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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Licenses Two Potential COVID-19 Treatments…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB01 and EB02, EDSA is valued at $5.00/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 (04/24/20)	$2.32
Valuation	**$5.00**

OUTLOOK

On April 20, 2020, Edesa Biotech, Inc. (EDSA) announced a licensing agreement with Light Chain Bioscience for two clinical stage monoclonal antibody assets that target toll like receptor 4 (TLR4) and C-X-C motif chemokine 10 (CXCL10). The company plans to initially pursue development of these compounds as potential treatments to prevent acute respiratory distress syndrome (ARDS) and lung injury resulting from infection with SARS-CoV-2, the virus that causes COVID-19. Edesa had originally sought these assets for other indications, but given the preclinical data showing they can dampen an exaggerated immune response, the company will be preparing regulatory applications and seeking non-dilutive funding to study their ability to ameliorate acute injury from COVID-19 pneumonia.

SUMMARY DATA

52-Week High	**$11.70**
52-Week Low	**$1.64**
One-Year Return (%)	**-62.10**
Beta	**-0.15**
Average Daily Volume (sh)	**111,486**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$21**
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	**-0.3**
P/E using 2020 Estimate	**-0.4**

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)
2019	0.1 A	0.1 A	0.1 A	0.1 A	0.4 A
2020	0.1 A	0.1 E	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	-$0.12 E	-$0.18 E	-$0.15 E	-$0.62 E
2021					-$0.53 E
2022					-$0.52 E

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WHAT'S NEW

Business Update

Licenses Two Assets for Potentially Treating COVID-19

On April 20, 2020, Edesa Biotech, Inc. (EDSA) 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.

Conclusion

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 may be ready to enter the clinic in the next two to three months, as an IND is in place and the drug product is manufactured. We believe the company will be targeting patients who present at the hospital with hypoxia caused by COVID-19, but prior to needing admittance to the intensive care unit (ICU) or the use of mechanical ventilation. The goal will be to keep the patients from progressing to more severe disease and developing 'cytokine storm', which carries a very grim prognosis. We anticipate updates from the company on this program in the coming months after the clinical protocol is finalized. Our valuation is $5.00.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2019 A	Q1FY20 A	Q2FY20 E	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	$0.6	$0.8	$1.0	$2.9	$5.0	$6.0
General & Administrative	$2.0	$0.7	$0.7	$0.8	$0.8	$3.0	$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)	($1.2)	($1.5)	($1.7)	($5.5)	($7.8)	($9.1)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	($0.0)	($0.1)	($0.1)	($0.1)	($0.3)	($0.2)	($0.2)
Pre-Tax Income	($2.8)	($1.1)	($1.1)	($1.6)	($1.8)	($5.8)	($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)**	**($1.1)**	**($1.6)**	**($1.8)**	**($5.8)**	**($8.0)**	**($9.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.55)**	**($0.15)**	**($0.12)**	**($0.18)**	**($0.15)**	**($0.62)**	**($0.53)**	**($0.52)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	5.0	7.5	8.9	9.0	12.0	9.4	15.0	18.0

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

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