Zacks Small-Cap Research
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Soligenix, Inc.

(SNGX-NASDAQ)

SNGX: Presentation Highlights HyBryte Potential in CTCL…

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 (02/24/25)	$2.43
Valuation	**$35.00**

OUTLOOK

In January 2025, Dr. Neal Bhatia presented at two dermatology conferences on the off-label use of photodynamic therapy. Dr. Bhatia is the Director of Clinical Dermatology at Therapeutics Clinical Research, is a member of Soligenix's scientific advisory board, and was a participating investigator in the Phase 3 FLASH trial of HyBryte in CTCL. Dr. Bhatia's presentation included a comparison of efficacy results seen thus far for HyBryte to those from a Phase 3 trial of Valchlor®, an FDA-approved second line therapy for the treatment of CTCL. Those results show that HyBryte appears to have a faster onset of activity than Valchlor and provides solid support for what we believe will be a positive outcome from the ongoing Phase 3 FLASH2 trial of HyBryte. We anticipate continued updates from the company regarding the FLASH2 trial throughout 2025.

SUMMARY DATA

52-Week High	**$13.11**
52-Week Low	**$2.00**
One-Year Return (%)	**-80.20**
Beta	**1.83**
Average Daily Volume (sh)	**28,991**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$6**
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 2025 Estimate	**-0.8**
P/E using 2026 Estimate	**-1.3**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
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

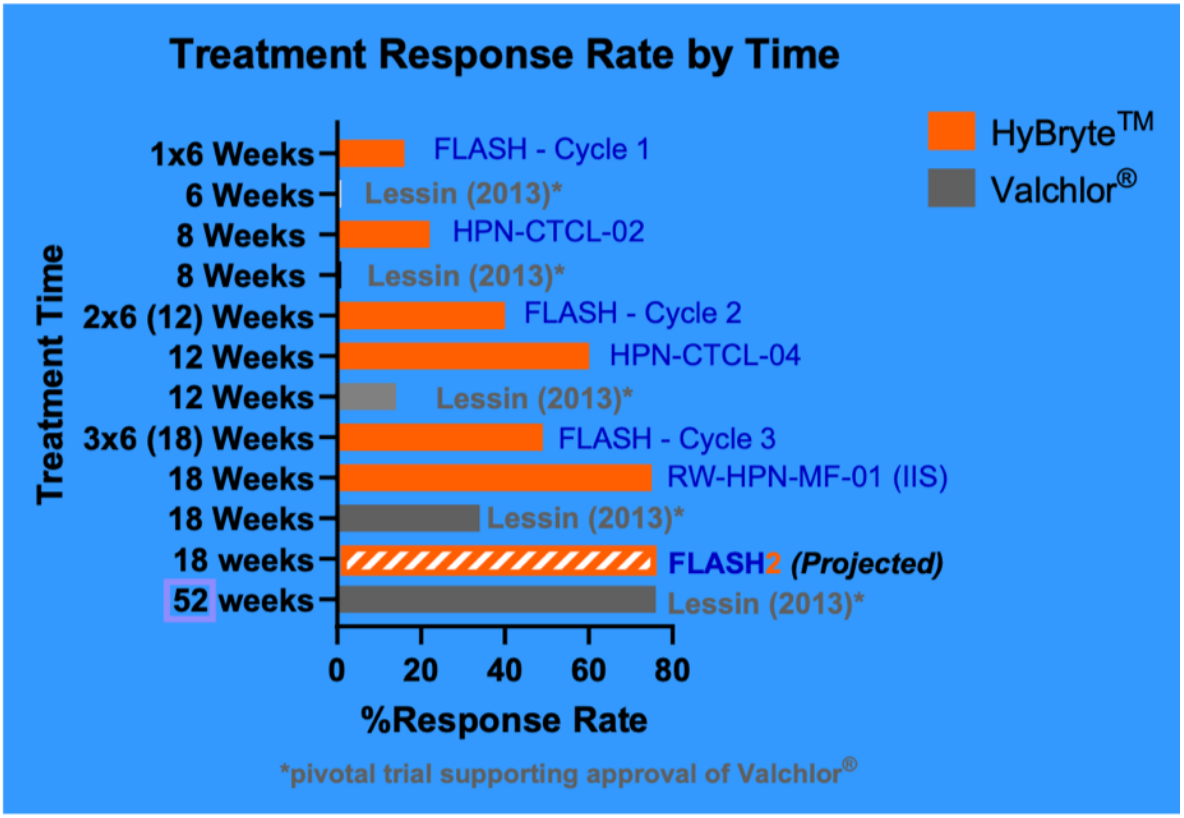
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Business Update

Presentation Highlights HyBryte Potential in CTCL

In January 2025, Dr. Neal Bhatia presented at two dermatology conferences on "Off-Label Uses of PDT" (photodynamic therapy). Dr. Bhatia is the Director of Clinical Dermatology at Therapeutics Clinical Research, a member of Soligenix's scientific advisory board, and was a participating investigator in the Phase 3 HyBryte trial. During his presentation, Dr. Bhatia discussed the efficacy results from multiple studies of HyBryte along with results from studies examining Valchlor® (topical mechlorethamine), also known as nitrogen mustard (NM), which is indicated for the treatment of Stage IA and IB mycosis fungoides-type cutaneous T cell lymphoma (CTCL). Valchlor was approved based in part on the results of a Phase 3 trial in which it was compared to a compounded 0.02% mechlorethamine ointment (Lessin *et al*., 2013). The study was successful and showed that Valchlor was superior to the ointment (P<0.01).

The following figure shows the response rate at different time points for the Lessin *et al*. study as well as response rates observed from various trials of HyBryte in CTCL. A patient is considered a responder if there is a ≥50% improvement in the cumulative mCAILS (modified Composite Assessment of Index Lesion Severity). As shown in the figure, HyBryte performed better than Valchlor at every comparable time point. This increase in efficacy for HyBryte was seen even though Valchlor is dosed once daily while HyBryte is dosed twice per week. The full efficacy for Valchlor was not seen until 52 weeks, while similar efficacy results for HyBryte were seen at 18 weeks in the investigator-initiated study (IIS) RW-HPN-MF-01. Dr. Bhatia also listed projected results from the ongoing FLASH2 trial of HyBryte in patients with CTCL based on results from the IIS study seen at 18 weeks.



Source: Bhatia, 2025

While it's not possible to draw definitive conclusions when comparing results from different clinical trials, we think there are a number of important points for investors to consider regarding HyBryte and Valchlor, including:

- HyBryte works faster than Valchlor. This is consistently shown by the increased response rates at comparable time points for studies involving HyBryte and the Lessin *et al*. study.
- HyBryte has a more convenient dosing schedule as it is applied twice per week compared to Valchlor's once-daily dosing
- HyBryte appears to have a more benign safety profile. For example, Lessin *et al*. showed that 20.3% of patients withdrew from that study in the Valchlor arm due to a treatment limited skin adverse event. In contrast, only 1.2% of patients treated with HyBryte withdrew from the FLASH Phase 3 study due to an adverse event (Kim *et al*., 2022).

Soligenix has initiated the Phase 3 FLASH2 trial of HyBryte in patients with CTCL. The FLASH2 trial will be very similar in design to the successful Phase 3 FLASH trial, as shown in the following figure, which provides a comparison between the two studies. One key difference between the trials is that in the FLASH trial patients were treated for three cycles of six-weeks each, with a two-week break in between cycles and the primary efficacy endpoint was measured after the first treatment cycle, while in the FLASH2 trial patients will be treated for 18 consecutive weeks before the primary efficacy endpoint is assessed. Based on the results shown above from Dr. Bhatia's presentation, we believe the trial has a high probability of success given the response rate at 18 weeks in the FLASH study and the IIS trial.

Conclusion

Dr. Bhatia's presentation provides additional support for our belief that the ongoing FLASH2 trial of HyBryte in CTCL will be successful. In addition, HyBryte has a number of advantages over other CTCL treatments, including Valchlor, as it appears to be a safer, more tolerable treatment that leads to faster treatment responses. We look forward to continued updates from the company regarding the FLASH2 trial, which we anticipate throughout 2025. With no changes to our model, our valuation remains at $35 per share.

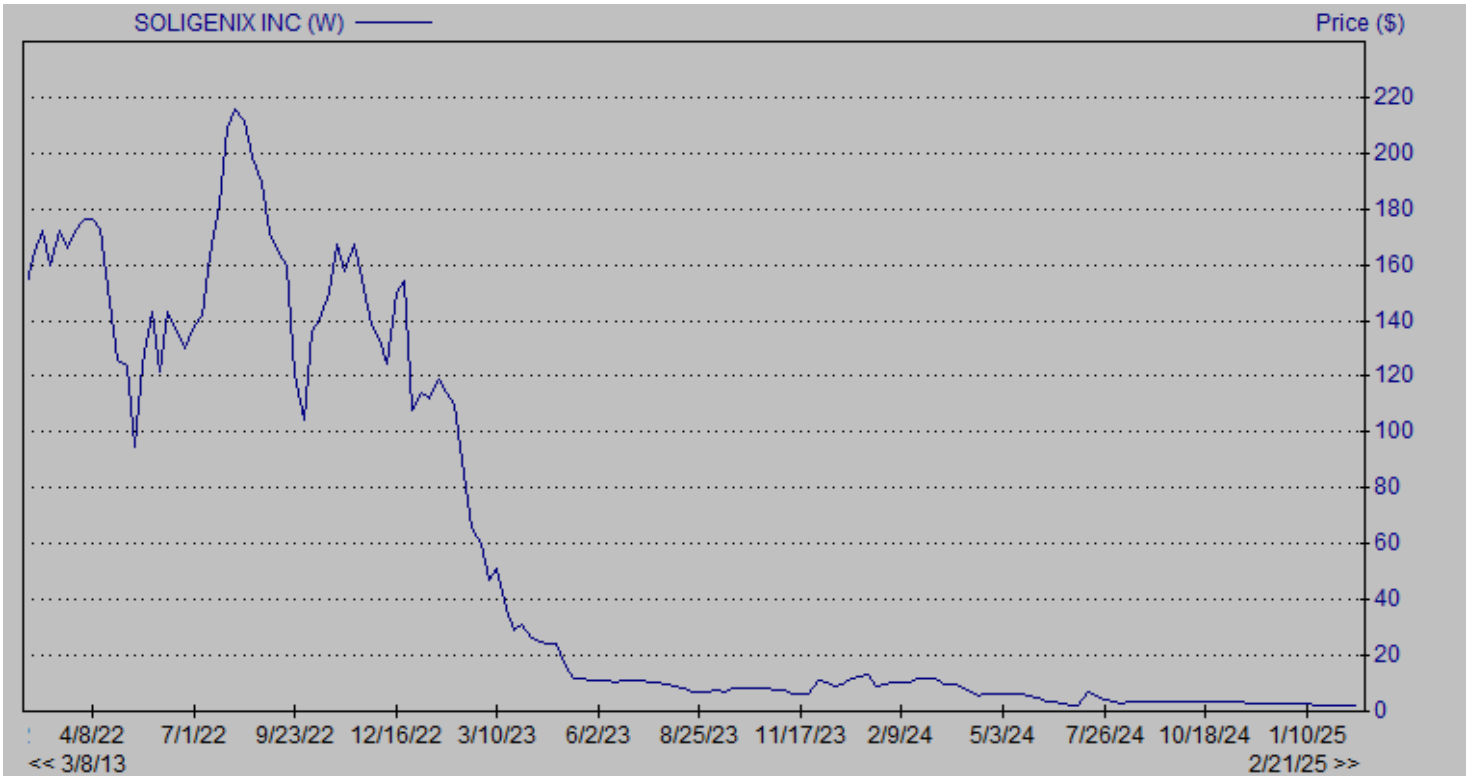
PROJECTED FINANCIALS

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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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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