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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Awaiting End of Phase 2 Analysis of Phase 2/3 Study of EB05 in COVID19…

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 (09/01/21)	$5.87
Valuation	**$16.00**

OUTLOOK

On August 13, 2021, Edesa Biotech, Inc. (EDSA) announced financial results for the third quarter of fiscal year 2021 and provided a business update. During the quarter, the company received positive interim results for both EB05 and EB01. The company recently announced that more than 525 patients have been randomized into the Phase 2/3 clinical trial of EB05 in patients hospitalized with COVID-19. The interim analysis is expected in the current quarter and we anticipate the company providing a detailed clinical update when those data are available. In addition, Edesa is randomizing patients for the final part of the Phase 2b clinical trial of EB01 in patients with chronic Allergic Contact Dermatitis following positive interim results that showed a 1.7-fold difference between the treatment groups for the primary efficacy endpoint.

SUMMARY DATA

52-Week High	**$9.33**
52-Week Low	**$4.20**
One-Year Return (%)	**-34.99**
Beta	**0.70**
Average Daily Volume (sh)	**60,197**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$78**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
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	**-5.6**
P/E using 2020 Estimate	**-4.4**

Risk Level	**Average**
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 A	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	-$0.36 A	-$0.42 E	-$1.26 E
2022					-$0.66 E
2023					-$0.65 E

WHAT'S NEW

Business Update

Nearing End of Phase 2 Analysis for EB05 Phase 2/3 Trial 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 up to 398 patients across 40 hospitals in Stage I to allow for 316 evaluable in a blinded interim analysis (NCT04401475).

In June 2021, the company reported that the independent Data and Safety Monitoring Board (DSMB) recommended that the study continue as planned following a pre-planned review of blinded comparative data that assessed treatment data for safety and futility. As of August 25, 2021, more than 525 subjects had been enrolled into the study in the U.S., Canada, and Colombia with the next planned interim analysis on 316 evaluable patients once treatment is completed and subject data is validated and aggregated. We anticipate results from that interim analysis in the current quarter.

Edesa also recently filed a trial amendment with the U.S. FDA to streamline the U.S. protocol and align it with other jurisdictions. The company will be adjusting the current patient segmentation and associated endpoints and will remain blinded through to the end of Phase 3. These changes could result in a reduction in the number of patients enrolled in Stage II of the study and could lead to generating results faster.

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).

A recent publication proposes that SARS-CoV-2 spike protein binds to and activates TLR4 (Zhao *et al*., 2021). Results of a surface plasmon resonance assay showed that the SARS-CoV-2 spike trimer directly bound to TLR4 with an affinity of ~300 nM, which is comparable to other virus/receptor interactions. The authors utilized IL1B as a marker for TLR4 activation and showed that treatment of THP-1 cells with the purified spike protein of SARS-CoV-2 could induce IL1B production. In addition, spike proteins from multiple coronaviruses were able to induce IL1B production, which was abrogated either in the presence of a TLR4 inhibitor (resatorvid) or in $TLR4^{-/-}$ mice. Lastly, the interaction between spike protein and TLR4 did not appear to be affected by the presence or absence of ACE2, which is a receptor the virus uses to enter cells. These results show that a TLR4 inhibitor may be important not just for downregulating an aberrant immune response to SARS-CoV-2 infection, but may be able to disrupt direct activation of TLR4 by the virus itself.

Positive Interim Analysis for EB01 in Phase 2b Trial

In June 2021, Edesa announced positive interim results for EB01 in the Phase 2b clinical trial in patients with allergic contact dermatitis (ACD). 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.

Now that the interim analysis is complete, Edesa will focus on enrolling the second cohort of patients into the Phase 2b trial. We estimate that approximately 120 patients will be enrolled in the second cohort and the company reported that as of June 2, 2021 a total of 66 patients (including the first cohort) have been randomized into the study, thus leaving approximately 100 more patients to enroll before the final data analysis can be completed. The company is focused on getting those patients enrolled as expeditiously as possible, which may include opening additional centers in the study.

ACD Market Opportunity

ACD is a very common condition, with some studies suggesting a prevalence as high as 20% of the general population (Alinaghi *et al*., 2019). If one member of a family develops ACD then others in the same family have a higher prevalence of developing the condition, which would suggest a genetic predisposition, although environmental exposure most likely contributes as well. Women tend to develop ACD more than men, although this is likely due to a higher prevalence of wearing jewelry, which increases contact with nickel, a known trigger of ACD.

We estimate there are approximately 2.5 million individuals in the U.S. that suffer from ACD and that approximately 1.0 million suffer from the condition chronically. However, given how difficult it is to distinguish ACD from irritant contact dermatitis (ICD) we may be underestimating the potential number of patients. In addition, we are unaware of any FDA-approved therapies for ACD.

Financial Update

On August 13, 2021, Edesa announced financial results for the third quarter of fiscal year 2021 that ended June 30, 2021. The company did not report any revenues during the third quarter of fiscal year 2021, compared to $0.11 million for the three months ending June 30, 2020, which reflects the winddown and discontinuation of sales of product inventory from legacy operations.

R&D expenses for the third quarter of fiscal year 2021 were $4.5 million, compared to $1.1 million for the third quarter of fiscal year 2020. The increase was primarily due to increased external research expenses associated with the ongoing clinical studies, increased investigational drug product expenses, and increased non-cash stock-based compensation.

G&A expenses for the three months ending June 30, 2021 were $1.6 million, compared to $0.7 million for the three months ending June 30, 2020. The increase was primarily due to higher salary and personnel expenses along with higher non-cash stock-based compensation. Total other income was $1.3 million for the third quarter of fiscal year 2021, compared to less than $0.01 million for the third 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 June 30, 2021, Edesa had approximately $8.1 million in cash and cash equivalents. As of August 12, 2021, Edesa had approximately 13.3 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 15.1 million.

Conclusion

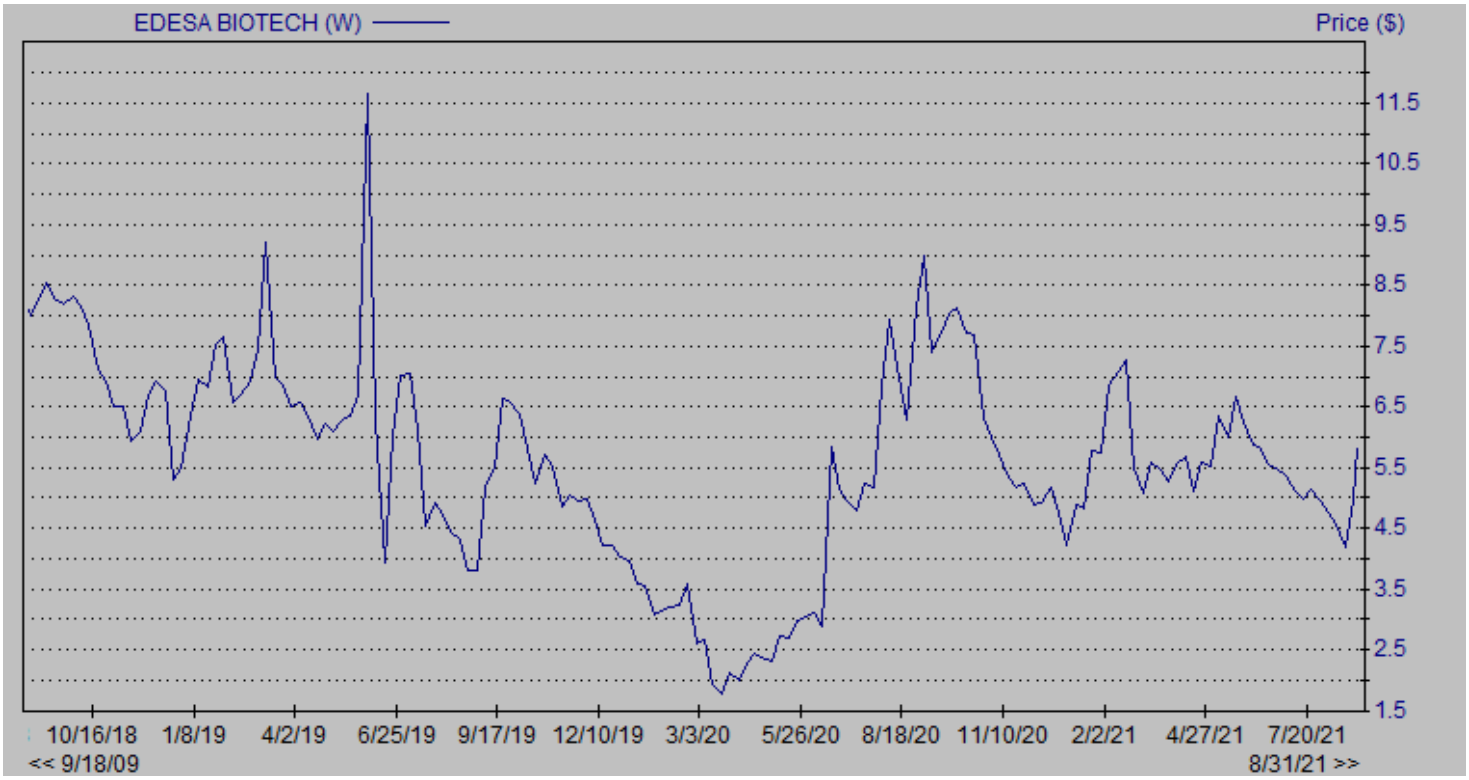
We are looking forward to an update on the Phase 2/3 trial of EB05 in hospitalized patients with COVID-19 and, if the results of the next blinded interim analysis are positive, what the company has planned for Stage 2 of the trial. We also look forward to additional updates from the company regarding patient enrollment in the Phase 2b trial of EB01 and when the topline data could be available. 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 A	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	$4.5	$4.0	$17.8	$6.0	$7.0
General & Administrative	$3.4	$1.2	$1.5	$1.6	$1.7	$6.1	$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)	($6.1)	($5.7)	($23.9)	($10.5)	($11.7)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	($0.0)	$7.3	$1.3	$0.0	$8.5	$0.0	$0.0
Pre-Tax Income	($6.4)	($2.6)	($2.3)	($4.8)	($5.7)	($15.4)	($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)**	**($4.8)**	**($5.7)**	**($15.4)**	**($10.5)**	**($11.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.74)**	**($0.26)**	**($0.19)**	**($0.36)**	**($0.42)**	**($1.26)**	**($0.66)**	**($0.65)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	8.6	10.3	11.6	13.3	13.5	12.2	16.0	18.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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