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May 27, 2020
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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Interim Analysis of Phase 2b Trial of EB01 in second half of 2020…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB01 and EB02, EDSA is valued at $10.00/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 (05/27/20)	$3.08
Valuation	**$10.00**

OUTLOOK

Edesa Biotech, Inc. (EDSA) is currently conducting a Phase 2b clinical trial of EB01, an $sPLA_2$ inhibitor, for the topical treatment of chronic allergic contact dermatitis. The ongoing coronavirus epidemic has resulted in some clinical sites temporarily pausing enrollment, although the company is actively investigating additional sites to decrease any potential slowdown in enrollment. The company has also modified the clinical trial protocol to allow for fewer in-person visits and remote telehealth appointments to mitigate the potential impact of the epidemic. We now anticipate the interim analysis of the Phase 2b trial in the second half of 2020.

The company recently in-licensed two antibody assets to develop as treatments for acute respiratory distress syndrome caused by COVID-19. The company has applied for non-dilutive funding to advance development of those assets and we anticipate an update on the status of the two programs over the next few months.

SUMMARY DATA

52-Week High	**$11.70**
52-Week Low	**$1.64**
One-Year Return (%)	**-53.74**
Beta	**0.09**
Average Daily Volume (sh)	**38,126**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$27**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**61**
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	**-4.2**
P/E using 2020 Estimate	**-6.2**

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)
2019	0.1 A	0.1 A	0.1 A	0.1 A	0.4 A
2020	0.1 A	0.1 A	0.1 E	0.1 E	0.4 E
2021					0.4 E
2022					0.4 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2019	-$0.26 A	-$0.31 A	-$0.30 A	-$0.15 A	-$0.55 A
2020	-$0.15 A	-$0.17 A	-$0.18 E	-$0.15 E	-$0.65 E
2021					-$0.53 E
2022					-$0.52 E

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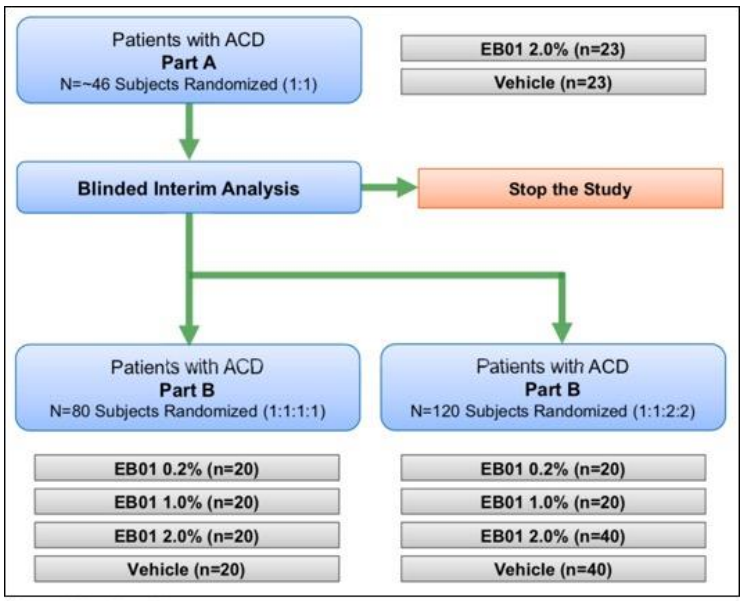
WHAT'S NEW

Business Update

Update on Phase 2b Trial of EB01

Edesa Biotech, Inc. (EDSA) is currently conducting a Phase 2b clinical trial of EB01 2.0% cream in patients with ACD. The randomized, double blind, placebo controlled, sample size adaptive design trial is expected to enroll approximately 46 patients in Part A randomized 1:1 between EB01 and placebo for 28 days of treatment. Following the enrollment of the first cohort, a blinded interim analysis will be conducted 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 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 April 2020, the company filed a protocol amendment with the FDA for the ongoing Phase 2b trial. The amendment was filed such that changes to the study protocol could be made to mitigate the impact of the ongoing coronavirus pandemic. Included in the amendment were allowances for a reduction in the number of in-person office visits, remote telehealth appointments, and other procedural updates to simplify enrollment and patient care. Since March 2020, at least five investigation sites have paused new patient enrollment and the company is currently identifying new sites to replace or supplement current sites. While it is unclear exactly what impact the coronavirus epidemic will have on the timeline for completing the trial, we anticipate that there will be some delay in the interim readout, most likely into the second half of 2020.

Licenses Two Assets for Potentially Treating COVID-19

In April 2020, Edesa announced an exclusive licensing agreement with Light Chain Bioscience for two clinical-stage monoclonal antibody assets targeting toll-like receptor 4 (TLR4) and C-X-C motif chemokine 10 (CXCL10). Light Chain will receive Series A-1 Convertible Preferred Shares at a value of $2.5 million with a fixed conversion price, up to $6.0 million for drug product inventory and other milestone fees, and the potential to receive up to $363.5 million in aggregate development, approval, and commercial milestone payments. Light Chain will also be eligible to receive royalties based on sales. Edesa will be responsible for development, product registration, and commercialization.

The company will be prioritizing the development of both assets as potential treatments for the exaggerated immune response seen in some patients with COVID-19. These patients can eventually progress to acute lung injury (ALI) and acute respiratory distress syndrome (ARDS), both of which are life threatening and require intensive medical care. Below we highlight some of the data we were able to identify that supports the development of the anti-TLR4 and anti-CXCL10 assets for ALI and ARDS.

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.

CXCL10

CXCL10 is a chemokine that activates its receptor, CXCR3, which is predominantly expressed on T cells, natural killer (NK) cells, inflammatory dendritic cells, macrophages, and B cells (Loetscher *et al*., 1998). It plays a significant role in leukocyte recruitment to inflamed tissues, and because of this it can lead to excessive inflammation and tissue damage (Lee *et al*., 2009). Patients who suffer from ARDS are known to exhibit unusually high levels of CXCL10. The role of CXCL10 in ARDS and ALI is shown in the following publications:

- Wang *et al*., 2013: This study showed that patients suffering from ARDS caused by H1N1 infection had significantly elevated levels of CXCL10 in their serum compared to a control group. An anti-CXCL10 monoclonal antibody increased survival time, reduced lung edema, and significantly decreased ALI in a mouse model of H1N1 infection.

- Ichikawa *et al*., 2013: In this study, ARDS was induced in mice by both non-viral and viral means. Mice deficient in CXCL10 or CXCR3 had improved severity and survival of both viral and non-viral ARDS. The high levels of CXCL10 seen in ARDS mice appears to come from infiltrated pulmonary neutrophils, and the interaction of CXCL10 and CXCR3 acts in an autocrine fashion leading to pulmonary inflammation.

- Lang *et al*., 2017: This study explored the role of CXCL10 in a rat model of LPS-induced ARDS. Expression of CXCL10 and CXCR3 increased after LPS-induction. An anti-CXCL10 antibody decreased the severity of ARDS through a reduction of pulmonary edema, inhibition of inflammatory mediators (IFN-γ, IL-6, ICAM-1), a reduction in inflammatory cells into the lung, and a reduction in CXCR3 expression in neutrophils and macrophages.

Financial Update

On May 15, 2020, Edesa announced financial results for the second quarter of fiscal year 2020 that ended Mar. 31, 2020. The company reported revenues of $0.11 million, which was derived from the sale of product inventory obtained in the reverse merger in June 2019. The cost of sales and services was $0.01 million for the second quarter of fiscal year 2020, due to the sales of product inventory obtained in the reverse merger acquisition. R&D expenses in the three months ending Mar. 31, 2020 were $0.5 million, compared to $0.11 million for the same period last year. The increase was primarily due to increased expenses associated with initiating clinical studies of EB01 along with increased salary and related expenses. G&A expenses totaled $1.1 million in the second quarter of fiscal year 2020 compared to $0.43 million for the same period of 2019. The increase was primarily due to increased salary and personnel expenses, increased legal fees, and public company expenses.

As of Mar. 31, 2020, Edesa had approximately $7.0 million in cash and cash equivalents. We estimate that the company has sufficient capital to fund operations for at least the next 12 months. As of May 13, 2020, Edesa had approximately 8.8 million shares outstanding and when factoring in the Series A-1 convertible preferred, stock options, and warrants a fully diluted share count of approximately 12.4 million.

Conclusion

While disappointed in the likely delay for the interim analysis for the Phase 2b trial of EB01, we are not surprised as most every company has experienced some type of delay due to the ongoing coronavirus epidemic. The interim analysis had previously been expected in mid-2020, but we now estimate that it will occur in the second half of 2020.

Based upon the publications we were able to identify, we believe there is sufficient evidence to support the development of both the anti-TLR4 antibody and anti-CXCL10 antibody as treatments to prevent ARDS caused by infection with the novel coronavirus SARS-CoV-2. The TLR4 antibody is farther along in development and thus we have added it to our model, although the development of an ARDS treatment, particularly as it relates to COVID-19, is highly fluid. For now, we model it as a potential $150 million opportunity, but this will likely change as more information becomes available regarding the asset and the potential market opportunity. Our valuation has increased to $10.00.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2019 A	Q1FY20 A	Q2FY20 A	Q3FY20 E	Q4FY20 E	FY2020 E	FY2021 E	FY2022 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	$0.4	$0.1	$0.1	$0.1	$0.1	$0.4	$0.4	$0.4
Total Revenues	**$0.4**	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0.4**	**$0.4**	**$0.4**
Cost of Sales	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	*75%*	-	-	-	-	-	-	-
Research & Development	$1.1	$0.5	$0.5	$0.8	$1.0	$2.8	$5.0	$6.0
General & Administrative	$2.0	$0.7	$1.1	$0.8	$0.8	$3.4	$3.2	$3.5
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($2.8)	($1.1)	($1.5)	($1.5)	($1.7)	($5.8)	($7.8)	($9.1)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	($0.0)	($0.0)	($0.1)	($0.1)	($0.2)	($0.2)	($0.2)
Pre-Tax Income	($2.8)	($1.1)	($1.5)	($1.6)	($1.8)	($6.0)	($8.0)	($9.3)
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	**($2.8)**	**($1.1)**	**($1.5)**	**($1.6)**	**($1.8)**	**($6.0)**	**($8.0)**	**($9.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.55)**	**($0.15)**	**($0.17)**	**($0.18)**	**($0.15)**	**($0.65)**	**($0.53)**	**($0.52)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	5.0	7.5	8.7	9.0	12.0	9.3	15.0	18.0

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

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