Zacks Small-Cap Research
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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Enrollment of Phase 2b Trial of EB01 to Complete in 4Q22…

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 (05/19/22)	$1.91
Valuation	**$15.00**

OUTLOOK

On May 13, 2022, Edesa Biotech, Inc. (EDSA) announced financial results for the second quarter of fiscal year 2022 that ended March 31, 2022 and provided a business update. For EB01, the company recently announced that its Phase 2b study in chronic allergic contact dermatitis (ACD) is recruiting faster than anticipated. At the current rate, enrollment should be complete during the fourth calendar quarter of 2022 and topline results could be available as early as the first calendar quarter of 2023. The company's other lead asset, EB05, is currently in a Phase 3 clinical trial in Canada for the treatment of acute respiratory distress syndrome (ARDS) caused by COVID-19. Thus far, more than 25% of patients have been enrolled into the trial. Edesa is positioning additional investigational centers in anticipation of current and future waves of hospitalizations.

SUMMARY DATA

52-Week High	**$11.92**
52-Week Low	**$1.77**
One-Year Return (%)	**-69.63**
Beta	**0.83**
Average Daily Volume (sh)	**59,586**
Shares Outstanding (mil)	**15**
Market Capitalization ($mil)	**$30**
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	**-1.5**
P/E using 2023 Estimate	**3.5**

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 E	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	-$0.41 E	-$0.42 E	-$1.52 E
2022					-$1.42 E
2023					-$1.34 E

WHAT'S NEW

Business Update

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

Edesa Biotech, Inc. (EDSA) 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.

The company recently announced that enrollment is occurring faster than initially anticipated and based on the current trajectory the trial should be 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.

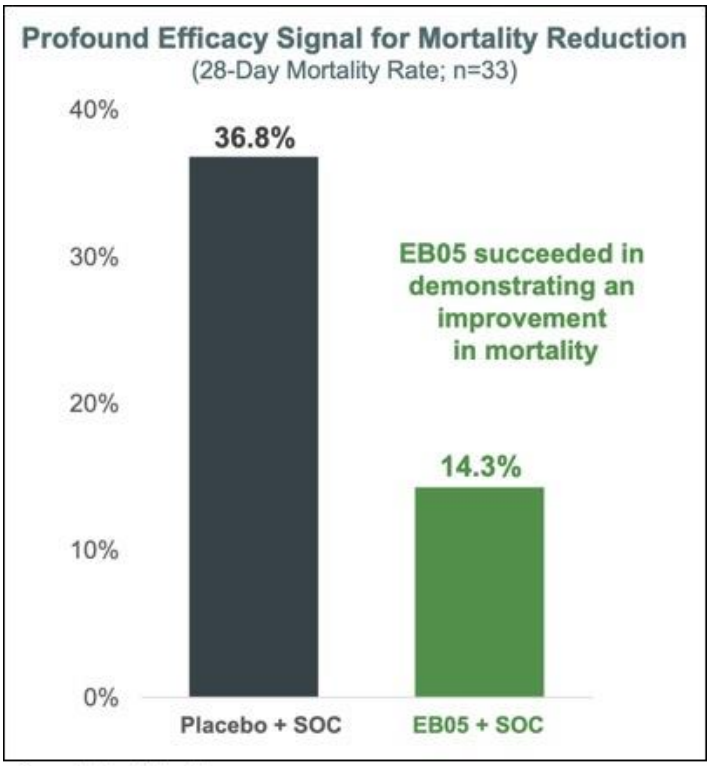
Phase 3 Trial of EB05 Hits 25% Enrollment

In February 2022, Edesa announced that more than 25% of the subjects have been randomized under the Phase 3 protocol approved by Health Canada for the ongoing clinical trial of EB05 for the treatment of acute respiratory distress syndrome (ARDS) in critically ill COVID-19 patients (NCT04401475).

The Phase 3 trial is designed to test the efficacy of a single dose of EB05 in 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 primary endpoint 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. A similar protocol has been filed with the U.S. FDA and the company 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.

Financial Update

On May 13, 2022, Edesa announced financial results for the second quarter of fiscal year 2022 that ended March 31, 2022. There were no revenues reported for the second quarter of fiscal year 2022. R&D expenses in the second quarter of fiscal year 2022 were $3.0 million, compared to $8.0 million for the second quarter of fiscal year 2021. The decrease was primarily due to decreased milestone and bulk drug substance payments,

lower license fees, and lower external research expenses. G&A expenses totaled $1.5 million for the second quarters of both fiscal year 2022 and 2021.

As of March 31, 2022, Edesa had approximately $15.9 million in cash and cash equivalents. In March 2022, Edesa closed on a $10 million registered direct offering in which a single healthcare-focused institutional investor purchased approximately 2.74 million shares at a purchase price of $3.65 per share. As of May 12, 2022, Edesa had approximately 15.5 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 21.4 million.

Conclusion

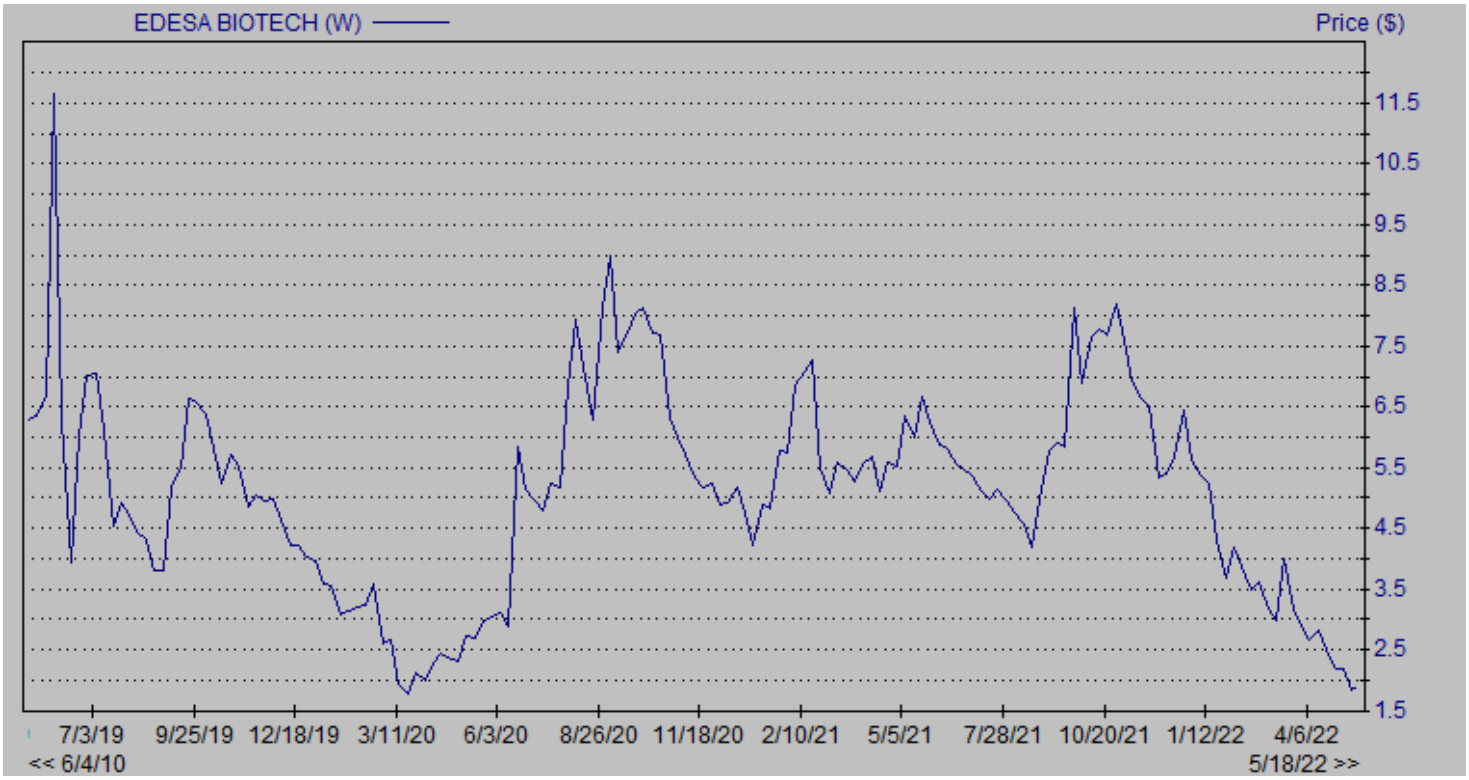
We are glad that Edesa has been able to exceed its recruitment forecasts for the Phase 2b trial of EB01 in ACD and we look forward to topline results potentially being announced as early as the first calendar quarter of 2023. After accounting for the March 2022 financing in our model, our valuation has been reduced to $15 per share.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2021 A	Q1FY22 A	Q2FY22 A	Q3FY22 E	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	$5.0	$5.0	$17.0	$19.0	$20.0
General & Administrative	$5.7	$1.2	$1.5	$1.6	$1.7	$6.1	$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)	($6.6)	($6.7)	($23.0)	($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)	($6.6)	($6.7)	($22.2)	($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)**	**($6.6)**	**($6.7)**	**($22.2)**	**($25.5)**	**($26.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.10)**	**($0.33)**	**($0.33)**	**($0.43)**	**($0.43)**	**($1.52)**	**($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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