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August 13, 2024
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Phase 3 Trial of HyBryte™ in CTCL to Initiate in 2H24…

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 (08/13/24)	$3.09
Valuation	**$35.00**

OUTLOOK

On August 9, 2024, Soligenix, Inc. (SNGX) announced financial results for the second quarter of 2024 and provided a business update. The company is on track to initiate the confirmatory Phase 3 trial of HyBryte™ (synthetic hypericin) in the treatment of patients with early stage cutaneous T cell lymphoma (CTCL) in the second half of 2024. In support of this, the company recently announced positive clinical results from a comparability study between HyBryte and Valchlor®, which showed a three-fold higher response rate over a 12-week treatment period and a more favorable safety profile for HyBryte. In addition, the company announced promising interim data from the ongoing, open label, investigator-initiated study evaluating extended HyBryte treatment. Lastly, we anticipate a Phase 2 study of SGX945 (dusquetide) in Behcet's disease initiating in the second half of 2024 with results from that study and the Phase 2 trial of SGX302 (synthetic hypericin) in mild-to-moderate psoriasis being available in the first half of 2025.

SUMMARY DATA

52-Week High	**$15.68**
52-Week Low	**$2.00**
One-Year Return (%)	**-64.06**
Beta	**1.87**
Average Daily Volume (sh)	**231,730**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$7**
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	**-0.4**

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	0.2 E	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	-$1.09 E	-$0.95 E	-$5.10 E
2025					-$2.93 E
2026					-$1.86 E

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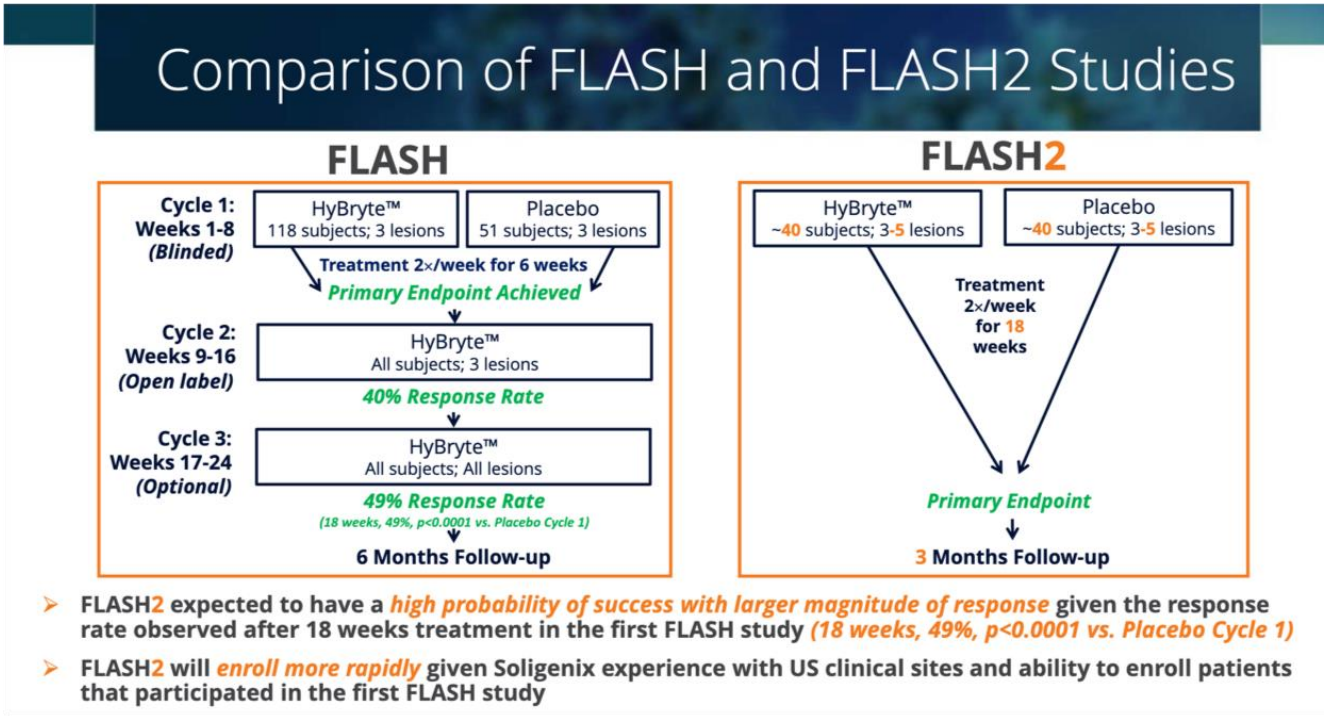
Business Update

Plans in Place for Confirmatory Phase 3 Trial of HyBryte in CTCL

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.

Multiple Recent Positive Readouts for HyBryte

Over the past couple of months, Soligenix has announced positive results from clinical studies examining HyBryte in the treatment of CTCL:

- In July 2024, the company announced positive interim results from an open-label, investigator-initiated study, which is being supported by a $2.6 million FDA Orphan Products Development Grant. This study is designed to enroll up to 50 patients at select U.S. clinical sites, with patients having the potential to be treated for up to 12 months with twice a week dosing. There is also an option for the patients to transition to a "real-world" setting with home use. The primary endpoint is evaluating the number of "treatment successes", which is defined as ≥50% reduction in the cumulative mCAILS (modified Composite Assessment of Index Lesion Severity).

Results thus far show that of the four evaluable patients enrolled and treated with HyBryte for at least 12 weeks of therapy, three of them already achieved "treatment success". The fourth evaluable patient had a substantial improvement documented at the Week 18 visit but has not achieved the success threshold. Importantly, HyBryte continues to be safe and well tolerated by patients and no treatment-related adverse events have been reported.

- In June 2024, Soligenix announced positive results from a comparability study evaluating HyBryte versus Valchlor® (mechlorethamine gel) in the treatment of CTCL. The results showed that 60% of patients treated with HyBryte achieved "treatment success" compared to 20% of Valchor-treated patients. In addition, HyBryte had a more favorable safety profile than Valchlor and all patients tolerated HyBryte well and had no adverse events.

Phase 2 Trial in Behcet's Disease to Initiate in 2H24

Soligenix is planning to initiate a Phase 2 clinical trial of SGX945 in Behcet's Disease (BD) in the second half of 2024. In January 2024, the FDA granted Fast Track designation to SGX945 for the treatment of oral lesions of 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-α) therapy, and anti-tumor necrosis factor alpha (TNF-α) therapy are all used as first-line agents and have shown good efficacy. Apremilast (Otezla®), a phosphodiesterase 4 inhibitor, was effective in a Phase 3 clinical trial in BD patients with oral ulcers (Hatemi *et al*., 2019). It was subsequently approved by the FDA for the treatment of oral ulcers in BD patients.

Dusquetide was previously tested as a treatment for oral mucositis in which it showed biological activity against aphthous ulcers induced by chemotherapy and radiation, thus serving as a proof-of-concept for the treatment of oral ulcers in BD.

Financial Update

On August 9, 2024, Soligenix announced financial results for the second quarter of 2024. The company reported revenues of less than $0.1 million for the second quarter of 2024, compared to $0.2 million for the second 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 second quarter of 2024 were $0.5 million, compared to $0.8 million for the second quarter of 2023. The decrease was primarily due to adjustment of estimated accruals for completed clinical trials offset by preliminary costs associated with the anticipated initiation of the Phase 2 trial in Behcet's disease and the second Phase 3 CTCL trial. G&A expenses for the second quarter of 2024 were $1.2 million, compared to $0.9 million for the second quarter of 2023. The increase was primarily due to an increase in legal and professional fees.

Soligenix exited the second quarter of 2024 with approximately $9.1 million in cash and cash equivalents. Subsequent to the end of the quarter, the company raised net proceeds of $4.1 million through the exercise of warrants. As of August 2, 2024, Soligenix had approximately 2.3 million shares outstanding, and when factoring in stock options, warrants, and the potential convertible debt the fully diluted share count is approximately 2.8 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 in the second half 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 E	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	$0.2	$0.2	$0.5	$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**	**$0.2**	**$0.2**	**$0.5**	**$1.0**	**$1.0**
Cost of Revenue	$0.7	$0.1	$0.0	$0.2	$0.2	$0.5	$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%*	*10.0%*	*10.0%*	*7.7%*	*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	$1.2	$1.2	$4.7	$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)	($2.2)	($2.2)	($8.2)	($8.8)	($9.3)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.2	$0.2	$0.1	$0.0	$0.0	$0.3	$0.0	$0.0
Pre-Tax Income	**($7.9)**	**($1.9)**	**($1.6)**	**($2.2)**	**($2.2)**	**($7.9)**	**($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)**	**($2.2)**	**($2.2)**	**($7.9)**	**($8.8)**	**($9.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($12.66)**	**($2.91)**	**($1.31)**	**($1.09)**	**($0.95)**	**($5.10)**	**($2.93)**	**($1.86)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	0.5	0.7	1.3	2.0	2.3	1.6	3.0	5.0

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

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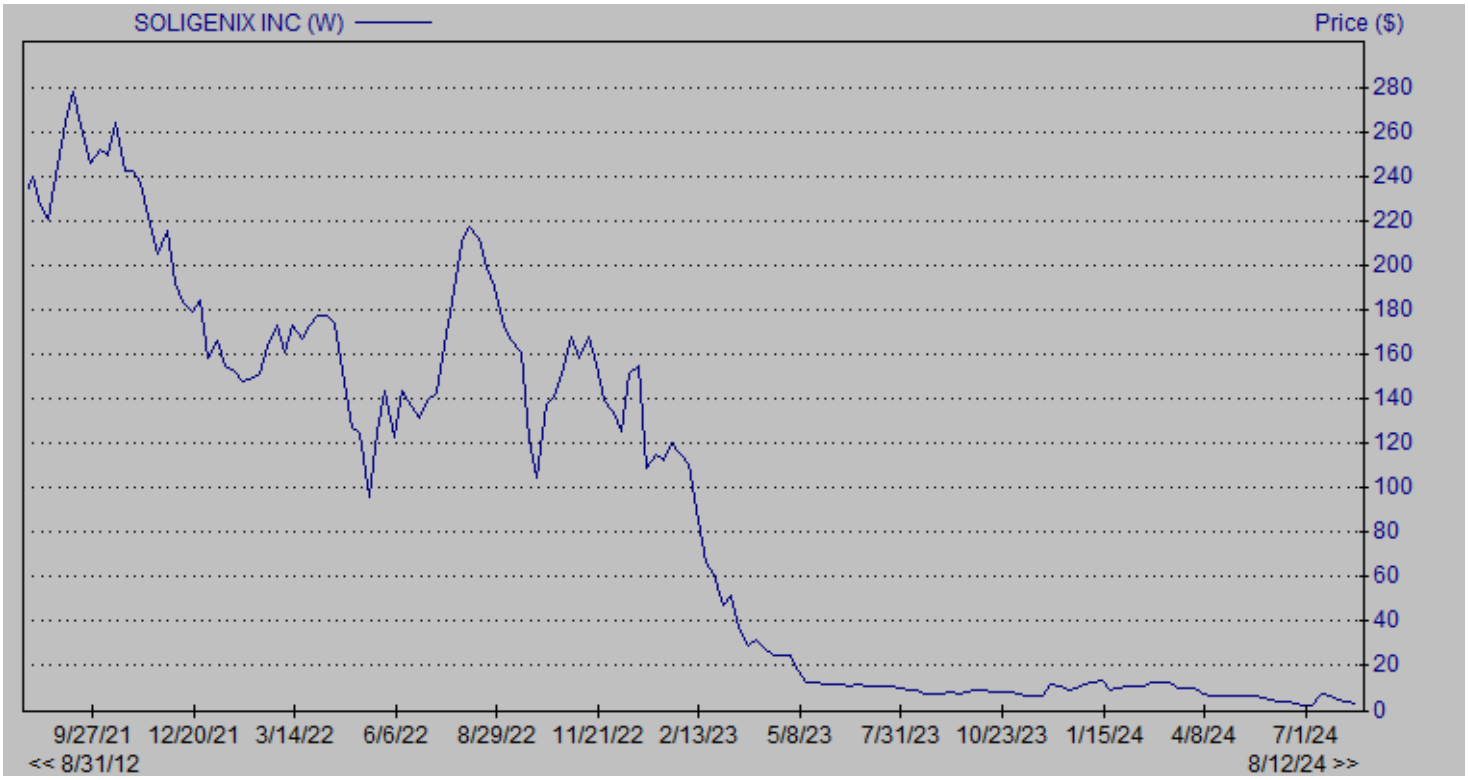

Source: Zacks Small Cap Research

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