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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Advancing EB06 for the Treatment of Vitiligo…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB05 and EB06, EDSA is valued at $17.00/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 (05/19/25)	$2.03
Valuation	**$17.00**

OUTLOOK

On May 14, 2025, Edesa Biotech, Inc. (EDSA) announced financial results for the second quarter of fiscal year 2025 that ended March 31, 2025 and provided a business update. The company has initiated outreach to potential investigators along with manufacturing-related activities to support U.S. regulatory approval for a Phase 2 study of EB06 in the treatment of vitiligo. Manufacturing of EB06 is likely to be finished in the second half of 2025 such that the company can submit the manufacturing data to the FDA as part of the Investigational New Drug (IND) application. Once cleared by the FDA, topline results could be available in approximately 12-18 months.

SUMMARY DATA

52-Week High	**$5.42**
52-Week Low	**$1.59**
One-Year Return (%)	**-55.38**
Beta	**0.55**
Average Daily Volume (sh)	**14,695**
Shares Outstanding (mil)	**7**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**23**
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 2025 Estimate	**N/A**
P/E using 2026 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)
2024	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2025	0.0 A	0.0 A	0.0 E	0.0 E	0.0 E
2026					0.0 E
2027					0.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2024	-$0.54 A	-$0.58 A	-$0.52 A	-$0.30 A	-$1.93 A
2025	-$0.48 A	-$0.30 A	-$0.23 E	-$0.26 E	-$1.17 E
2026					-$0.56 E
2027					-$0.45 E

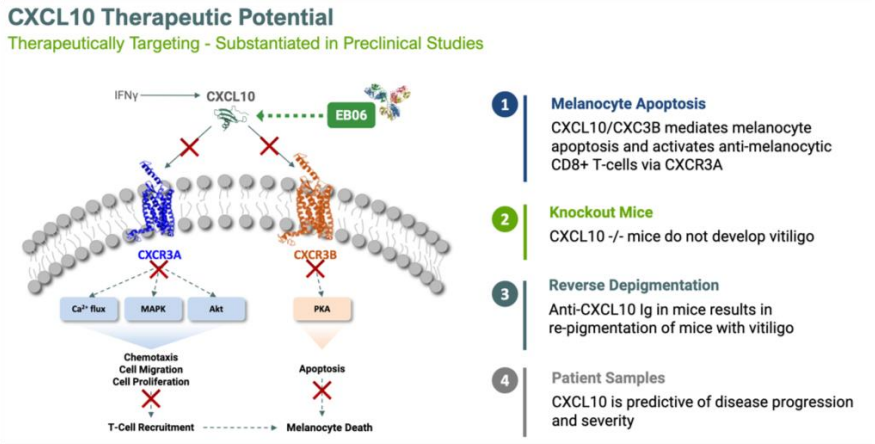
WHAT'S NEW

Business Update

Advancing EB06 for Treating 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.

A 2022 publication reported that the estimated prevalence of vitiligo patients in the U.S. is between 1.9 million and 2.8 million (Gandhi *et al*., 2022). This corresponds to a vitiligo market that is projected to reach approximately $1 billion by 2030 (EvaluatePharma). In support of this, the following two transactions 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 >$600 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.

The company is continuing IND-enabling work in 2025 and has already received approval from Health Canada to conduct a Phase 2 trial. Manufacturing activities have begun and are likely to be concluded in the second half of 2025. In addition, the company has begun outreach to potential investigators for the Phase 2 trial. The study as currently planned will enroll approximately 150 patients with severe nonsegmental vitiligo, will evaluate three different doses of EB06, and will have a primary efficacy outcome of the percentage of patients that achieve ≥50% decrease from baseline in facial Vitiligo Area Scoring Index (F-VASI50), a composite measurement of the overall area of facial vitiligo patches and degree of depigmentation within patches. The final trial protocol will be contingent on feedback from the FDA. We anticipate the IND being filed before the end of 2025.

Financial Update

On May 14, 2025, Edesa announced financial results for the second quarter of fiscal year 2025 that ended March 31, 2025. There were no revenues reported for the second quarter of fiscal year 2025. R&D expenses in the second quarter of fiscal year 2025 were $0.5 million, compared to $1.2 million for the second quarter of fiscal year 2024. The decrease was primarily due to decreases in external research expenses related to the manufacturing of paridiprubart partially offset by an increase in EB06-related expenses. G&A expenses totaled $1.2 million for the second quarter of fiscal year 2025 compared to $1.0 million for the second quarter of fiscal year 2024. The increase was primarily due to increased salaries and related costs partially offset by a decrease in noncash share-based compensation and professional service fees.

As of March 31, 2025, Edesa had approximately $13.9 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations through the end of fiscal 2026. As of May 14, 2025, Edesa had approximately 7.0 million shares outstanding and, when factoring in stock options, warrants and the Series B-1 convertible preferred shares, a fully diluted share count of approximately 12.8 million.

Conclusion

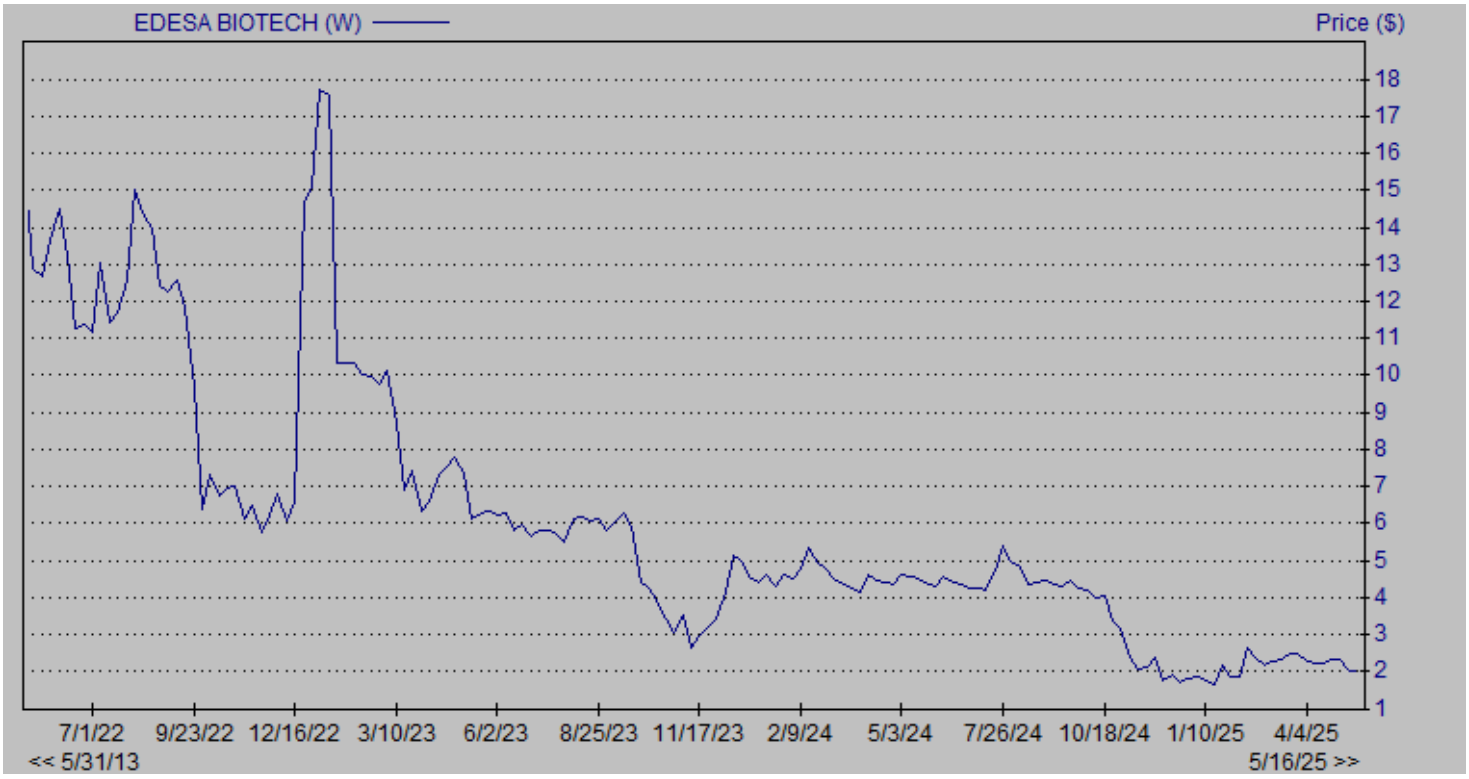
Now that Edesa has raised the capital to advance EB06 in vitiligo we look forward to updates as the company works towards filing an IND with the FDA before the end of 2025. We estimate that data from a Phase 2 trial of EB06 could be available in 12-18 months following IND acceptance. With no changes to our model our valuation remains at $17 per share.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2024 A	Q1FY25 A	Q2FY25 A	Q3FY25 E	Q4FY25 E	FY2025 E	FY2026 E	FY2027 E
EB06	$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	$2.9	$1.0	$0.5	$0.8	$1.0	$3.3	$3.5	$3.8
General & Administrative	$4.1	$0.9	$1.2	$1.0	$1.0	$4.0	$4.0	$4.2
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($7.0)	($1.9)	($1.6)	($1.8)	($2.0)	($7.3)	($7.5)	($8.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.8	$0.3	$0.0	$0.2	$0.2	$0.7	$0.8	$0.8
Pre-Tax Income	($6.2)	($1.6)	($1.6)	($1.6)	($1.8)	($6.6)	($6.7)	($7.2)
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	**($6.2)**	**($1.6)**	**($1.59)**	**($1.6)**	**($1.8)**	**($6.6)**	**($6.7)**	**($7.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.93)**	**($0.48)**	**($0.30)**	**($0.23)**	**($0.26)**	**($1.17)**	**($0.56)**	**($0.45)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	3.2	3.3	5.3	7.0	7.0	5.7	12.0	16.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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