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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Positive News Flow to Start 2023…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB01, EB02, and EB05, EDSA is valued at $10.00/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 (02/15/23)	$1.39
Valuation	**$10.00**

OUTLOOK

On February 10, 2023, Edesa Biotech, Inc. (EDSA) announced financial results for the first quarter of fiscal year 2023 that ended December 31, 2022 and provided a business update. Edesa recently announced positive topline results from the Phase 2b clinical trial of EB01 in allergic contact dermatitis. The company will meet with the FDA later this year to map out a Phase 3 program. The company recently received approval from Health Canada to conduct a Phase 2 clinical trial of EB06, which targets CXCL10, for the treatment of vitiligo, an autoimmune skin disease that causes skin to lose its color in patches. In December 2022, the U.S. FDA granted Fast Track designation to EB05, the company's monoclonal antibody drug candidate that targets toll-like receptor 4 (TLR4). EB05 is currently being investigated in a Phase 2/3 clinical trial in hospitalized COVID-19 patients with acute respiratory distress syndrome (ARDS). Fast Track designation allows for more frequent communication with the FDA along with a rolling review for the marketing application and the potential for accelerated approval.

SUMMARY DATA

52-Week High	**$4.02**
52-Week Low	**$0.80**
One-Year Return (%)	**-65.42**
Beta	**0.47**
Average Daily Volume (sh)	**177,465**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$28**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**45**
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)
2022	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2023	0.0 A	0.0 E	0.0 E	0.0 E	0.0 E
2024					0.0 E
2025					0.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2022	-$0.33 A	-$0.33 A	-$0.37 A	-$0.12 A	-$1.05 A
2023	-$0.13 A	-$0.24 E	-$0.22 E	-$0.23 E	-$0.83 E
2024					-$0.70 E
2025					-$0.67 E

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WHAT'S NEW

Business Update

Positive News Flow to Start 2023

Edesa Biotech, Inc. (EDSA) has started 2023 with multiple positive developments, including positive topline results for the Phase 2b clinical trial of EB01 as a treatment for chronic moderate-to-severe Allergic Contact Dermatitis (ACD), the FDA granting Fast Track designation to EB05, and Health Canada giving approval for a Phase 2 clinical trial of EB06 for the treatment of vitiligo.

- On January 17, 2023, Edesa announced topline results for the Phase 2b clinical trial of EB01 as a treatment for chronic moderate-to-severe Allergic Contact Dermatitis (ACD). The results showed that 1.0% EB01 cream demonstrated a statistically significant improvement over placebo. For the primary endpoint, subjects treated with 1.0% EB01 cream had a 60% average improvement in symptoms from baseline at Day 29 on the CDSI compared to 39% for placebo-treated subjects (*P*=0.02). The effect was observed as early as 15 days (44% for 1.0% EB01 compared to 29% for placebo; *P*=0.05) and continued at follow up (64% for 1.0% EB01 compared to 44% for placebo; *P*=0.04). For the ISGA secondary endpoint, 53% of 1.0% EB01-treated subjects achieved a score of 'clear' or 'almost clear' with at least a 2-point improvement from baseline after treatment at Day 29 compared to only 29% of placebo-treated subjects (*P*=0.04).

  While the 2.0% and 0.2% EB01 creams did not reach statistical significance, it was likely due to too little active ingredient in the 0.2% EB01 cream and formulation issues with the 2.0% cream, as it is known that the active ingredient begins to aggregate at concentrations at and above 2.0%. In regards to safety, all of the strengths were well tolerated with very few serious adverse events in the study. In particular, the 0.2% and 1.0% concentrations were both very well tolerated with no adverse events reported for the 1.0% cream and only one adverse event reported for the 0.2% cream. This is in contrast to the 2.0% cream, in which 37% of patients reported an adverse event (none serious), compared to 25% of patients receiving placebo cream reporting an adverse event.

  We anticipate Edesa requesting an 'end-of-Phase 2' meeting with the FDA to map out a Phase 3 program once the company finishes analyzing the full dataset. We anticipate two Phase 3 trials, each with approximately 500 patients testing 1.0% EB01 cream compared to placebo. Edesa may look to enter into a partnership before embarking on the Phase 3 program, however the company is also prepared to advance the drug on its own.

- At the end of December 2022, Edesa announced that the U.S. FDA had granted EB05 Fast Track designation. Fast Track designation allows for more frequent communication with the FDA along with a rolling review for the marketing application and the potential for accelerated approval. EB05 is currently being evaluated in a Phase 2/3 clinical trial in hospitalized COVID-19 patients with Acute Respiratory Distress Syndrome (ARDS). Recruitment for the Phase 3 study is already underway in Canada, Colombia, and Poland. The first cohort of patients being enrolled in the Phase 3 study are critically ill COVID-19 patients that are receiving extracorporeal membrane oxygenation (ECMO) and/or invasive mechanical ventilation plus organ support (Level 7 on the WCSS). The second cohort will consist of hospitalized COVID-19 patients on invasive mechanical ventilation alone (Level 6 on the WCSS). The primary endpoint for the Level 7 cohort will be 28-day mortality. The primary endpoint for the Level 6 cohort will be the number of ventilator-free days at Day 28.

  In September 2022, Edesa announced final results from the Phase 2 portion of its ongoing Phase 2/3 clinical trial of EB05. At the 28-day timepoint, patients treated with EB05 in addition to standard of care (SOC) had a mortality rate of 7.7% compared to 40% for patients treated with placebo and SOC (*P*=0.04). Using the Cox's Proportional Hazard Model, this survival benefit translated to an 84.0% reduction in the risk of dying for patients treated with EB05 plus SOC compared to placebo plus SOC

at 28 days. Additional efficacy signals were observed in the proportion of patients who were alive and without the need for oxygen support at Day 28 in severe COVID-19 patients at WCSS level ≥5 (99% of patients had ARDS at baseline) along with the proportion of patients who achieved at least a 2-point improvement on the WCSS.

- On February 1, 2023, Edesa announced that Health Canada has approved a Phase 2 clinical trial of EB06, the company's investigational monoclonal antibody candidate that targets CXCL10, for the treatment of vitiligo. Vitiligo is an autoimmune skin disease that causes loss of pigment and disfiguring white spots caused by autoreactive, melanocyte-specific CD8+ T cells. Evidence for the role of CXCL10 in vitiligo includes its elevated level in vitiligo patient skin and serum, mice treated with a CXCL10-neutralizing antibody exhibit minimal depigmentation, and mice with established, widespread depigmentation saw reversal of disease as evidenced by repigmentation when treated with a CXCL10 neutralizing antibody (Rashighi *et al*., 2014). Results from 65 subjects in three previous clinical trials showed that EB06 produced the pharmacodynamic/biological activity required to address the dysfunctional immune response associated with vitiligo while being safe and well tolerated.

  The planned Phase 2 clinical trial will evaluate the safety and efficacy of EB06 compared to placebo in approximately 120 adults with moderate to severe vitiligo. The primary endpoint will be improvement from baseline on the Face Vitiligo Area Scoring Index (F-VASI), a quantitative clinical tool that estimates the overall area of vitiligo patches and the degree of macular re-pigmentation in those patches over time.

Financial Update

On February 14, 2022, Edesa announced financial results for the first quarter of fiscal year 2023 that ended December 31, 2022. There were no revenues reported for the first quarter of fiscal year 2023. R&D expenses in the first quarter of fiscal year 2023 were $1.4 million, compared to $4.0 million for the first quarter of fiscal year 2022. The decrease was primarily due to decreases in costs associated with ongoing clinical studies and manufacturing of investigational drugs. G&A expenses totaled $1.1 million for the first quarter of fiscal year 2023 compared to $1.2 million for the first quarter of fiscal year 2022. The decrease was primarily due to a decrease in non-cash, stock-based compensation.

As of December 31, 2022, Edesa had approximately $8.3 million in cash and cash equivalents. Subsequent to the end of the first quarter of fiscal year 2023, Edesa raised gross proceeds of approximately $0.8 million from the exercise of common share purchase warrants. We estimate that the company has sufficient capital to fund operations through the end of calendar 2023. As of February 9, 2022, Edesa had approximately 20.1 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 28.6 million.

Conclusion

Edesa has had a spate of positive news to start out 2023 and we look forward to a number of catalysts later this year, including the full analysis of the Phase 2b trial results for EB01, the Phase 3 plan for EB01, and updates for the Phase 2/3 clinical trial of EB05 and the proposed Phase 2 trial for EB06. With no changes to our model our valuation remains at $10 per share.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2022 A	Q1FY23 A	Q2FY23 E	Q3FY23 E	Q4FY23 E	FY2023 E	FY2024 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	$13.3	$1.4	$3.4	$3.7	$3.9	$12.4	$15.0	$17.0
General & Administrative	$5.0	$1.0	$1.3	$1.5	$1.7	$5.5	$6.0	$6.5
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($18.4)	($2.4)	($4.7)	($5.2)	($5.6)	($17.9)	($21.0)	($23.5)
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	($17.5)	($2.4)	($4.7)	($5.2)	($5.6)	($17.9)	($21.0)	($23.5)
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	**($17.5)**	**($2.4)**	**($4.7)**	**($5.2)**	**($5.6)**	**($17.9)**	**($21.0)**	**($23.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.05)**	**($0.13)**	**($0.24)**	**($0.22)**	**($0.23)**	**($0.83)**	**($0.70)**	**($0.67)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	16.7	18.4	19.5	24.0	24.5	21.6	30.0	35.0

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

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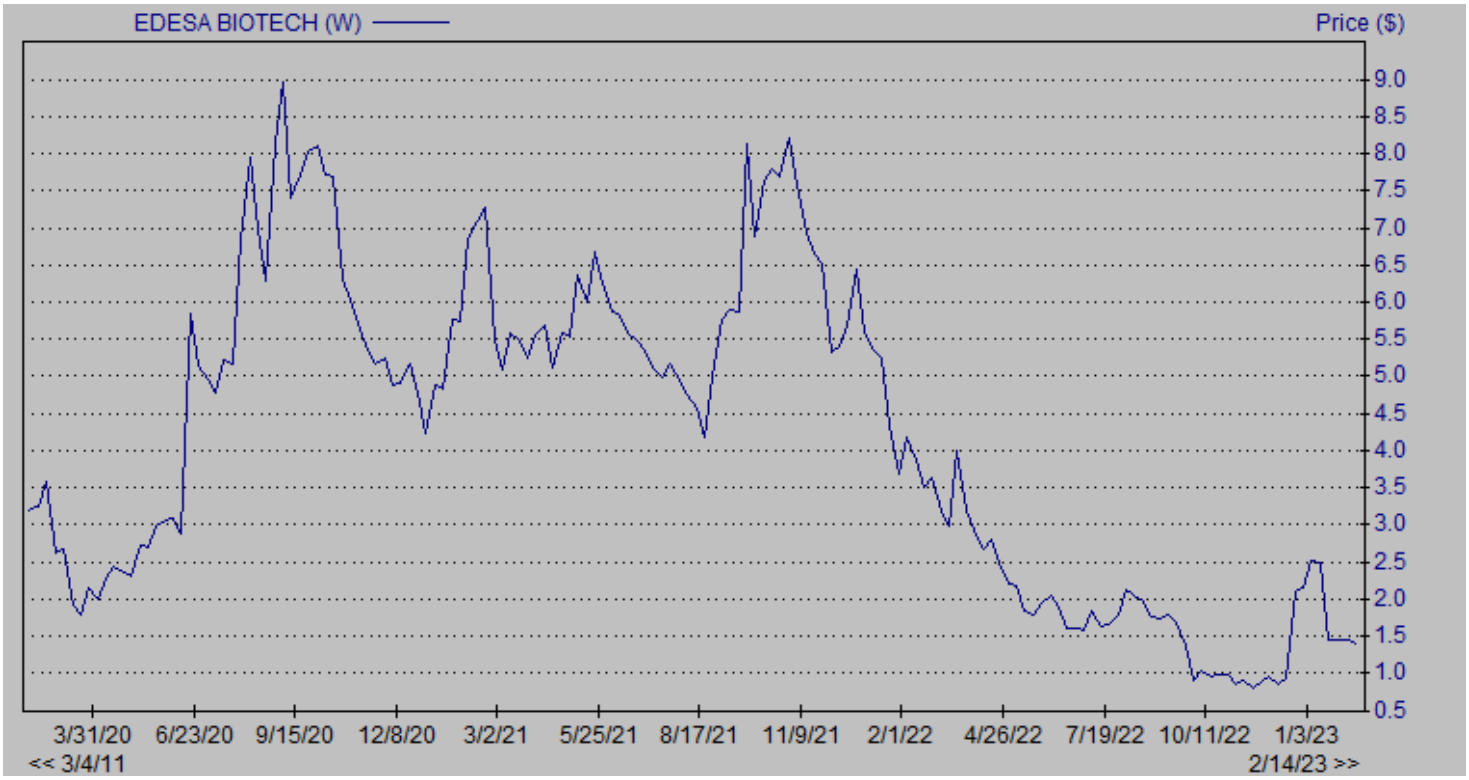
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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