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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Nearing Enrollment Completion for Phase 2 Portion of EB05 Trial in COVID-19…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB01, EB02, and EB05, EDSA is valued at $16.00/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 (05/18/21)	$6.01
Valuation	**$16.00**

OUTLOOK

On May 14, 2021, Edesa Biotech, Inc. (EDSA) announced financial results for the second quarter of fiscal year 2021 ending March 31, 2021 and provided a business update. The company reported that 285 patients have been enrolled in the ongoing Phase 2/3 clinical trial of EB05 as a single-dose treatment for hospitalized COVID-19 patients either with or at risk of developing acute respiratory distress syndrome (ARDS). The trial may enroll up to 396 patients such that 316 are evaluable for a blinded interim analysis.

In addition, Edesa has completed enrollment of the first cohort in the Phase 2b clinical trial of EB01 as a monotherapy for chronic allergic contact dermatitis. A blinded interim analysis is currently ongoing. The company is preparing to rapidly advance both studies to the next phase should the interim results be positive.

SUMMARY DATA

52-Week High	**$9.45**
52-Week Low	**$2.56**
One-Year Return (%)	**120.15**
Beta	**0.65**
Average Daily Volume (sh)	**253,656**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$79**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
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 2019 Estimate	**-6.3**
P/E using 2020 Estimate	**-3.3**

Risk Level	**Above Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2020	0.1 A	0.1 A	0.1 A	0.1 A	0.4 A
2021	0.0 A	0.0 A	0.0 E	0.0 E	0.0 E
2022					0.0 E
2023					0.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2020	-$0.15 A	-$0.17 A	-$0.19 A	-$0.22 A	-$0.74 A
2021	-$0.26 A	-$0.19 A	-$0.18 E	-$0.20 E	-$0.83 E
2022					-$0.66 E
2023					-$0.65 E

WHAT'S NEW

Business Update

Enrolled 285 Patients Thus Far in Phase 2/3 Trial of EB05 in COVID-19

Edesa Biotech, Inc. (EDSA) is currently conducting a Phase 2/3 clinical trial of EB05 in patients hospitalized with COVID-19 with or at risk of developing acute lung injury (ALI) and acute respiratory distress syndrome (ARDS). The trial is a randomized, multicenter, double blind, placebo-controlled study that is expected to enroll approximately 316 patients across 40 hospitals (NCT04401475). As of May 12, 2021, the trial has enrolled more than 285 patients, with the potential to enroll up to 398 to allow for 316 evaluable in a blinded interim analysis. Patients will receive a single dose of either EB05 (15 mg/kg) + standard of care (SOC) or SOC only. If the results of the interim analysis look promising, the protocol allows for continuation of enrollment as a pivotal Phase 3 trial.

In February 2020, Edesa announced that that the Government of Canada has committed up to CAD$14 million (US$11 million) in nonrepayable funding to complete the Phase 2 portion of the ongoing Phase 2/3 clinical trial of EB05 in COVID-19. The CAD$14 million will be utilized to not only fund the remainder of the Phase 2 portion of the study but also to perform preclinical research on whether EB05 is effective in other areas, including as a treatment for other respiratory pathogens.

Background on TLR4 and ARDS

EB05 is a monoclonal antibody that targets toll-like receptor 4 (TLR4). Toll-like receptors (TLRs) belong to the pattern recognition receptor family of proteins and are an important part of the innate immune system. They are responsible for detecting invading pathogens and initiating an immediate immune response. TLR4 recognizes a number of different pathogens, including bacterial lipopolysaccharide (LPS) (Miller *et al*., 2005), mannuronic acid polymers from Gram-negative bacteria (Flo *et al*., 2002), and viral components (Haynes *et al*., 2001). Its activation leads to production of pro-inflammatory cytokines and chemokines (Janssens *et al*., 2003).

In addition to being involved in the innate immune response to pathogens, TLRs are known to be involved in exaggerated immune responses, with TLR4 shown to induce inflammatory responses that can lead to ALI (Jiang *et al*., 2005). Additional examples for TLR4's role in ALI and ARDS include:

- Imai *et al*., 2008: This study looked at the role of TLR4 in ALI. Mice deficient in TLR4 (*Tlr4*$^{-/-}$) were resistant to acid-induced ALI and while H5N1 influenza rapidly induced ALI in wild-type mice, TLR4 deficient mice were resistant to H5N1-induced ALI, suggesting a causative role for TLR4 in ALI.

- Shirey *et al*., 2016: This research group had previously reported that *Tlr4*$^{-/-}$ mice are resistant to influenza-induced lethality and a novel small molecule TLR4 inhibitor (eritoran) reduced influenza-induced lethality. In this study, an anti-TLR4 antibody protected mice from lethal influenza infection.

- Perrin-Cocon *et al*., 2017: A novel small molecule TLR4 antagonist (FP7) was tested in an *in vivo* mouse model of influenza. FP7 blocked TLR4 stimulation and protected mice from influenza-induced lethality and reduced inflammatory cytokine expression and ALI.

- Zhou *et al*., 2018: An anti-TLR4 monoclonal antibody was studied in a rat model of ARDS. The rats treated with the anti-TLR4 antibody showed lower respiratory frequency, lung permeability, lung edema, inflammatory infiltration, and tumor necrosis factor (TNF)-α and interleukin (IL)-1β expression levels in lungs along with lower TLR4, TLR9, MyD88, and nuclear factor (NF)-κB expression in macrophages.

- Domitrovic 2018: TLR4 monoclonal antibodies were evaluated both *in vitro* and in a rat model of ARDS. Stimulating macrophages with TNF-α along with anti-TLR4 antibody eliminated the upregulation and

secretion of cytokines. Pre-treating rats with anti-TLR4 antibody prior to ventilation decreased lung injury, inflammatory infiltration, lung edema, and TLR4, TLR9, MyD88, and NF-κB expression.

- Zhang *et al*., 2019: This study examined the role of TLR4 and NF-κB in ALI and found inhibition of the TLR4/NF-κB signaling pathway decreased oxidative stress and improved ALI.

A number of studies have been published this year showing how TLR4 signaling is involved in COVID-19, including data showing that the level of TLR4 ligands (specifically calprotectin) can differentiate patients with severe COVID-19 compared to mild cases. Calprotectin, otherwise known as S100A8/A9, is a TLR4 ligand that promotes NF-κB activation (Riva *et al*., 2012) and the secretion of multiple inflammatory proteins such as IL-6 (Wang *et al*., 2018). Taken together, these studies provide the rationale for testing TLR4 signaling inhibition as a treatment for COVID-19.

- Silvin *et al*., 2020: This study examined peripheral blood cells in patients suffering from COVID-19 and included 27 with mild disease, 16 with moderate disease, and 43 with severe disease. The results showed that high levels of calprotectin correlated with severe COVID-19. The authors propose that calprotectin may trigger the cytokine release syndrome seen in severe COVID-19.

- Shi *et al*., 2020: This retrospective study examined the level of calprotectin in 172 COVID-19 patients and showed that all of the patients had elevated levels of calprotectin compared to healthy controls. In addition, when examined on day 1 or 2 of hospitalization (n=94 patients), calprotectin levels were significantly higher in patients who would go on to require mechanical ventilation (n=32) compared to those who were not intubated (P<0.0001).

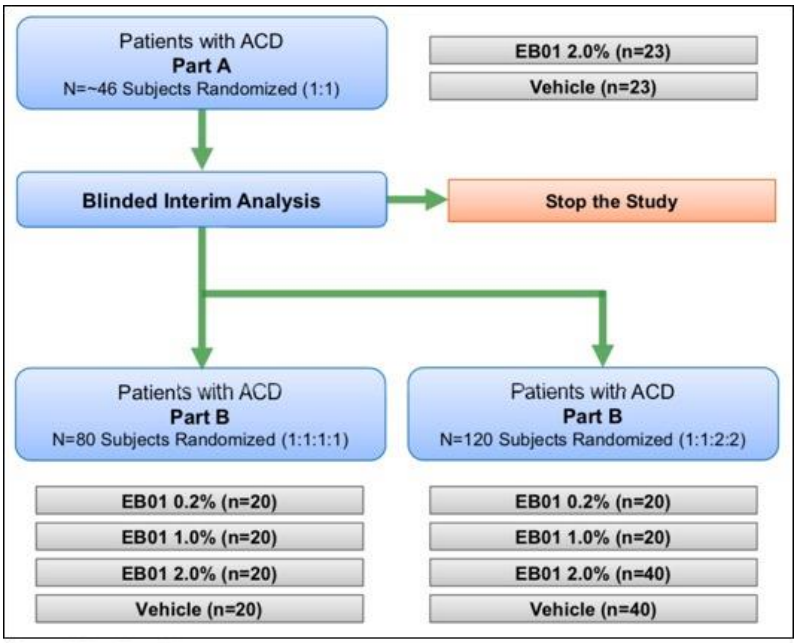
- Chen *et al*., 2020: This was a prospective study of 121 COVID-19 patients with 40 in the ICU and 81 in general wards at enrollment. Results showed that higher calprotectin resulted in significantly worse overall survival (P<0.0001). In addition, the level of calprotectin correlated with a range of inflammatory cytokines and chemokines, with three myeloid chemokines (IL-8, MCP-3, MCP-1) being the most significantly correlated and representing a distinct cytokine storm signature in COVID-19 patients.

Update on Phase 2b Trial of EB01

Edesa is currently conducting a Phase 2b clinical trial of EB01 2.0% cream in patients with allergic contact dermatitis (ACD). The randomized, double blind, placebo controlled, sample size adaptive design trial enrolled 46 patients in Part A randomized 1:1 between EB01 and placebo for 28 days of treatment. Now that all the patients from the first cohort have completed the 28-day treatment period, Edesa is currently conducting a blinded interim analysis that can have the following outcomes:

1) stop the study for futility;
2) continue to the dose ranging portion of the trial with 80 additional subjects; or
3) continue to the dose ranging portion of the trial with 120 additional subjects.

The primary endpoint of the trial will measure the mean percent change from baseline in Contact Dermatitis Severity Index (CDSI) at Day 29, with secondary endpoints examining symptom reduction, dose-response relationships, and safety. An outline of the trial is shown below.



Source: Edesa Biotech, Inc.

In March 2021, Edesa announced that a definitive license agreement in which the company acquired additional global rights to a non-steroidal anti-inflammatory technology that forms the basis for EB01 and EB02. This expands the company's intellectual property portfolio for a technology that could be applicable to multiple indications.

Financial Update

On May 24, 2021, Edesa announced financial results for the second quarter of fiscal year 2021 that ended March 31, 2021. The company did not report any revenues during the second quarter of fiscal year 2021, compared to $0.11 million for the three months ending March 31, 2020, which reflects the winddown and discontinuation of sales of product inventory from legacy operations. R&D expenses for the second quarter of fiscal year 2021 were $7.98 million, compared to $0.50 million for the second quarter of fiscal year 2020. The increase was primarily due to milestone payments related to advancement of the EB05 program, increased clinical costs, increased drug product expenses, and increased non-cash share-based compensation. G&A expenses for the three months ending March 31, 2021 were $1.54 million, compared to $1.11 million for the three months ending March 31, 2020. The increase was primarily due to higher salary and personnel expenses along with higher legal fees and professional service costs. Total other income was $7.25 million for the second quarter of fiscal year 2021, compared to $0.03 million for the second quarter of fiscal year 2020. The increase was due to grant income related to the federal grant with the Canadian government's Strategic Innovation Fund.

As of March 31, 2021, Edesa had approximately $11.0 million in cash and cash equivalents due in part to a bought deal offering of common shares, in which the company sold 1.5626 million shares at a price of $6.40 per share for net proceeds of $8.85 million. As of May 13, 2021, Edesa had approximately 13.2 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 15.1 million.

Conclusion

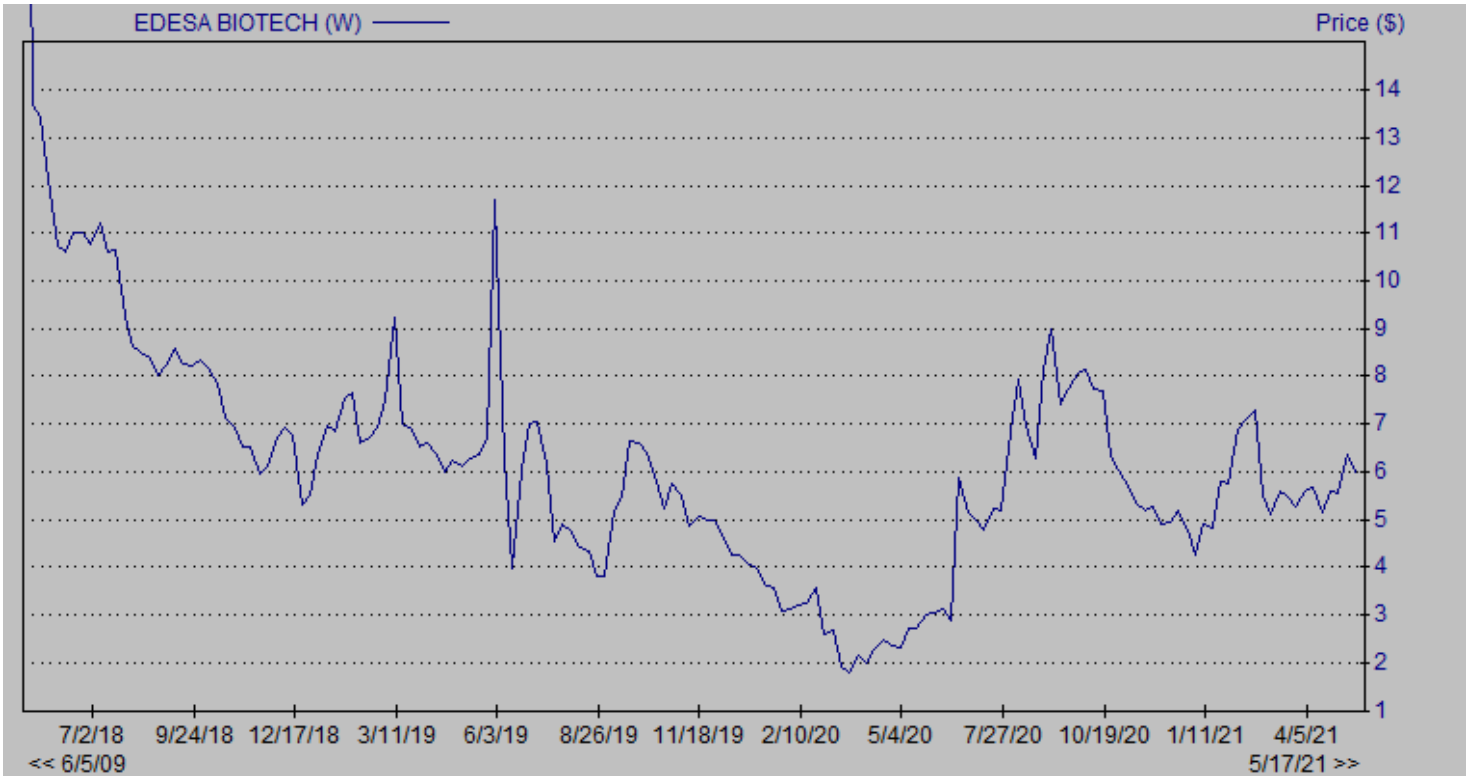
Edesa is getting close to having the 316 evaluable patients for the Phase 2 portion of the EB05 COVID-19 study in order to perform a blinded interim analysis. We look forward to the outcome of that analysis as the company prepares to be able to move into the Phase 3 portion of the trial shortly after the interim analysis is complete. In addition, we look forward to the outcome of the interim analysis for the Phase 2b trial of EB01. With no changes to our model our valuation remains at $16 per share.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2020 A	Q1FY21 A	Q2FY21 A	Q3FY21 E	Q4FY21 E	FY2021 E	FY2022 E	FY2023 E
EB01	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
EB02	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.3**	**$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	$3.3	$1.4	$8.0	$1.4	$1.6	$12.4	$6.0	$7.0
General & Administrative	$3.4	$1.2	$1.5	$1.0	$1.1	$4.9	$4.5	$4.7
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($6.4)	($2.6)	($9.5)	($2.4)	($2.7)	($17.2)	($10.5)	($11.7)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	($0.0)	$7.3	$0.0	$0.0	$7.2	$0.0	$0.0
Pre-Tax Income	($6.4)	($2.6)	($2.3)	($2.4)	($2.7)	($10.0)	($10.5)	($11.7)
Income Taxes	$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	**($6.4)**	**($2.6)**	**($2.3)**	**($2.4)**	**($2.7)**	**($10.0)**	**($10.5)**	**($11.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.74)**	**($0.26)**	**($0.19)**	**($0.18)**	**($0.20)**	**($0.83)**	**($0.66)**	**($0.65)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	8.6	10.3	11.6	13.0	13.5	12.1	16.0	18.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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