Zacks Small-Cap Research
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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Updated Phase 3 Protocol for EB05 Trial Approved by Canadian Regulators…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB01, EB02, and EB05, EDSA is valued at $32.00/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 (01/02/24)	$4.57
Valuation	**$32.00**

OUTLOOK

On December 15, 2023, Edesa Biotech, Inc. (EDSA) announced financial results for fiscal year 2023 that ended September 30, 2023 and provided a business update. The company recently announced that Health Canada has approved Edesa's plan to harmonize the clinical trial designs in the U.S. and Canada for the ongoing Phase 3 study of EB05 (paridiprubart). The updated study protocol calls for enrollment of approximately 600 patients hospitalized with acute respiratory distress syndrome (ARDS) caused by SARS-CoV-2 infection. The primary endpoint of the study is the mortality rate at 28 days. COVID-19-related hospitalizations seem to have become more predictable and seasonal in nature, thus the company is planning to increase the number of investigational centers from 23 up to 60 hospitals, adjusting the timing of opening them to manage the company's working capital.

SUMMARY DATA

52-Week High	**$18.40**
52-Week Low	**$2.55**
One-Year Return (%)	**-69.77**
Beta	**0.48**
Average Daily Volume (sh)	**51,771**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**31**
Insider Ownership (%)	**27**
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 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**

Risk Level	**High**
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 E	0.0 E	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	-$0.80 E	-$0.83 E	-$0.45 E	-$0.45 E	-$2.31 E
2025					-$1.50 E
2026					-$1.42 E

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WHAT'S NEW

Business Update

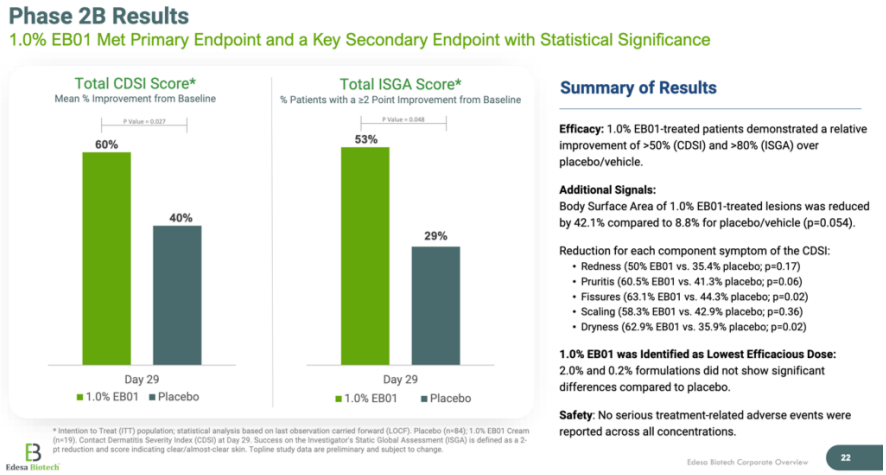
Canadian Regulators Approve Updated Phase 3 Trial Design

In October 2023, Edesa Biotech, Inc. (EDSA) announced that Health Canada has approved the company's plan to harmonize the trial designs in the U.S. and Canada for the ongoing Phase 3 clinical trial of EB05 (paridiprubart). The updated trial protocol calls for approximately 600 patients hospitalized with acute respiratory distress syndrome (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 of the study is the mortality rate at 28 days. The updated protocol replaces the previous protocol that called for more than 800 subjects with two independent cohorts and cohort-specific endpoints. The company believes that hospitalizations due to COVID-19 have become more seasonal in nature, with increased rates anticipated in the fall and winter. Thus, the pace of future enrollment will likely be linked to the number and location of investigational sites that are active as opposed to the unpredictable waves of the pandemic. Edesa plans to increase the number of investigational centers from 23 to up to 60 hospitals in the U.S. and Canada.

Earlier in October 2023, Edesa announced it has secured a commitment of up to CAD$23 million from the Government of Canada to help cover expenses for the Phase 3 portion of the Phase 2/3 clinical trial for EB05 via the Strategic Innovation Fund (SIF). 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.

Final Results for Phase 2b Trial of EB01

In November 2023, Edesa announced final results from the Phase 2b clinical trial of EB01 (daniluromer) for the treatment of moderate-to-severe chronic Allergic Contact Dermatitis (ACD). The final results showed that patients treated with 1.0% EB01 cream demonstrated a 60% average improvement in symptoms from baseline to Day 29 on the Contact Dermatitis Severity Index (CDSI) compared to 40% for placebo (P=0.027). For the ISGA secondary efficacy endpoint, 53% of patients treated with EB01 achieved a score of "clear" or "almost clear" with at least a two-point improvement from baseline to Day 29 compared to 29% of placebo-treated patients (P=0.048).



Source: Edesa Biotech, Inc.

With the full positive dataset in hand, the company will be evaluating potential partnerships and funding opportunities to continue the development of EB01.

Financial Update

On December 15, 2023, Edesa announced financial results for fiscal year 2023 that ended September 30, 2023. As expected, there were no revenues reported for fiscal year 2023. R&D expenses in fiscal year 2023 were $4.8 million, compared to $13.3 million for fiscal year 2022. The decrease was primarily due to decreased external R&D expenses related to ongoing clinical studies and manufacturing of drug product. G&A expenses totaled $4.4 million for fiscal year 2023 compared to $5.0 million for fiscal year 2022. The decrease was primarily due to decreased noncash, share-based payments.

As of September 30, 2023, Edesa had approximately $5.4 million in cash and cash equivalents. As of December 13, 2023, Edesa had approximately 3.2 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 3.3 million.

Conclusion

We look forward to updates on the ongoing Phase 3 clinical trial of EB05, which is now supported by up to CAD$23 million from the Canadian government. With the full dataset from the Phase 2b trial of EB01 in hand we believe the company can focus on potential partnerships and/or funding to advance that program into Phase 3 testing. In addition, Edesa owns EB06, a monoclonal antibody that targets chemokine ligand 10 (CXCL10), for the treatment of vitiligo and is currently evaluating potential funding options for that project. We have advanced our DCF model ahead one year, which has raised our valuation to $32 per share.

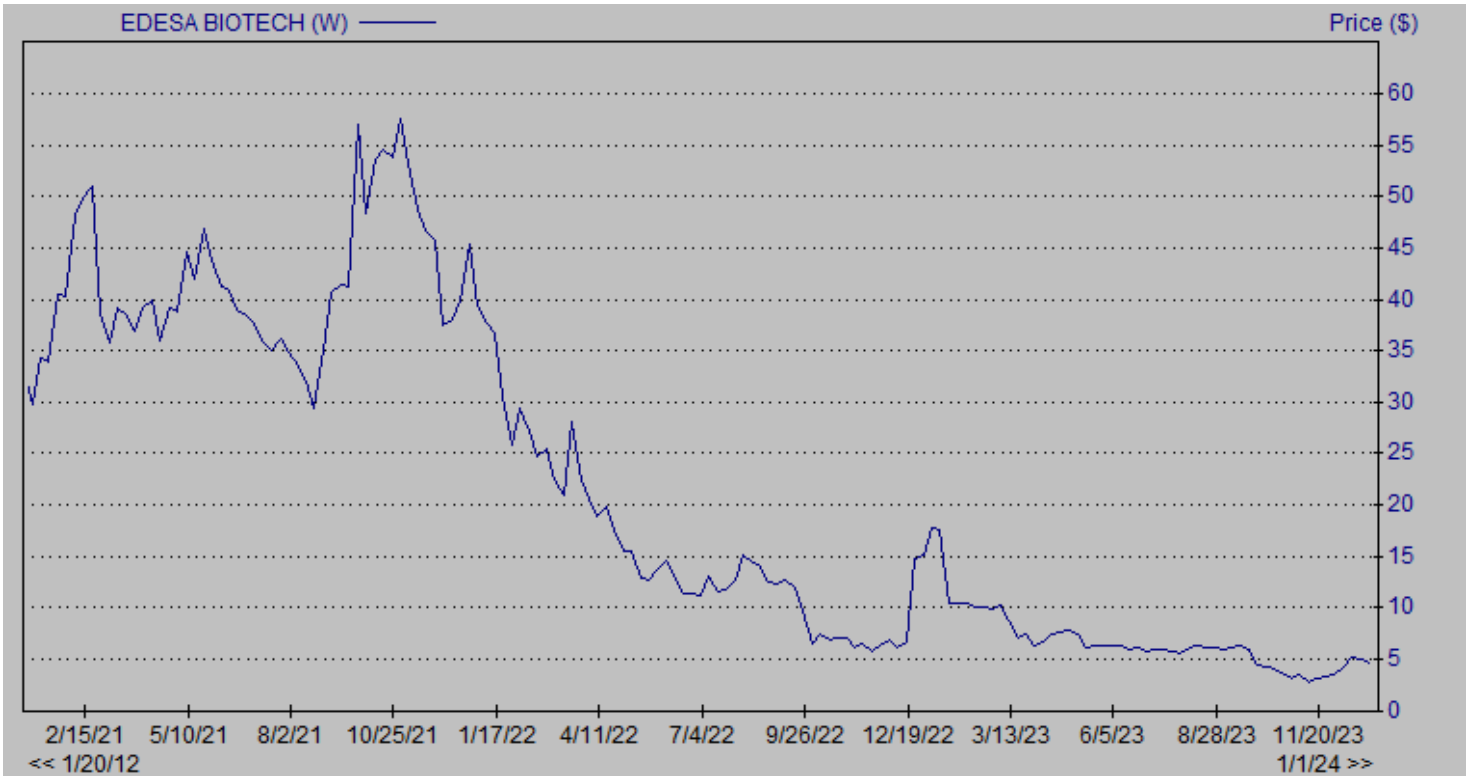
PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2023 A	Q1FY24 E	Q2FY24 E	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	$1.4	$1.5	$1.5	$1.5	$5.8	$7.0	$9.0
General & Administrative	$4.4	$1.2	$1.2	$1.2	$1.2	$4.8	$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)	($2.6)	($2.7)	($2.7)	($2.7)	($10.6)	($12.0)	($14.2)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($8.4)	($2.6)	($2.7)	($2.7)	($2.7)	($10.6)	($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)**	**($2.6)**	**($2.7)**	**($2.7)**	**($2.7)**	**($10.6)**	**($12.0)**	**($14.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.93)**	**($0.80)**	**($0.83)**	**($0.45)**	**($0.45)**	**($2.31)**	**($1.50)**	**($1.42)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.9	3.2	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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