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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Phase 3 ARDS Study Expanded to Include Mechanically Ventilated Patients…

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 (08/23/22)	$1.82
Valuation	**$15.00**

OUTLOOK

On August 12, 2022, Edesa Biotech, Inc. (EDSA) announced financial results for the third quarter of fiscal year 2022 that ended June 30, 2022 and provided a business update. In May 2022, the company expanded the Phase 3 clinical trial of EB05 in hospitalized COVID-19 patients to include hospitalized patients on invasive mechanical ventilation alone (WHO Level 6 patients), while previously the study had only been recruiting patients receiving mechanical ventilation plus additional organ support, including extracorporeal membrane oxygenation (ECMO) therapy (WHO Level 7 patients). The protocol for the Level 6 cohort will include approximately 500 patients while the protocol for the Level 7 cohort will include approximately 315 patients.

SUMMARY DATA

52-Week High	**$11.92**
52-Week Low	**$1.47**
One-Year Return (%)	**-59.19**
Beta	**0.94**
Average Daily Volume (sh)	**111,142**
Shares Outstanding (mil)	**15**
Market Capitalization ($mil)	**$28**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
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	**-1.3**
P/E using 2023 Estimate	**3.6**

Risk Level	**Above Avg.**
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)
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

WHAT'S NEW

Business Update

Phase 3 ARDS Study Expanded to Include Mechanically Ventilated Patients

In May 2022, Edesa Biotech, Inc. (EDSA) announced the initiation of enrollment of a second cohort of patients for the Phase 3 portion of the Phase 2/3 trial of EB05 in critically ill COVID-19 patients with Acute Respiratory Distress Syndrome (ARDS). The first cohort consists of critically ill COVID-19 patients that are receiving extracorporeal membrane oxygenation (ECMO) and/or invasive mechanical ventilation plus organ support, defined as Level 7 on the World Health Organization's COVID-19 Severity Scale. The second cohort will consist of hospitalized COVID-19 patients on invasive mechanical ventilation alone (WHO Level 6).

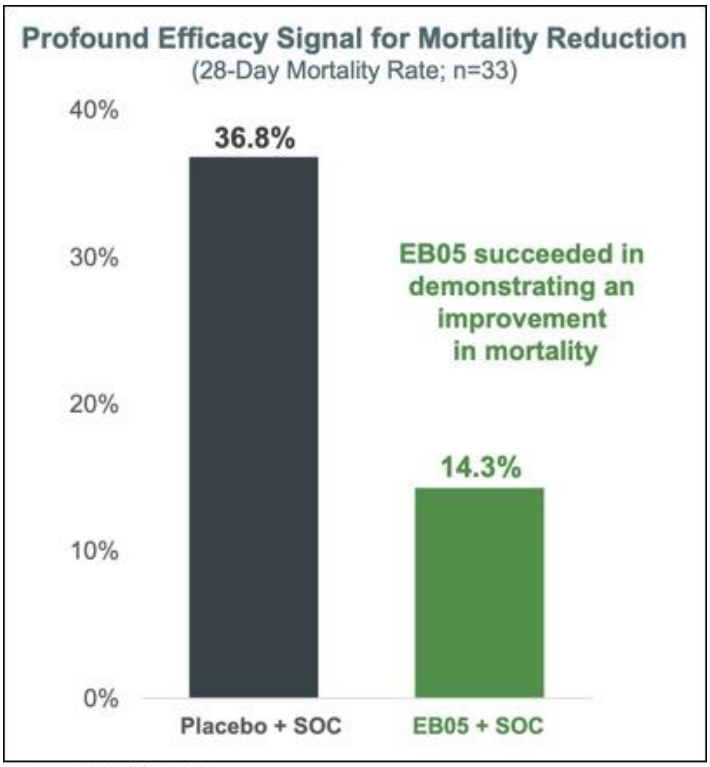
The primary endpoint for the Level 7 cohort will be 28-day mortality. Secondary endpoints will assess ventilator-free days and 60-day mortality. The protocol approved by Health Canada calls for approximately 315 evaluable subjects being enrolled.

The primary endpoint for the Level 6 cohort will be the number of ventilator free days at Day 28. Secondary endpoints will include ventilator free days at Day 60 along with mortality rates at Day 28 and Day 60. The protocol for the Level 6 cohort calls for approximately 500 evaluable subjects being enrolled.

The inclusion of both Level 6 and Level 7 patient populations was previously approved by regulators in Canada, Columbia, and Poland. Edesa had initially focused on Level 7 patients since they are the more severe cohort with the most urgent medical need. Enrollment for the two cohorts being evaluated now will run in parallel and each cohort will be evaluated independently.

The company has filed a similar protocol with the U.S. FDA and is currently in discussions with the agency on the design of the final Phase 3 protocol.

In September 2021, Edesa announced positive results from the Phase 2 portion of the trial that included approximately 360 patients, age 24-93, from clinical trial sites in the U.S., Canada, and Columbia. The independent Data and Safety Monitoring Board (DSMB) identified an important treatment effect regarding 28-day mortality in which treatment with EB05 in addition to standard of care (SOC) resulted in a 68.5% reduction in the risk of dying when compared to placebo and requested that the study be preemptively unblinded. The Phase 2 portion of the study was originally designed to guide the patient stratification and statistical powering for the Phase 3 trial, however the DSMB noted that "a clinically important efficacy signal" was detected along with the fact that the study "met its objective". In addition, the DSMB recommended that the study continue into a Phase 3 confirmatory trial.



Source: Edesa Biotech, Inc.

In October 2021, Edesa announced additional results from the Phase 2 portion of the ongoing Phase 2/3 clinical trial of EB05:

- The DSMB noted a mortality benefit in 136 hospitalized COVID-19 patients receiving supplemental oxygen (28-day mortality rate of 8.2% [5/61] in the EB05 + SOC arm vs. 12.0% [9/75] in the placebo + SOC arm; HR=1.52). Among this group there was a strong signal for patients with severe acute respiratory distress syndrome (ARDS) at baseline (defined as PaO2/FiO2 < 100 mm Hg). The DSMB concluded that patients with severe ARDS receiving supplemental oxygen at baseline had "a clinically important efficacy signal" with a 28-day mortality rate of 16.7% (2/12) in the EB05 + SOC arm vs. 42.9% (6/14) in the placebo + SOC arm. This corresponds to a 66.0% reduction in the risk of death at Day 28 for subjects treated with EB05 + SOC compared to placebo + SOC (HR=2.94, 95% CI: 0.59 – 14.60; *P*=0.19) when using the Cox Proportional Hazard Model.

- Efficacy signals were also noted in the 190 patients with mild to moderate ARDS at baseline (28-day mortality rate of 7.8% [7/90] in the EB05 + SOC arm vs. 11.0% [11/100] in the placebo + SOC arm; HR=1.46). Among this group, patients with mild to moderate ARDS receiving oxygen beyond supplemental oxygen had a 28-day mortality rate of 10.8% (4/37) in the EB05 + SOC arm vs. 20.5% (8/39) in the placebo + SOC arm. This corresponded to a 50.7% reduction in the risk of dying when comparing the EB05 + SOC arm to placebo + SOC (HR=2.03, 95% CI: 0.61-6.74, *P*=0.25). In this cohort there was also an increase of 6.1 days alive and free of invasive mechanical ventilation at 28 days when comparing the EB05 + SOC arm to placebo + SOC.

Enrollment for Phase 2b Trial of EB01 Estimated to Complete in 4Q22

Edesa is currently conducting a double blind, placebo controlled trial to evaluate the safety and efficacy of 2.0% EB01 cream in approximately 170 evaluable subjects in total suffering from chronic allergic contact dermatitis (ACD) (NCT03680131). The company is also conducting an exploratory, dose-ranging component of the study, which will separately evaluate lower-strength concentrations of EB01 in 40 additional subjects.

In June 2021, Edesa announced positive interim results for EB01 in the Phase 2b trial. 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.

We anticipate the trial being fully enrolled by the end of the fourth calendar quarter of 2022. This could lead to topline data being announced as soon as the first calendar quarter of 2023.

Financial Update

On August 10, 2022, Edesa announced financial results for the third quarter of fiscal year 2022 that ended June 30, 2022. There were no revenues reported for the third quarter of fiscal year 2022. R&D expenses in the third quarter of fiscal year 2022 were $4.6 million, compared to $4.5 million for the third quarter of fiscal year 2021. The increase was primarily due to contractual payment for bulk drug product of EB05, which was substantially offset by decreased external research expenses. G&A expenses totaled $1.3 million for the third quarter of fiscal year 2022 compared to $1.6 million for the third quarter of fiscal year 2021. The decrease was primarily due to decreased noncash share-based compensation.

As of June 30, 2022, Edesa had approximately $12.8 million in cash and cash equivalents. As of August 10, 2022, Edesa had approximately 15.5 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 21.3 million.

Conclusion

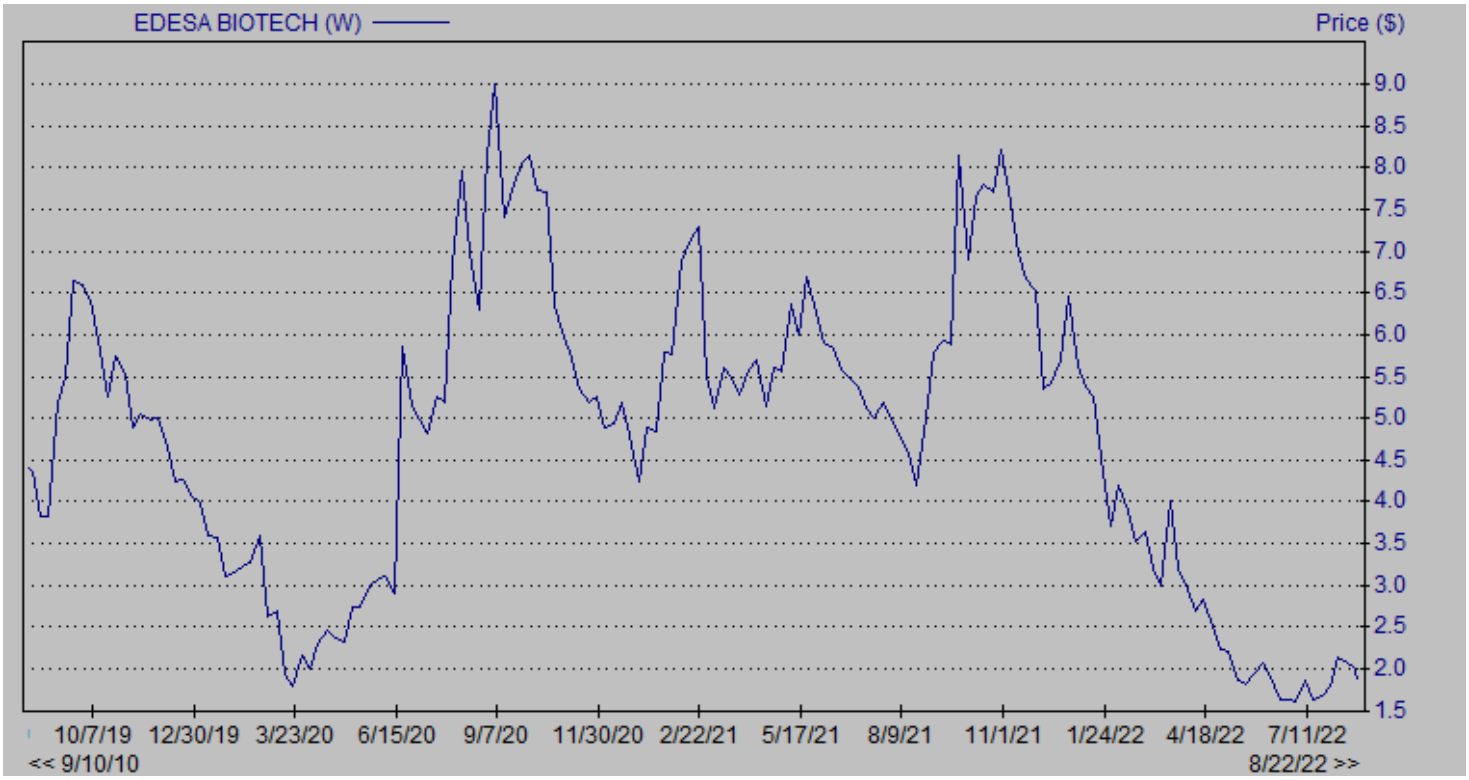
We're glad to see the expansion of the Phase 2/3 trial of EB05 in critically ill COVID-19 patients as it could lead to a potentially larger market opportunity as well as provide a larger overall data set for how EB05 performs in patients with ARDS. Enrollment in the Phase 2b trial of EB01 is continuing on pace and we look forward to results from that trial, possibly as early as the first calendar quarter of 2023. We have made no changes to our model and 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*

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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