# **Zacks Small-Cap Research**

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July 31, 2025 David Bautz, PhD 312-265-9471 dbautz@zacks.com

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

# Soligenix, Inc.

SNGX: Encouraging Results from Phase 2a Study of SGX945 in Behcet's Disease...

Based on our probability adjusted DCF model that takes into account potential future revenues from HyBryte™, SGX302, and SGX945, SNGX is valued at \$35.00 per share. This model is highly dependent upon continued clinical success of the company's pipeline and will be adjusted accordingly based upon future clinical results.

Current Price (07/31/25) \$1.25 **Valuation** \$35.00

# (SNGX-NASDAQ)

## **OUTLOOK**

On July 31, 2025, Soligenix, Inc. (SNGX) announced encouraging results from the Phase 2a clinical trial of SGX-945 (dusquetide) for the treatment of Behcet's disease (BD) in which the compound demonstrated biological efficacy. This was an open-label study designed to be highly comparable to the Phase 3 trial of apremilast (Otezla®) that was the basis for marketing approval for oral ulcers in BD. Using the same primary endpoint as the Phase 3 apremilast study (area under the curve of the mean number of ulcers vs. time), after four weeks of treatment the SGX945 group had a 40% improvement relative to the placebo group from the Phase 3 apremilast study, while apremilast had a 37% improvement relative to placebo. Soligenix will be reformulating SGX945 to enable home-based treatment before embarking on a placebo-controlled Phase 2 study.

# **SUMMARY DATA**

52-Week High 52-Week Low One-Year Return (%) Beta	\$5.18 \$1.12 -70.31 1.87	Risk Level Type of Stock Industry				Above Avg. Small-Value Med-Biomed/Gene		
Average Daily Volume (sh)	210,290	ZACKS ESTIMATES						
Shares Outstanding (mil) Market Capitalization (\$mil) Short Interest Ratio (days) Institutional Ownership (%) Insider Ownership (%) Annual Cash Dividend Dividend Yield (%)	3 \$4 N/A 4 3 \$0.00 0.00	2024 2025 2026 2027		<b>Q2</b> (Jun) 0.0 A 0.0 E	<b>Q3</b> (Sep) 0.0 A 0.0 E	<b>Q4</b> (Dec) 0.0 A 0.0 E	Year (Dec) 0.1 A 0.0 E 1.0 E 1.0 E	
5-Yr. Historical Growth Rates Sales (%) Earnings Per Share (%) Dividend (%)  P/E using TTM EPS P/E using 2025 Estimate P/E using 2026 Estimate	N/A N/A N/A -0.4 -0.6	2024 2025 2026 2027	<b>Q1</b> (Mar) -\$2.91 A -\$1.06 A	<b>Q2</b> (Jun) -\$1.31 A	<b>Q3</b> (Sep) -\$0.78 A -\$0.82 E	<b>Q4</b> (Dec) -\$1.18 A -\$0.79 E	Year (Dec) -\$4.98 A -\$3.45 E -\$2.02 E -\$1.75 E	

### WHAT'S NEW

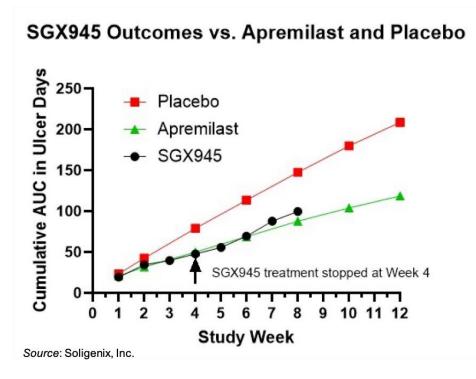
### **Business Update**

Encouraging Results from Phase2a Trial of SGX945 in Behcet's Disease

On July 31, 2025, Soligenix, Inc. (SNGX) <u>announced</u> encouraging results from a Phase 2a clinical trial of SGX945 in Behcet's disease (BD) in which the compound exhibited biological efficacy. These results are supportive of advancing the compound into a placebo-controlled Phase 2b trial, which will be pursued by the company following a reformulation of the drug, which is currently administered intravenously.

The Phase 2a study was modeled after the Phase 3 clinical trial of apremilast (Otezla®), which served as the basis for marketing approval of that drug for oral ulcers in BD (<u>Hatemi et al., 2019</u>). A total of eight patients were enrolled in the study and administered SGX945 IV twice a week for four weeks. A four-week follow-up was also conducted following cessation of SGX945 treatment. The primary endpoint was the area under the curve (AUC) of the mean number of ulcers versus time.

The results of the trial showed that after 4 weeks of treatment, the SGX945-treated group had a 40% improvement relative to the placebo group from the Phase 3 apremilast study. This compares to a 37% improvement for the apremilast group relative to placebo. The improvement in the SGX945-treated group was sustained through the 4-week follow-up period. A 32% improvement relative to placebo was noted at Week 8, even though treatment had stopped at Week 4. Apremilast-treated patients, who were administered drug continuously through Week 12, showed a 41% improvement at Week 8.



Notable reports from the SGX945 study include 7/8 patients reporting a perceived benefit from treatment, including reduced duration of oral ulcers, reduced number of oral ulcers, and reduced oral pain. One of the patients had a skin ulcer that resolved during the 4-week treatment period with SGX945. Importantly, SGX945 was well tolerated with no treatment-related adverse events. Commonly reported adverse events in the apremilast study included diarrhea (41%) and nausea (19%), neither of which were reported for SGX945-treated patients.

Since SGX945 is currently administered intravenously, Soligenix is planning to reformulate SGX945 as a subcutaneous injection that can administered by patients at home, similar to GLP-1 therapies. Following the reformulation, we anticipate the company performing a placebo-controlled Phase 2b trial of SGX945 in BD patients.

### Background on BD

BD is a chronic recurrent multisystemic disease that causes oral aphthous ulcers, genital ulcers, skin lesions, and other pathologies (Mendes et al., 2009). Interestingly, the epidemiology of BD is distributed along the ancient Silk Road from Mediterranean countries (Turkey has 370 cases per 100,000 population), to Middle Eastern and East Asian countries. In contrast, there are very few cases found in Northern Europe (0.64 cases per 100,000 population), North America (0.12-0.33 cases per 100,000 population), Australia, and Africa (Deuter et al., 2007). Thus, BD is an orphan disease in the U.S., however there may be as many as 500,000 people worldwide with the disease.

There are no standardized regimens for treating BD. Systemic corticosteroids, interferon-alpha (INF- $\alpha$ ) therapy, and anti-tumor necrosis factor alpha (TNF- $\alpha$ ) therapy are all used as first-line agents and have shown good efficacy. As mentioned above, apremilast was approved by the FDA for the treatment of oral ulcers in BD patients.

### Conclusion

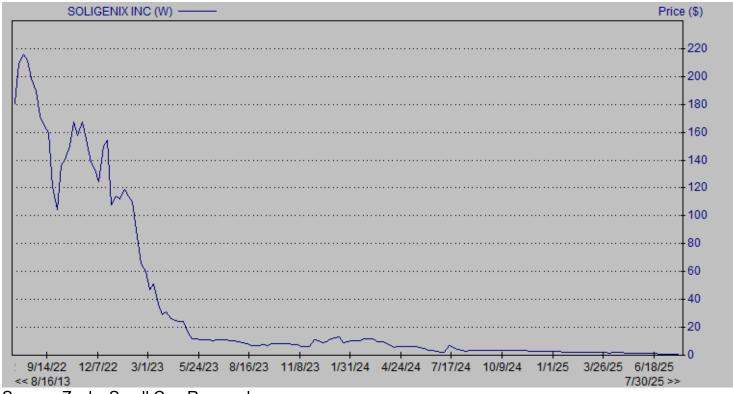
The encouraging results from the Phase 2a trial of SGX945 in BD patients is a positive catalyst for the company and fully supports moving into a placebo-controlled Phase 2b trial. The company will be reformulating the compound to make it easier for patients to administer, as SGX945 is currently dosed intravenously. We look forward to additional updates regarding the reformulation and potential timelines for when a Phase 2b trial could get underway. With no changes to our model our valuation remains at \$35 per share.

# **PROJECTED FINANCIALS**

\$0.0 \$0.1	\$0.0	\$0.0					2027 E
		ψ0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$1.0	\$1.0
\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
\$0.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$1.0	\$1.0
\$0.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.8	\$0.8
\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.2	\$0.2
0.0%	#DIV/0!	100.0%	#DIV/0!	#DIV/0!	100.0%	20.0%	20.0%
\$5.2	\$2.2	\$1.3	\$1.4	\$1.5	\$6.4	\$5.3	\$5.5
\$4.2	\$1.1	\$1.2	\$1.3	\$1.2	\$4.8	\$5.0	\$5.2
\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
(\$9.4)	(\$3.3)	(\$2.5)	(\$2.7)	(\$2.7)	(\$11.3)	(\$10.1)	(\$10.5)
-	-	-	-	-	-	-	-
\$0.8	\$0.1	\$0.0	\$0.0	\$0.0	\$0.1	\$0.0	\$0.0
(\$8.7)	(\$3.2)	(\$2.5)	(\$2.7)	(\$2.7)	(\$11.2)	(\$10.1)	(\$10.5)
\$0.4	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
4.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
(\$8.3)	(\$3.2)	(\$2.5)	(\$2.7)	(\$2.7)	(\$11.2)	(\$10.1)	(\$10.5)
-	-	-	-	-	-	-	-
\$4.98)	(\$1.06)	(\$0.79)	(\$0.82)	(\$0.79)	(\$3.45)	(\$2.02)	(\$1.75)
-		-	-	-	-	-	-
1.7	3.0	3.2	3 3	3.4	3.2	5.0	6.0
\$	\$9.4) - \$0.8 \$8.7) \$0.4 4.7% \$8.3) - 4.98)	\$9.4) (\$3.3)	\$9.4) (\$3.3) (\$2.5)	\$9.4) (\$3.3) (\$2.5) (\$2.7)	\$9.4) (\$3.3) (\$2.5) (\$2.7) (\$2.7)  \$0.8 \$0.1 \$0.0 \$0.0 \$0.0  \$8.7) (\$3.2) (\$2.5) (\$2.7) (\$2.7)  \$0.4 \$0.0 \$0.0 \$0.0 \$0.0  \$4.7% 0.0% 0.0% 0.0% 0.0%  \$8.3) (\$3.2) (\$2.5) (\$2.7) (\$2.7)  \$	\$9.4) (\$3.3) (\$2.5) (\$2.7) (\$2.7) (\$11.3)	\$9.4) (\$3.3) (\$2.5) (\$2.7) (\$11.3) (\$10.1)

Source: Zacks Investment Research, Inc.

# HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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