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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Preparing IND for Phase 2 Trial of EB06 in Vitiligo…

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 (05/28/24)	$4.38
Valuation	**$20.00**

OUTLOOK

On May 10, 2024, Edesa Biotech, Inc. (EDSA) announced financial results for the second quarter of fiscal year 2024 that ended March 31, 2024 and provided a business update. Edesa is planning to seek regulatory approval for a Phase 2 trial of its anti-CXCL10 mAb in patients with moderate-to-severe nonsegmental vitiligo. For EB05, the company has expanded site selection activities for the Phase 3 study in acute respiratory distress syndrome (ARDS) caused by COVID-19 and has begun transitioning the day-to-day management of the trial to a new clinical research organization (CRO). Lastly, Edesa is planning to file an IND for a Phase 2 study of its anti-TLR4 mAb in pulmonary fibrosis.

SUMMARY DATA

52-Week High	**$6.93**
52-Week Low	**$2.55**
One-Year Return (%)	**-31.22**
Beta	**0.31**
Average Daily Volume (sh)	**7,465**
Shares Outstanding (mil)	**3**
Market Capitalization ($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-Blend**
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 E	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	-$0.45 E	-$0.45 E	-$1.95 E
2025					-$1.50 E
2026					-$1.42 E

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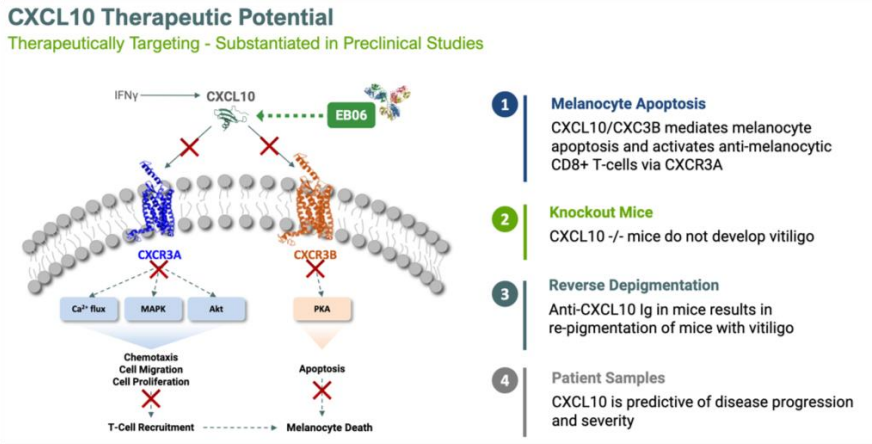
WHAT'S NEW

Business Update

Readying IND for EB06 in Vitiligo

Edesa Biotech, Inc. (EDSA) 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.

Update on EB05 Development in ARDS

Edesa is developing EB05 (paridiprubart) as a treatment for acute respiratory distress syndrome (ARDS). The drug is currently being evaluated in a 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.

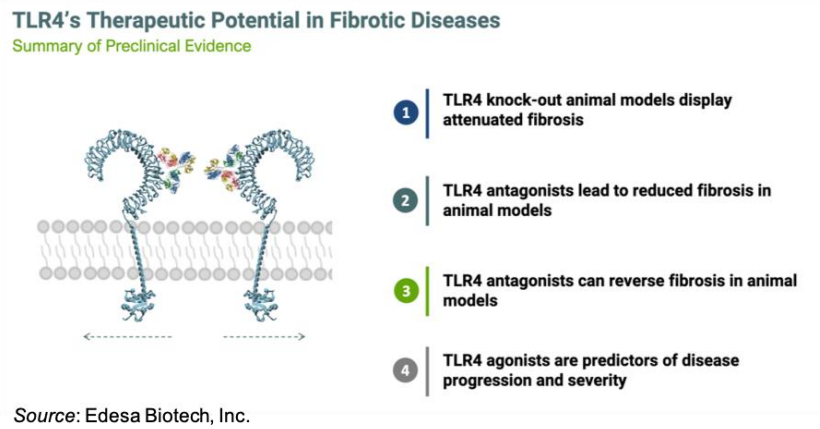
To support this Phase 3 study, in October 2023 Edesa secured a commitment of up to CAD$23 million from the Government of Canada via the Strategic Innovation Fund (SIF) to help cover expenses for the Phase 3 trial. The SIF funding will be applied toward study expenses, including hospital and physician 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.

The company has plans to evaluate EB05 in a broader ARDS population, however the best regulatory pathway forward for the drug is still being determined. Were the company to amend the current protocol to include all ARDS patients it would likely change the powering assumptions for the study and potentially introduce additional risks and variables. In addition, EB05 has the emergency use authorization (EUA) pathway still available to it in ARDS caused by COVID, and the addition of non-COVID patients to the trial may affect the potential to use the EUA pathway. Edesa is interested in getting EB05 approved in the most expeditious manner possible and the company is continuing to evaluate how best to do that while at the same time maintaining the goal of testing the drug in a general ARDS population.

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 May 10, 2024, Edesa announced financial results for the second quarter of fiscal year 2024 that ended March 31, 2024. There were no revenues reported for the second quarter of fiscal year 2024. R&D expenses in the second quarter of fiscal year 2024 were $1.2 million, compared to $1.5 million for the second quarter of fiscal year 2023. The decrease was primarily due to decreases in external research expenses related to the EB01 trial and a reduction in noncash share-based compensation. G&A expenses totaled $1.0 million for the second quarter of fiscal year 2024 compared to $0.9 million for the second quarter of fiscal year 2023. The increase was primarily due to increased fees for professional services.

As of March 31, 2023, Edesa had approximately $2.8 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 $6.4 million of available capacity on the Canaccord ATM. As of February 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

Edesa is currently evaluating the best way to advance its pipeline forward. The company will be filing an IND for EB06 in vitiligo, and will then determine the best path forward for that program through either financing a Phase 2 study itself or looking to partner the asset before initiating clinical trials. For both EB01 and EB07, Edesa will seek a partnership before advancing those programs in the clinic. Lastly, the company is continuing to evaluate how best to advance EB05 in a broader ARDS population.

Based on how the company is re-prioritizing the pipeline we have made a number of changes to our model. For EB05, we believe the ongoing Phase 3 trial can be completed in the next two years and that the compound will still qualify for approval under the EUA. We estimate for peak sales of $500 million seven years after approval. Using a 15% discount rate and a 70% probability of approval leads to an NPV of $62 million. For EB06, we estimate that following a successful Phase 2 readout in 3 years the asset would be valued similarly to auremolimab at $70 million. Using a 15% discount rate and a 65% probability of success leads to an NPV for EB06 of $30 million. For EB01, we calculate an NPV of $10 million based on potential peak sales of $80 million, a 15% discount rate, and a 70% probability of approval. Combining the NPVs for the company's assets and the company's cash position leads to a total NPV of $105 million. Dividing by the current number of outstanding shares plus an additional two million shares for the next financing leads to a valuation of $20 per share.

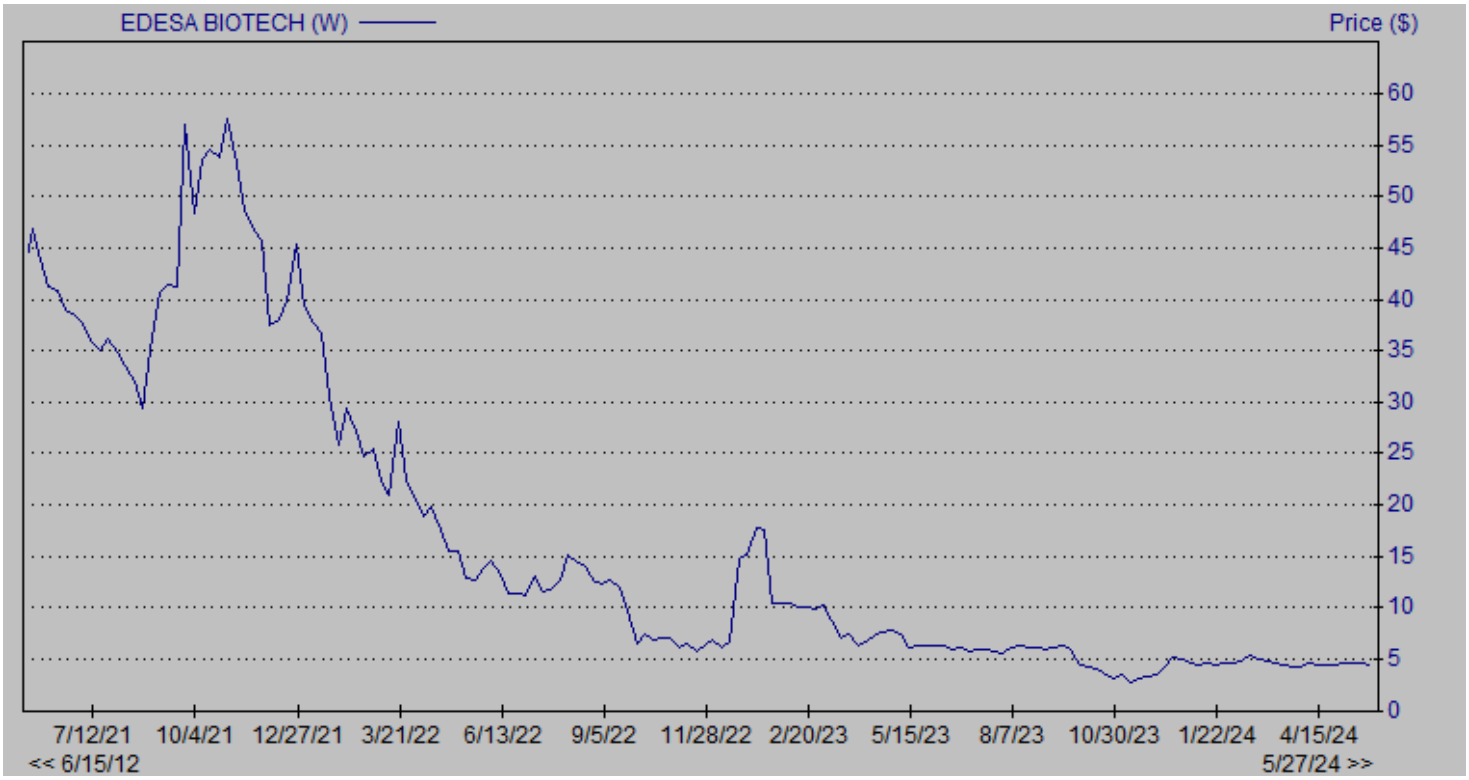
PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2023 A	Q1FY24 A	Q2FY24 A	Q3FY24 E	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	$1.5	$1.5	$4.9	$7.0	$9.0
General & Administrative	$4.4	$1.2	$1.0	$1.2	$1.2	$4.6	$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)	($2.7)	($2.7)	($9.5)	($12.0)	($14.2)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.8	$0.2	$0.4	$0.0	$0.0	$0.5	$0.0	$0.0
Pre-Tax Income	($8.4)	($1.7)	($1.9)	($2.7)	($2.7)	($8.9)	($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)**	**($2.7)**	**($2.7)**	**($8.9)**	**($12.0)**	**($14.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.93)**	**($0.54)**	**($0.58)**	**($0.45)**	**($0.45)**	**($1.95)**	**($1.50)**	**($1.42)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.9	3.1	3.2	6.0	6.0	4.6	8.0	10.0

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

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Source: Zacks Small Cap Research

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