

Edesa Biotech, Inc.

(EDSA-NASDAQ)

EDSA: Preparing for Mid-2026 Start to Phase 2 Vitiligo Trial

Based on our probability adjusted DCF model that takes into account potential future revenues of EB05 and EB06, EDSA is valued at \$19.00/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 (05/22/26) \$10.87
Valuation \$19.00

OUTLOOK

On May 14, 2026, Edesa Biotech, Inc. (EDSA) announced financial results for the second quarter of fiscal year 2026 that ended March 31, 2026. The company continues preparations for an upcoming Phase 2 clinical trial of EB06 (anti-CXCL10 monoclonal antibody) in patients with moderate-to-severe nonsegmental vitiligo. Edesa has selected the clinical research company and outreach to potential clinical sites and investigators has begun. We continue to anticipate the trial initiating (in Canadian investigational sites) in mid-2026, subject to regulatory approval. Earlier this year, Edesa announced positive results for paridiprubart (EB05) that continued to show a mortality benefit in patients suffering from acute respiratory distress syndrome (ARDS). The company is planning to meet with regulatory authorities to discuss next steps for that program.

SUMMARY DATA

52-Week High \$18.27
52-Week Low \$0.80
One-Year Return (%) 440.80
Beta 1.26
Average Daily Volume (sh) 1,141,209

Shares Outstanding (mil) 9
Market Capitalization (\$mil) \$97
Short Interest Ratio (days) N/A
Institutional Ownership (%) 6
Insider Ownership (%) 24

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 2026 Estimate N/A
P/E using 2027 Estimate N/A

Risk Level High
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)
2025	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2026	0.0 A	0.0 A	0.0 E	0.0 E	0.0 E
2027					0.0 E
2028					0.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2025	-\$0.48 A	-\$0.30 A	-\$0.25 A	-\$0.31 A	-\$1.25 A
2026	-\$0.28 A	-\$0.49 A	-\$0.38 E	-\$0.40 E	-\$1.57 E
2027					-\$1.13 E
2028					-\$0.93 E

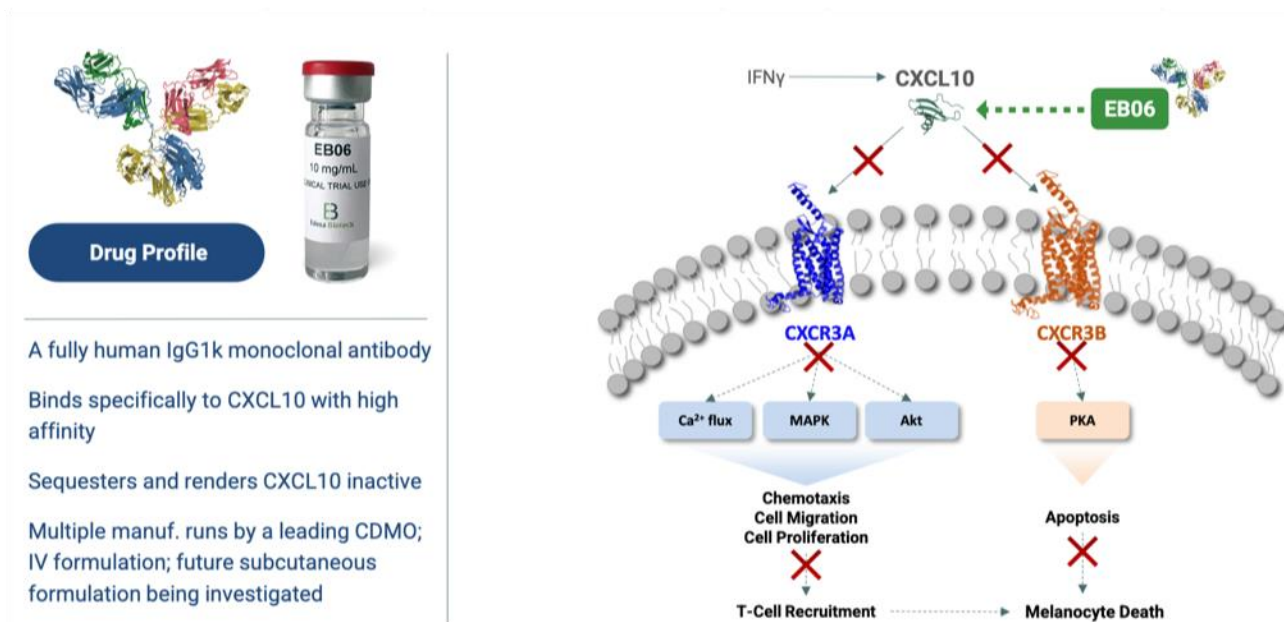
WHAT'S NEW

Business Update

Vitiligo Trial to Initiate in Mid-2026

Edesa Biotech, Inc. (EDSA) is planning for a Phase 2 study of EB06, 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 \$1.2 billion by 2030 (EvaluatePharma). Currently, the only FDA approved therapy is topical ruxolitinib (Opzelura®), which generated \$678 million in revenue in 2025, with approximately \$390 million of that coming from sales for vitiligo (EvaluatePharma). Opzelura carries a black-box warning due to the potential for serious infections, major adverse cardiovascular events, and thrombosis ([Opzelura prescribing information](#)). Thus, there is clearly an unmet need to additional safe and effective treatment options for vitiligo patients.

Edesa is currently readying an IND submission for EB06 and has already received approval from Health Canada to conduct a Phase 2 trial. In addition, the company has initiated manufacturing activities to supply drug product for the Phase 2 trial. Edesa has also begun outreach to potential investigators. The study as

currently planned will enroll approximately 160 patients with severe nonsegmental vitiligo, will evaluate three different doses of EB06 (2.5 mg/kg, 5 mg/kg, 10 mg/kg) administered IV every two weeks for up to 24 weeks followed by a 12-week follow up period, and will have a primary efficacy outcome of the percentage of patients that achieve $\geq 50\%$ 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 and we anticipate enrollment initiating in mid-2026, dependent upon completion of manufacturing and regulatory activities.

Updated Phase 3 ARDS Results Continue to Show Mortality Benefit

In February 2026, Edesa announced additional Phase 3 results from its paridiprubart (EB05) study in acute respiratory distress syndrome (ARDS) that extend beyond the initial 104-patient cohort that was previously disclosed in October 2025. The updated dataset includes the full 278-patient safety population, which is comprised of both invasive mechanical ventilation (IMV) patients and those who were not on IMV at baseline.

An examination of the full 278-patient population revealed:

- 28-day adjusted mortality was 24% on paridiprubart plus standard-of-care (SOC) compared to 33% on placebo + SOC, which represents a 27% relative reduction in risk of death ($P < 0.001$).
- Patients receiving paridiprubart also demonstrated a higher rate of clinical improvement at Day 28 based on WHO severity scoring.

Primary Endpoint: Mortality Rate at 28 Days
Multivariate Logistic Regression Derived Risk Differences, 95%CI

Population	Paridiprubart	Placebo	P-Value
All (n=278)	0.24 (0.21, 0.27)	0.33 (0.29, 0.37)	<0.001
IMV ITT (n=104)	0.39 (0.35, 0.44)	0.52 (0.47, 0.58)	<0.001

Adjusted model derived adjusted mortality estimates: variables included age, baseline WHO Covid-19 Severity Scale (WCSS), baseline antiviral use, baseline corticosteroid use, baseline immunomodulator use, concomitant antiviral use, concomitant corticosteroid use, concomitant immunomodulator use. All (safety population) n=278; Intent to treat (ITT) IMV population n=104

Source: Edesa Biotech, Inc.

Secondary Endpoint: Achievement of ≥ 2 -Point Improvement in WCSS at 28 Days
Multivariate Logistic Regression Derived Risk Differences, 95%CI

Population	Paridiprubart	Placebo	P-Value
All (n=278)	0.52 (0.48, 0.56)	0.45 (0.41-0.48)	<0.01
IMV ITT (n=104)	0.38 (0.31, 0.45)	0.27 (0.21, 0.33)	<0.05

Adjusted risk estimate: variables included age, baseline WCSS, baseline antiviral use, baseline corticosteroid use, baseline immunomodulator use, concomitant antiviral use, concomitant corticosteroid use, concomitant immunomodulator use. Safety population n=278; ITT IMV population n=104

Source: Edesa Biotech, Inc.

The company also conducted exploratory analyses across clinically relevant subgroups, which suggested patients receiving paridiprubart + SOC consistently had reduced adjusted mortality compared to those receiving placebo + SOC:

- **Acute Kidney Injury**, n=48: 35% relative reduction (35% vs. 53%; $P < 0.05$)
- **Sepsis**, n=41: 36% relative reduction (40% vs. 63%; $P < 0.05$)
- **Pneumonia**, n=108: 30% relative reduction (35% vs. 49%; $P < 0.05$)

Exploratory Analysis: Mortality Rate at 28 Days
Multivariate Logistic Regression Derived Risk Differences, 95%CI

Population	Paridiprubart	Placebo	P-Value*
Non-IMV (n=174)	0.15 (0.12, 0.18)	0.23 (0.19, 0.26)	<0.05
Pneumonia (n=108)	0.35 (0.29, 0.41)	0.49 (0.43, 0.55)	<0.05
Acute Kidney Injury (n=48)	0.35 (0.25, 0.44)	0.53 (0.44, 0.62)	<0.05
Sepsis (n=41)	0.40 (0.37, 0.43)	0.63 (0.59, 0.66)	<0.05

*Nominal p-value, not adjusted for multiplicity

Source: Edesa Biotech, Inc.

Importantly, the safety profile remained consistent compared to prior exposures, with similar rates of adverse events and infections in paridiprubart compared to placebo arms. Over 400 patients have now received paridiprubart.

Given the strength of this data, management has indicated plans to engage with regulatory agencies in both the U.S. and Canada to determine the most appropriate regulatory pathway. Discussions are likely to be focused on whether the robust mortality and clinical improvement signals in the full 278-patient dataset support a registrational submission, the potential for accelerated approval pathway given the high unmet need and the severity of ARDS, and the role of exploratory subgroup data in shaping labeling or accelerated pathways. We anticipate further updates from the company on the regulatory front as the year progresses.

As a reminder, paridiprubart is also being evaluated in an ongoing 200-patient study under funding from BARDA. That study is part of a broader ARDS platform evaluating multiple host-directed therapies and is likely to further inform regulatory decision-making and confirmatory evidence.

Edesa recently presented the data from the Phase 3 study in an oral presentation at the American Thoracic Society (ATS) 2026 International Conference. In addition, the company will be presenting new data on paridiprubart in acute kidney injury (AKI) at the European Renal Association (ERA) Congress on June 5, 2026 that will feature exploratory data and analysis from the Phase 3 trial regarding ARDS patients who also experienced AKI.

Financial Update

On May 14, 2026, Edesa announced financial results for the second quarter of fiscal year 2026 that ended March 31, 2026. There were no revenues reported for the second quarter of fiscal year 2026. R&D expenses in the second quarter of fiscal year 2026 were \$2.8 million, compared to \$0.5 million for the second quarter of fiscal year 2025. The increase was primarily due to higher manufacturing costs and other preparations for the planned Phase 2 clinical study of EB06 in vitiligo patients. G&A expenses totaled \$1.5 million for the second quarter of fiscal year 2026 compared to \$1.2 million for the second quarter of fiscal year 2025. The increase was primarily due to an increase in salaries and professional fees.

As of March 31, 2026, Edesa had approximately \$10.0 million in cash and cash equivalents. As of May 13, 2026, Edesa had approximately 8.9 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 15.7 million.

Conclusion

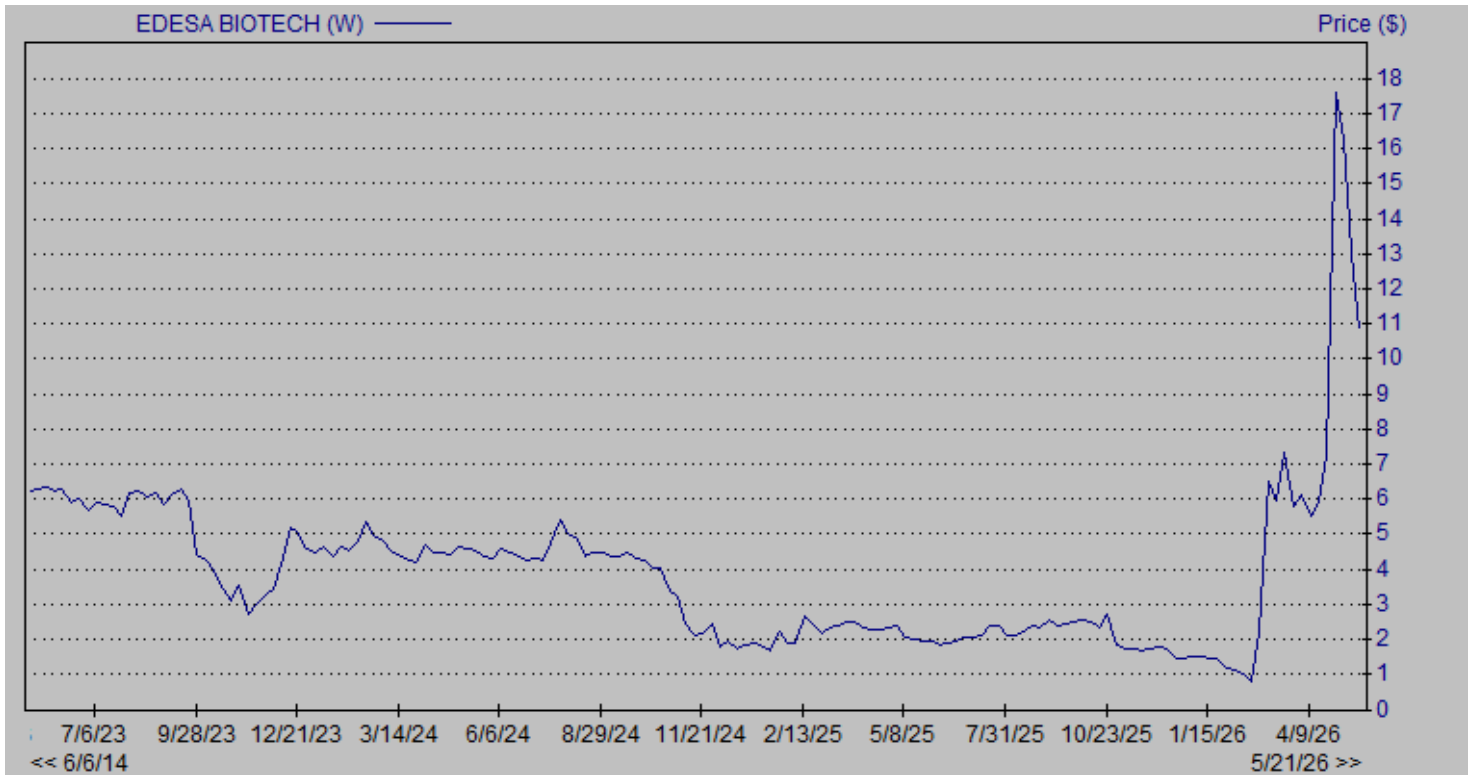
Edesa's stock has had an incredible run since our last update, rising from approximately \$2 to currently over \$10 as more investors have begun to appreciate the potential for the company's lead assets, EB05 and EB06. However, we believe there is additional upside to be had as Edesa gets set to initiate the Phase 2 trial in vitiligo for EB06 in mid-2026 and as discussions with regulatory agencies occur to determine the most appropriate path forward for EB05. With no changes to our model, our valuation remains at \$19 per share.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2025 A	Q1FY26 A	Q2FY26 A	Q3FY26 E	Q4FY26 E	FY2026 E	FY2027 E	FY2028 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
Research & Development	\$3.7	\$1.1	\$2.8	\$2.0	\$2.0	\$7.9	\$8.0	\$9.0
General & Administrative	\$4.2	\$1.2	\$1.5	\$1.5	\$1.7	\$5.9	\$6.0	\$6.3
Other (Income) Expense	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Operating Income	(\$7.9)	(\$2.3)	(\$4.3)	(\$3.5)	(\$3.7)	(\$13.8)	(\$14.0)	(\$15.3)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$0.8	\$0.1	\$0.1	\$0.1	\$0.1	\$0.4	\$0.5	\$0.5
Pre-Tax Income	(\$7.1)	(\$2.3)	(\$4.2)	(\$3.4)	(\$3.6)	(\$13.5)	(\$13.5)	(\$14.8)
Income Taxes	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$7.1)	(\$2.3)	(\$4.2)	(\$3.4)	(\$3.6)	(\$13.5)	(\$13.5)	(\$14.8)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$1.25)	(\$0.28)	(\$0.49)	(\$0.38)	(\$0.40)	(\$1.57)	(\$1.13)	(\$0.93)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Basic Shares Outstanding	5.7	8.0	8.5	8.9	8.9	8.6	12.0	16.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business. SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.