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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: EB05 Selected for BARDA-Funded Study in ARDS…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB05 and EB06, EDSA is valued at $20.00/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 (08/20/24)	$4.41
Valuation	**$20.00**

OUTLOOK

On August 9, 2024, Edesa Biotech, Inc. (EDSA) announced financial results for the third quarter of fiscal year 2024 that ended June 30, 2024 and provided a business update. In June 2024, the company announced that EB05 was selected by the Biomedical Advanced Research and Development Authority (BARDA) for evaluation in a U.S. government-funded clinical trial in hospitalized adult patients with acute respiratory distress syndrome (ARDS). The data from this study could provide additional support for expanding the use of EB05, with the ultimate goal being an approval for EB05 as a standard-of-care therapy for all-cause ARDS.

SUMMARY DATA

52-Week High	**$6.30**
52-Week Low	**$2.55**
One-Year Return (%)	**-25.86**
Beta	**0.87**
Average Daily Volume (sh)	**10,331**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**25**
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 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**

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)
2023	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2024	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2025					0.0 E
2026					0.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2023	-$0.90 A	-$0.82 A	-$0.68 A	-$0.56 A	-$2.93 A
2024	-$0.54 A	-$0.58 A	-$0.52 A	-$0.45 E	-$2.04 E
2025					-$1.50 E
2026					-$1.42 E

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WHAT'S NEW

Business Update

EB05 Selected for U.S. Government Funded Study in ARDS

In June 2024, Edesa Biotech, Inc. (EDSA) announced that EB05 (paridiprubart) was selected by the Biomedical Advanced Research and Development Authority (BARDA) for testing in a U.S. government-funded clinical trial to test three novel threat-agnostic host-directed therapeutics (HDTs) in hospitalized patients with acute respiratory distress syndrome (ARDS). The Phase 2 trial will be a randomized, double blind, placebo controlled, multi-center study. For the EB05 cohort of the study, patients will be randomized 1:1 to either EB05 plus standard of care (SOC) or to a placebo plus SOC.

EB05 is currently being evaluated in an Edesa-initiated Phase 3 clinical trial of approximately 600 patients hospitalized with ARDS caused by SARS-CoV-2 infections who are on invasive mechanical ventilation, both with and without additional organ support such as extracorporeal membrane oxygenation (ECMO). The primary endpoint for the study is the mortality rate at 28 days.

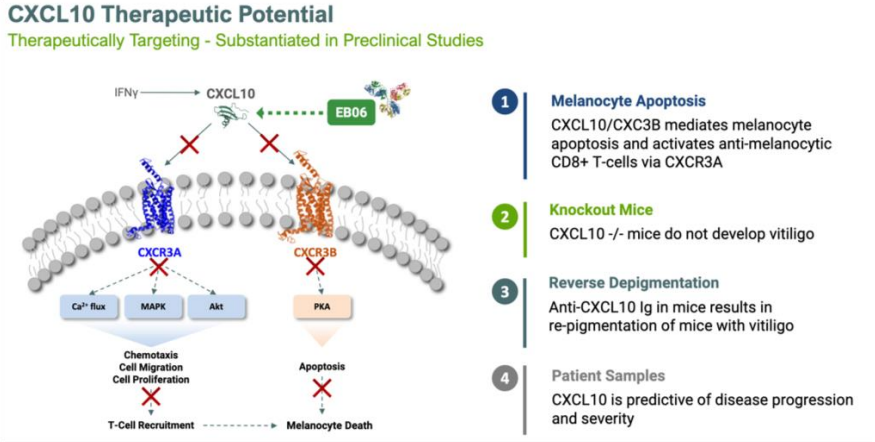
To support this Phase 3 study, in October 2023 Edesa secured a commitment of up to CAD$23 million from the Government of Canada via the Strategic Innovation Fund (SIF) to help cover expenses for the Phase 3 trial. The SIF funding will be applied toward study expenses, including hospital and physician expenditures, along with scale-up manufacturing for commercial drug product if development is successful. It will also allow for an expansion of the number of hospitals in the trial so that the company can fine-tune for places with the highest hospitalization rates. The SIF is an initiative by the Canadian government to expand and grow the life sciences sector and money is allocated from the SIF following a competitive review process. The company recently announced it is transitioning the day-to-day management of the ongoing Phase 3 trial to a new clinical research organization (CRO), which should provide access to more powerful analytical tools, expand recruitment capabilities, allow greater visibility of enrollment trends, and have a quicker turnaround of trial results.

Based on the selection of EB05 for the BARDA study, the company is currently evaluating its broader development strategy for the drug. Potential options include expanding the enrollment criteria for the Phase.3 trial, refocusing the project on manufacturing scale-up, or extending the timeline of the Phase 3 trial and/or pausing enrollment while awaiting the results of the BARDA study. It should be noted that changes made to the Phase 3 trial may require a renegotiation of the SIF agreement.

Readying IND for EB06 in Vitiligo

Edesa is planning for a Phase 2 study of its anti-CXCL10 monoclonal antibody for the treatment of moderate-to-severe non-segmental vitiligo patients. Vitiligo is a disease that causes areas of the skin to lose color, with non-segmental vitiligo being characterized by patches appearing on both sides of the body. It is caused when pigment-producing cells (melanocytes) die or stop producing melanin as a result of an autoimmune disease, genetics, or a triggering event (e.g., stress, sunburn, skin trauma).

Past research showed that the chemokine CXCL10 was elevated in both vitiligo patient skin and serum (El-Domyati *et al*., 2022). In a mouse model of vitiligo, which includes CXCL10 expression in the skin, neutralization of CXCL10 in mice with established, widespread depigmentation induced reversal of disease as shown by repigmentation (Rashighi *et al*., 2014). In addition, serum CXCL10 levels are significantly increased in vitiligo patients compared to controls, suggesting that CXCL10 may play a role in the pathogenesis of vitiligo in humans (Gharib *et al*., 2021). The following slide gives an overview of the mechanism of action of EB06 and data supporting its use in the treatment of vitiligo.



Source: Edesa Biotech, Inc.

The vitiligo market is projected to reach approximately $650 million by 2030 (EvaluatePharma), and two recent events show the potential for vitiligo treatments in development:

- In October 2022, Villaris Therapeutics was acquired by Incyte (INCY) for $70 million upfront and up to $1.3 billion in potential milestone payments. Villaris was developing auremolimab, an anti-IL-15Rβ monoclonal antibody in preclinical development for the treatment of vitiligo.

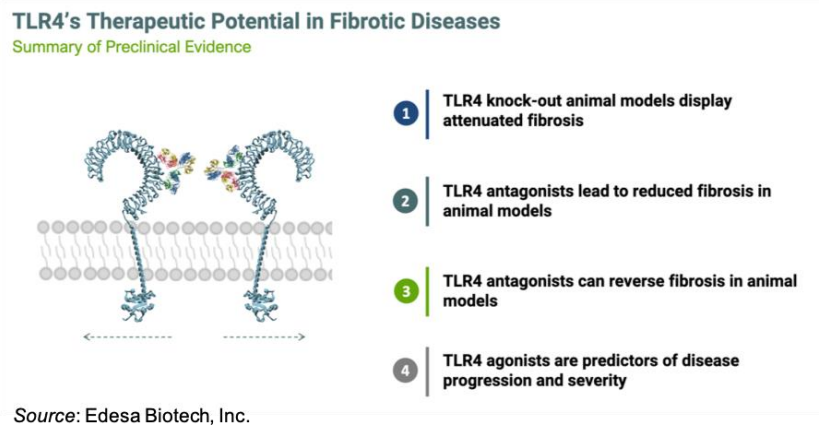
- In October 2023, VYNE Therapeutics (VYNE) announced positive results from the Phase 1b trial of VYN201 in patients with non-segmental vitiligo with a mean percentage reduction in F-VASI score for the 1.0% and 2.0% cohort of 30.3% and 39.0%, respectively. In addition, the drug was generally well tolerated with a favorable safety profile. Following the announced results, VYNE raised gross proceeds of $88 million in a private placement financing.

In addition, Opzelura® (ruxolitinib) was approved for the treatment of vitiligo in July 2022 and is projected to have sales of >$500 million for that indication in 2030 (EvaluatePharma). We believe that a successful Phase 2 trial with EB06 in vitiligo patients would result in a significant revaluation of that asset in line with the valuations assigned other vitiligo products as shown above.

Plans to File IND for Anti-TLR4 Antibody in IPF

Edesa is planning to file an Investigational New Drug (IND) application such that a Phase 2 trial of paridiprubart (EB07) can be initiated in pulmonary fibrosis (subject to securing funding or securing a partnership), which is the end stage of a broad range of interstitial lung diseases characterized by the progressive scarring of lung tissue. There are more than 200 known causes of pulmonary fibrosis, with idiopathic pulmonary fibrosis (IPF) being the most common form. IPF affects approximately 250,000 individuals in the U.S. (Pulmonary Fibrosis Foundation) and there are only two FDA approved therapies, pirfenidone and nintedanib. The median survival for IPF is 4.5 years (Kaunisto *et al*., 2019).

Research over the past decade has focused on the role of damage-associated molecular pattern (DAMP) molecules in the exacerbation and progression of pulmonary fibrosis (Ellson *et al*., 2014). Toll-like receptors (TLRs) are pattern recognition receptors of DAMPs and play a critical role in how DAMPs exert their effects in cellular microenvironments. TLR4 in particular was shown to have a profibrotic effect in the lung when activated by DAMPs (He *et al*., 2009). The interaction of TLR4 and DAMPs causes the release of numerous proinflammatory cytokines on macrophages and fibroblasts (Zhang *et al*., 2008). Thus, targeting the TLR4/DAMP interaction may be beneficial in the treatment of fibrotic lung diseases. A summary of the preclinical evidence supporting the use of anti-TLR4 therapy in treating IPF is shown below.



Source: Edesa Biotech, Inc.

Financial Update

On August 9, 2024, Edesa announced financial results for the third quarter of fiscal year 2024 that ended June 30, 2024. There were no revenues reported for the third quarter of fiscal year 2024. R&D expenses in the third quarter of fiscal year 2024 were $0.9 million, compared to $1.0 million for the third quarter of fiscal year 2023. The decrease was primarily due to decreases in external research expenses related to the EB05 and EB01 trials partially offset by an increase in expenses related to manufacturing EB05. G&A expenses totaled $1.0 million for both the third quarter of fiscal year 2024 and 2023.

As of June 30, 2023, Edesa had approximately $2.0 million in cash and cash equivalents, which does not include the CAD$23 million in potential funding from the Canadian government, the $10 million revolving credit agreement, or the approximately $6.3 million of available capacity on the Canaccord ATM. As of August 9, 2024, Edesa had approximately 3.2 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 4.2 million.

Conclusion

The selection of EB05 for inclusion in the BARDA study on ARDS is excellent news for the company as it presents the opportunity to acquire supportive data for its use in a broad ARDS population and not just in patients with ARDS caused by the SARS-CoV-2 virus, which is the focus of the ongoing Phase 3 trial. We look forward to additional details about the company's strategy regarding EB05 as management continues evaluating the best path forward. With no changes to our model our valuation remains at $20 per share.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2023 A	Q1FY24 A	Q2FY24 A	Q3FY24 A	Q4FY24 E	FY2024 E	FY2025 E	FY2025 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	$4.8	$0.7	$1.2	$0.9	$1.5	$4.3	$7.0	$9.0
General & Administrative	$4.4	$1.2	$1.0	$1.0	$1.2	$4.4	$5.0	$5.2
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($9.2)	($1.9)	($2.2)	($1.9)	($2.7)	($8.7)	($12.0)	($14.2)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.8	$0.2	$0.4	$0.3	$0.0	$0.8	$0.0	$0.0
Pre-Tax Income	($8.4)	($1.7)	($1.9)	($1.7)	($2.7)	($7.9)	($12.0)	($14.2)
Income Taxes	$0.0	$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	**($8.4)**	**($1.7)**	**($1.9)**	**($1.7)**	**($2.7)**	**($7.9)**	**($12.0)**	**($14.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.93)**	**($0.54)**	**($0.58)**	**($0.52)**	**($0.45)**	**($2.04)**	**($1.50)**	**($1.42)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.9	3.1	3.2	3.2	6.0	3.9	8.0	10.0

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

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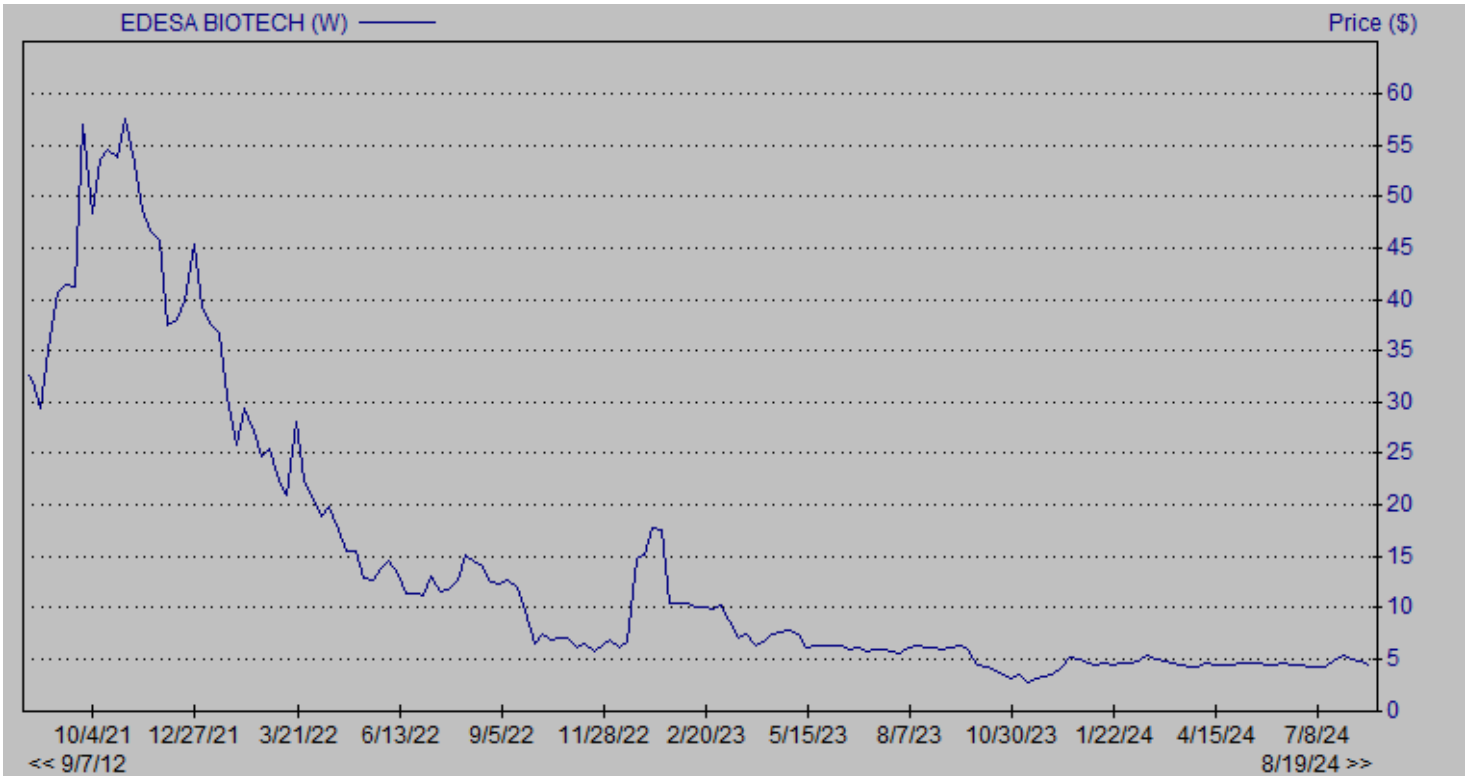
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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