population, which currently has very few effective options available. Edesa will be submitting its findings to regulatory agencies to determine the next steps for the program, and how the results from the ongoing Phase 2 BARDA study will fit in with its regulatory pathway. We remind investors that the company is continuing the manufacturing of EB06 for the upcoming Phase 2 trial in vitiligo, which we anticipate initiating in the first half of 2026. Following the Phase 3 ARDS results, we have slightly increased our probability of approval for EB05 and increased its potential market share. This has resulted in an increase in our valuation to $19 per share.

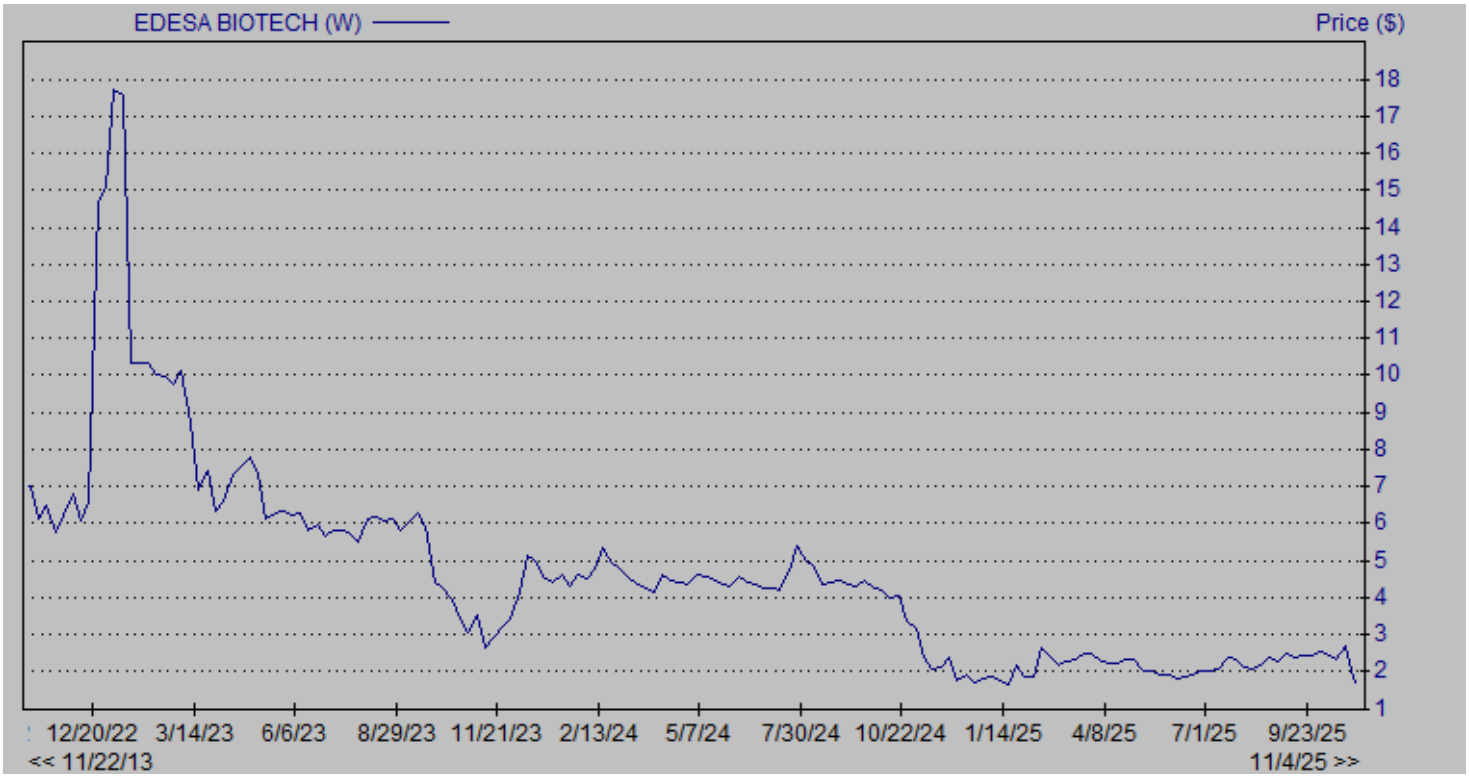
PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2024 A	Q1FY25 A	Q2FY25 A	Q3FY25 A	Q4FY25 E	FY2025 E	FY2026 E	FY2027 E
EB06	$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	$2.9	$1.0	$0.5	$0.9	$1.0	$3.4	$3.5	$3.8
General & Administrative	$4.1	$0.9	$1.2	$1.0	$1.0	$4.0	$4.0	$4.2
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($7.0)	($1.9)	($1.6)	($1.9)	($2.0)	($7.4)	($7.5)	($8.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.8	$0.3	$0.0	$0.2	$0.2	$0.7	$0.8	$0.8
Pre-Tax Income	($6.2)	($1.6)	($1.6)	($1.7)	($1.8)	($6.8)	($6.7)	($7.2)
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	**($6.2)**	**($1.6)**	**($1.59)**	**($1.7)**	**($1.8)**	**($6.8)**	**($6.7)**	**($7.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.93)**	**($0.48)**	**($0.30)**	**($0.25)**	**($0.26)**	**($1.19)**	**($0.56)**	**($0.45)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	3.2	3.3	5.3	7.0	7.0	5.7	12.0	16.0

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

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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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