Zacks Small-Cap Research
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Soligenix, Inc.

(SNGX-NASDAQ)

SNGX: Phase 3 CTCL Trial to Initiate Before End of 2024…

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 (11/11/24)	$3.50
Valuation	**$35.00**

OUTLOOK

On November 8, 2024, Soligenix, Inc. (SNGX) announced financial results for the third quarter of 2024 and provided a business update. The company has multiple milestones coming up in the near future, including the initiation of the Phase 3 clinical trial of HyBryte™ in the treatment of cutaneous T cell lymphoma (CTCL) before the end of 2024, the initiation of a Phase 2 trial of SGX945 in Behcet's disease with topline results expected in the first half of 2025, and topline results from the ongoing Phase 2 trial of SGX302 in mild-to-moderate psoriasis in the first half of 2025.

SUMMARY DATA

52-Week High	**$15.68**
52-Week Low	**$2.00**
One-Year Return (%)	**-48.04**
Beta	**1.85**
Average Daily Volume (sh)	**59,559**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**3**
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 2024 Estimate	**-0.6**
P/E using 2025 Estimate	**-1.2**

Risk Level	**High**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0.3 A	0.2 A	0.1 A	0.2 A	0.8 A
2024	0.1 A	0.0 A	0.0 A	0.2 E	0.5 E
2025					1.0 E
2026					1.0 E

Earnings per Share

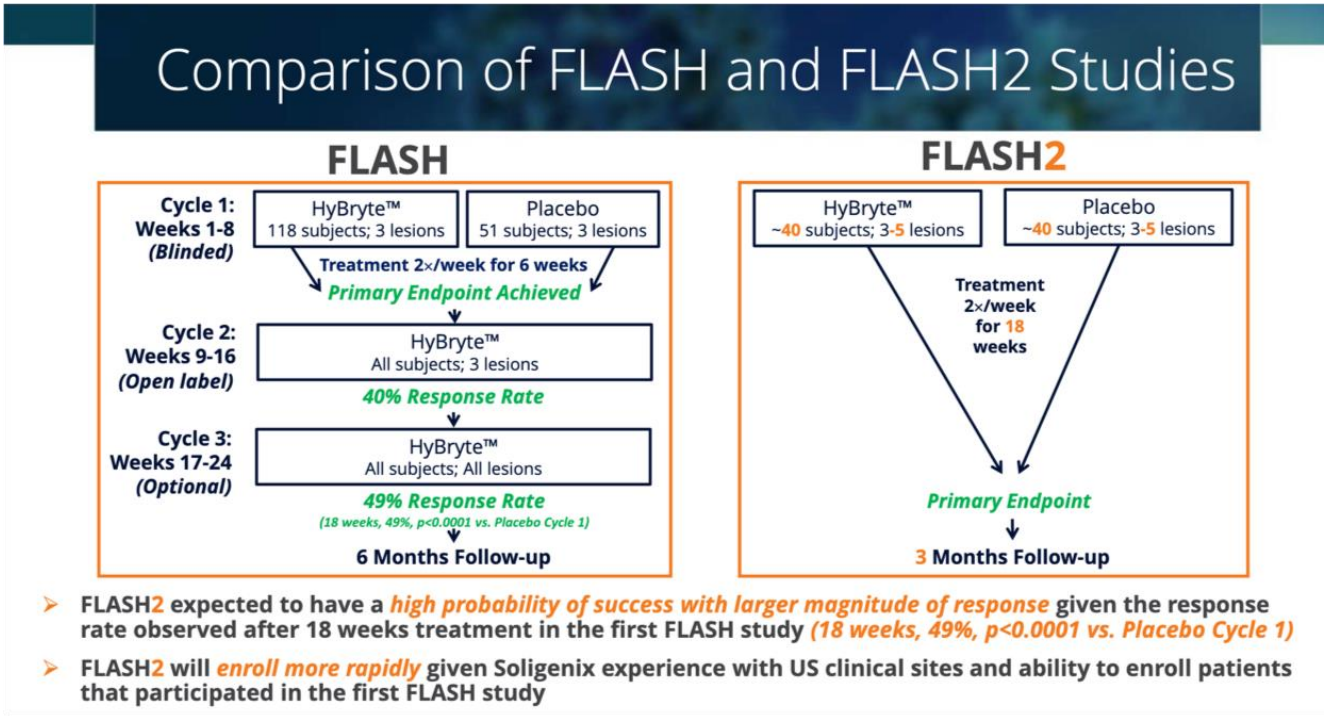
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$5.74 A	-$3.56 A	-$2.56 A	-$3.41 A	-$12.66 A
2024	-$2.91 A	-$1.31 A	-$0.78 A	-$0.95 E	-$4.65 E
2025					-$2.93 E
2026					-$1.86 E

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Business Update

Phase 3 CTCL Trial to Initiate Before End of 2024

Soligenix, Inc. (SNGX) is on track to initiate a confirmatory Phase 3 trial of HyBryte for the treatment of cutaneous T cell lymphoma (CTCL) before the end of 2024. The FLASH2 trial will be very similar in design to the Phase 3 FLASH trial, as shown in the following figure, which provides a comparison between the two studies. This similarity in design increases our confidence in a positive outcome for the FLASH2 trial. With the trial expected to begin enrollment prior to the end of 2024, we anticipate topline results in the second half of 2026. After reaching agreement with the European Medicines Agency (EMA) on the key design elements of the FLASH2 trial, the company is continuing discussions with the U.S. Food and Drug Administration (FDA) on an appropriate study design as the agency has expressed a preference for a longer duration comparative study over a placebo-controlled trial.



Source: Soligenix, Inc.

Results from Additional, Supportive Trials of HyBryte Presented at EORTC

On October 7, 2023, Soligenix announced that findings from recent additional, supportive trials with HyBryte in the treatment of CTCL were presented at the European Organization for Research and Treatment of Cancer (EORTC) Cutaneous Lymphoma Tumor Group Annual Meeting. The presentations included:

- An oral presentation by Dr. Brian Poligone on results from two expanded treatment studies: HPN-CTCL-02 that showed a lack of significant systemic exposure to hypericin after topical application and HPN-CTCL-04 that showed HyBryte treatment was more effective than Valchlor® along with a more favorable safety profile.

- A poster presentation by Dr. Ellen Kim that presented results from an investigator-initiated study examining longer treatment times with hypericin in CTCL. Thus far, eight patients have enrolled and six are actively receiving treatment (two patients withdrew for logistical reasons). One patient

completed 55 weeks, two completed at least 25 weeks, and three completed at least five weeks. Results show that 3/4 (75%) of patients who have received treatment for at least 18 weeks have achieved the primary endpoint of index lesion response rate, defined as ≥50% reduction in mCAILS score of index lesions from baseline to end of treatment. There have been no serious adverse events reported. Enrollment is continuing with the potential to include additional sites.

Partnership Agreement for Hypericin Production

On October 3, 2024, Soligenix announced a manufacturing partnership agreement with Sterling Pharma Solutions for a scalable production technology for synthetic hypericin, which is the active pharmaceutical ingredient in the topical drug product formulations for HyBryte and SGX302. The two companies are currently working to transfer and optimize the manufacturing processes to enable GMP manufacturing and establish a long-term collaboration. The ultimate goal is to reduce the overall cost of goods as the company pushes toward potential commercialization.

Financial Update

On November 9, 2024, Soligenix announced financial results for the third quarter of 2024. The company reported no revenues for the third quarter of 2024, compared to $0.1 million for the third quarter of 2023. The revenues are derived from government contracts and grants to support the development of SGX943 for treatment of emerging and/or antibiotic resistant infectious diseases, development of CiVax™, and evaluation of HyBryte for expanded treatment in patients with early-stage CTCL. R&D expenses for the third quarter of 2024 were $1.0 million, compared to $0.8 million for the third quarter of 2023. The increase was primarily due to the initiation of the Phase 2 trial in Behcet's disease and the second Phase 3 CTCL trial. G&A expenses for the third quarter of 2024 were $0.9 million, compared to $1.0 million for the third quarter of 2023. The decrease was primarily due to a decrease in legal and professional fees.

Soligenix exited the third quarter of 2024 with approximately $9.8 million in cash and cash equivalents. As of November 1, 2024, Soligenix had approximately 2.5 million shares outstanding, and when factoring in stock options, warrants, and the potential convertible debt the fully diluted share count is approximately 4.4 million.

Conclusion

We look forward to the initiation of the confirmatory Phase 3 trial in CTCL for HyBryte and the Phase 2 trial in Behcet's disease for SGX942 before the end of 2024. Looking ahead to next year, we anticipate data from the ongoing Phase 2 trial of SGX302 in mild-to-moderate psoriasis and the Phase 2 trial in Behcet's disease to be available in the first half of 2025. With no changes to our model our valuation remains at $35 per share.

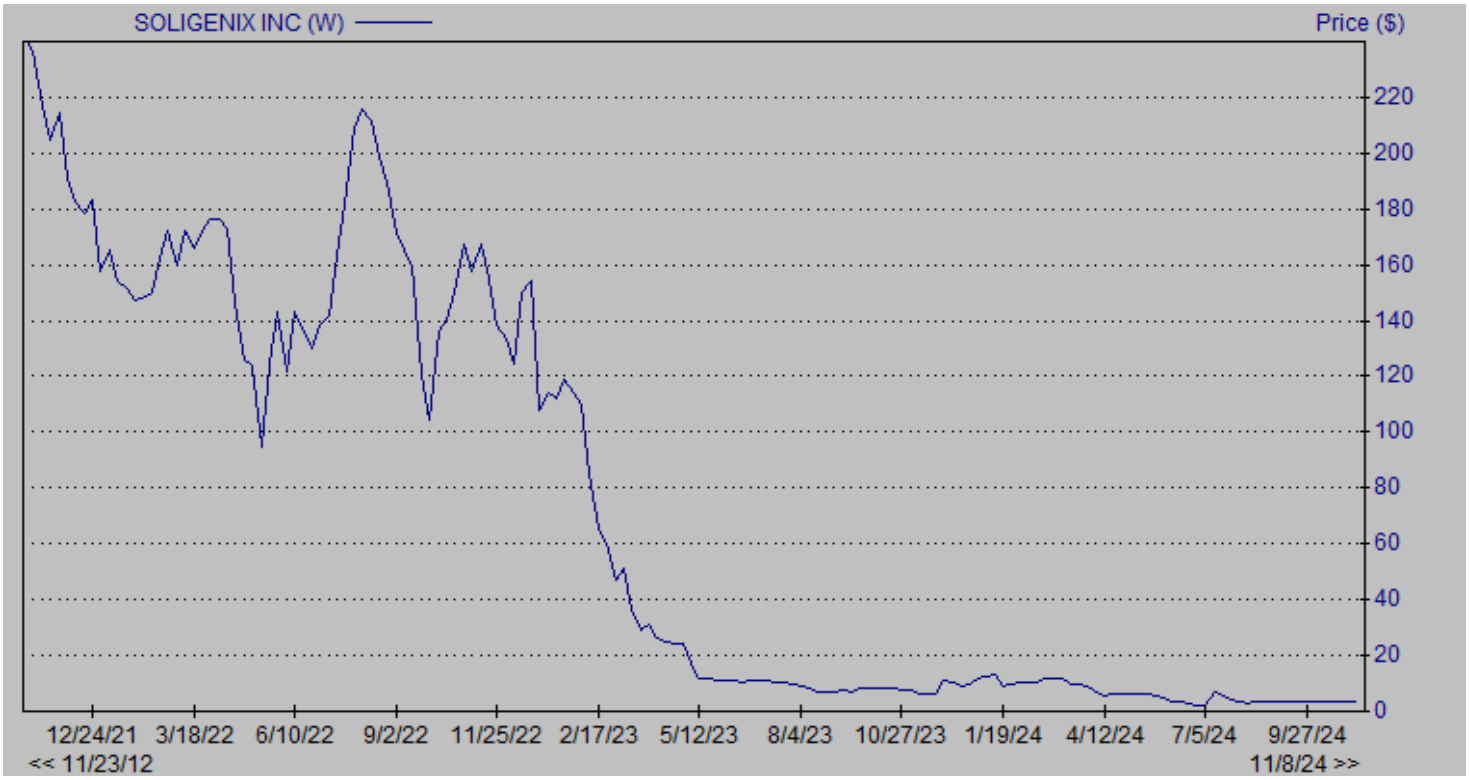
PROJECTED FINANCIALS

Soligenix, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$0.8	$0.1	$0.0	$0.0	$0.2	$0.3	$1.0	$1.0
HyBryte	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Public Health Solutions	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.8**	**$0.1**	**$0.0**	**$0.0**	**$0.2**	**$0.3**	**$1.0**	**$1.0**
Cost of Revenue	$0.7	$0.1	$0.0	$0.0	$0.2	$0.3	$0.8	$0.8
Gross Income	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.2**	**$0.2**
Gross Margin	*11.6%*	*0.0%*	*0.0%*	*#DIV/0!*	*10.0%*	*6.3%*	*20.0%*	*20.0%*
Research & Development	$3.3	$1.1	$0.5	$1.0	$1.0	$3.6	$4.0	$4.2
General & Administrative	$4.5	$1.0	$1.2	$0.9	$1.2	$4.4	$5.0	$5.3
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($7.7)	($2.1)	($1.7)	($1.9)	($2.2)	($7.9)	($8.8)	($9.3)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.2	$0.2	$0.1	$0.1	$0.0	$0.4	$0.0	$0.0
Pre-Tax Income	**($7.9)**	**($1.9)**	**($1.6)**	**($1.7)**	**($2.2)**	**($7.5)**	**($8.8)**	**($9.3)**
Net Taxes (benefit)	$1.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*22.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($6.1)**	**($1.9)**	**($1.6)**	**($1.7)**	**($2.2)**	**($7.5)**	**($8.8)**	**($9.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($12.66)**	**($2.91)**	**($1.31)**	**($0.78)**	**($0.95)**	**($4.65)**	**($2.93)**	**($1.86)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	0.5	0.7	1.3	2.2	2.3	1.6	3.0	5.0

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

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