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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Positive Interim Results for HyBryte™ in Investigator-Initiated Study in CTCL; Raising Valuation to $35…

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 (07/10/24)	$7.42
Valuation	**$35.00**

OUTLOOK

On July 9, 2024, Soligenix, Inc. (SNGX) announced positive interim results for HyBryte™ in an open-label, investigator-initiated study in patients with early-stage cutaneous T cell lymphoma (CTCL). Of the patients that have completed 12 weeks of therapy, 3 of 4 (75%) have achieved "Treatment Success", which is defined as ≥50% improvement in their cumulative mCAILS (modified Composite Assessment of Index Lesion Severity). Two patients have not reached their first efficacy evaluation visit (i.e., at Week 6) and the last patient had a substantial improvement documented by Week 18 but had not yet achieved the success threshold. In addition, the company announced positive results from a comparator trial of HyBryte and Valchlor®, in which HyBryte showed better tolerability and a more robust treatment response. Both of these results increase our confidence in a positive outcome to the upcoming Phase3 FLASH2 trial of HyBryte in CTCL and our valuation has increased to $35.

SUMMARY DATA

52-Week High	**$15.68**
52-Week Low	**$2.00**
One-Year Return (%)	**-32.69**
Beta	**1.88**
Average Daily Volume (sh)	**6,848,959**
Shares Outstanding (mil)	**1**
Market Capitalization ($mil)	**$7**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**1**
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	**-1.5**
P/E using 2025 Estimate	**-1.1**

Risk Level	**High**
Type of Stock	**Small-Growth**
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	0.2 E	0.2 E	0.2 E	0.7 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	-$2.11 E	-$2.21 E	-$2.18 E	-$9.20 E
2025					-$7.04 E
2026					-$6.20 E

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WHAT'S NEW

Business Update

Positive Interim Results for Investigator-Initiated Study of HyBryte™ in CTCL

On July 9, 2024, Soligenix, Inc. (SNGX) announced positive interim results from an open-label, investigator-initiated study evaluating HyBryte™ in patients with early-stage cutaneous T cell lymphoma (CTCL). The trial is being sponsored by Dr. Ellen Kim, who was also a leading enroller in the Phase 3 FLASH trial, and 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).

Thus far, six patients have been enrolled and treated with HyBryte. Of the four evaluable patients that have completed at least 12 weeks of therapy, three of them already achieved "treatment success". Of the three "treatment successes", two were achieved within the first 12 weeks of treatment and a third was within 18 weeks. The fourth evaluable patient had a substantial improvement documented at the Week 18 visit but has not achieved the success threshold. The other two patients have only recently initiated HyBryte therapy and have not yet reached their first efficacy evaluation (i.e., at Week 6). Importantly, HyBryte continues to be safe and well tolerated by patients and no treatment-related adverse events have been reported.

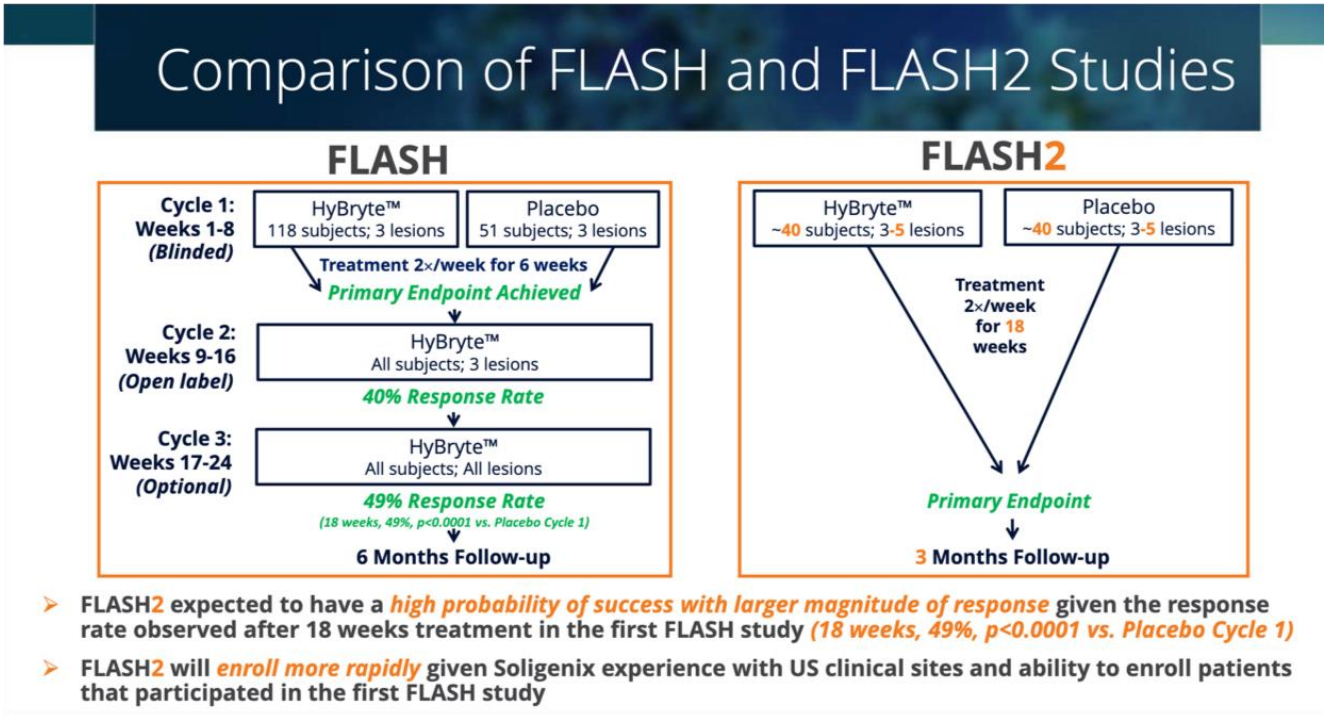
HyBryte Provides More Rapid and Robust Treatment Effect Compared to Valchlor®

In June 2024, Soligenix announced positive results from comparability study evaluating HyBryte versus Valchlor (mechlorethamine gel) in the treatment of CTCL. This was an open label study that enrolled 10 patients (5 per group) with treatment success defined as a ≥50% improvement in a patient's mCAILS score after 12 weeks of topical treatment compared to baseline. The results showed that 60% of patients treated with HyBryte achieved "treatment success" compared to 20% of Valchor-treated patients. Of the two HyBryte-treated patients who did not achieve "treatment success", both had a substantial (>30%) reduction in their mCAILS score. Conversely, of the four Valchlor-treated patients that did not achieve treatment success, one worsened (and dropped out of the study), one improved <30% and two improved ≥30%. The average cumulative improvement in mCAILS at 12 weeks was 52.5% in the HyBryte group compared to 34.7% in the Valchlor group.

HyBryte had a more favorable safety profile than Valchlor and all patients tolerated HyBryte well and had no adverse events. In contrast, 60% of Valchlor-treated patients had at least one adverse event "related" to therapy, which included rashes, application site sensitivity, allergic contact dermatitis, and dermatitis. In the Valchlor group, one patient required steroid treatment, one required temporary interruption of treatment, and one required permanent discontinuation. There were no such instances reported in the HyBryte group.

Confirmatory Phase 3 Trial of HyBryte Set to Initiate Before End of 2024

Soligenix is on track to initiate a confirmatory Phase 3 trial of HyBryte for the treatment of 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.

Conclusion

The interim results for the investigator-initiated study along with the comparative trial further increase our confidence in the likelihood of success for the upcoming FLASH2 trial, which similar to those studies is following a more “real world” treatment approach. The results of the investigator-initiated study were well received by the market, with the company’s stock rising ~300% on the news. However, even after the significant move in the stock price we continue to believe there is additional upside and our valuation has incrased to $35 per share.

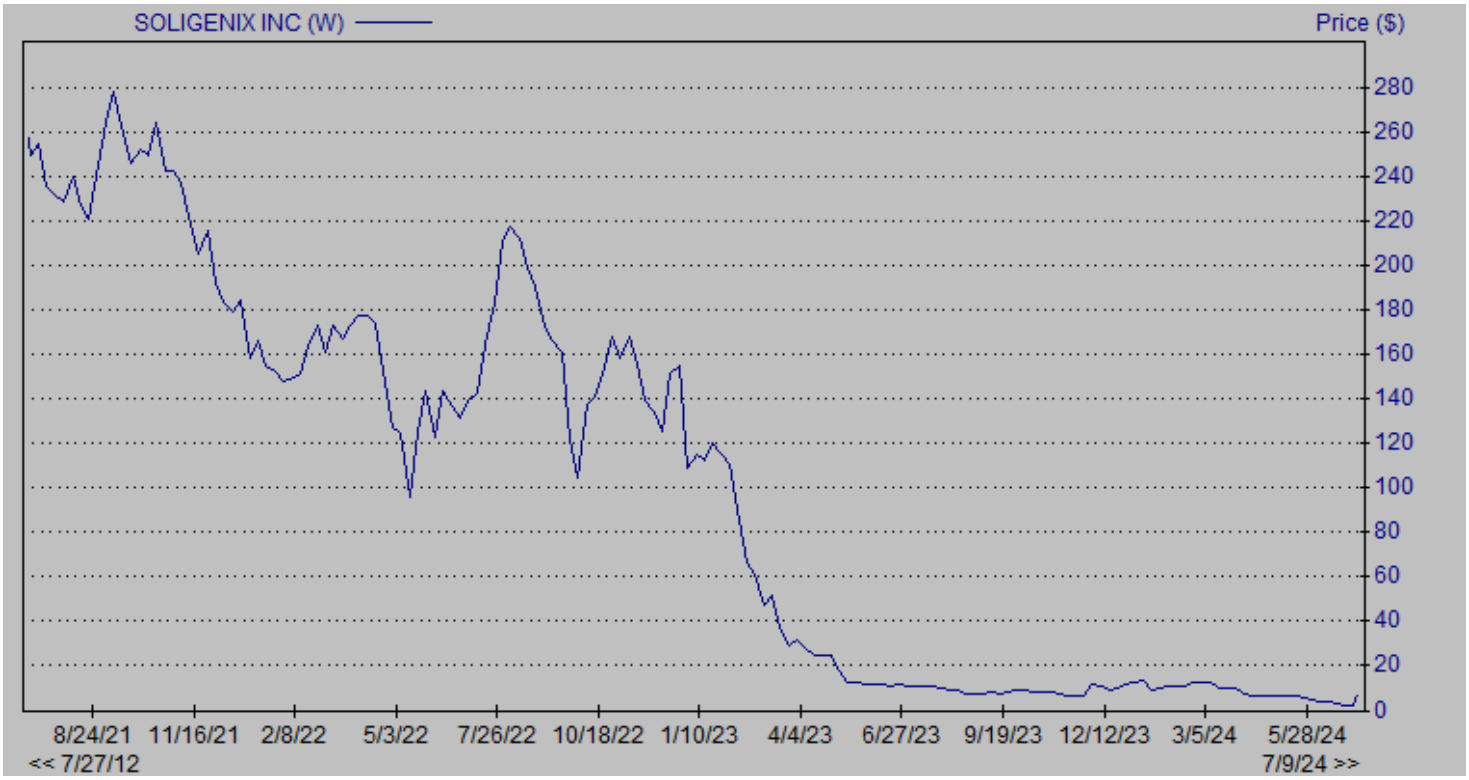
PROJECTED FINANCIALS

Soligenix, Inc.	2023 A	Q1 A	Q2 E	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	$0.2	$0.2	$0.2	$0.7	$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**	**$0.2**	**$0.2**	**$0.2**	**$0.7**	**$1.0**	**$1.0**
Cost of Revenue	$0.7	$0.1	$0.2	$0.2	$0.2	$0.7	$0.8	$0.8
Gross Income	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.1**	**$0.2**	**$0.2**
Gross Margin	*11.6%*	*0.0%*	*10.0%*	*10.0%*	*10.0%*	*8.4%*	*20.0%*	*20.0%*
Research & Development	$3.3	$1.1	$0.9	$1.0	$1.0	$4.0	$4.0	$4.2
General & Administrative	$4.5	$1.0	$1.2	$1.2	$1.2	$4.6	$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)	($2.1)	($2.2)	($2.2)	($8.6)	($8.8)	($9.3)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.2	$0.2	$0.0	$0.0	$0.0	$0.2	$0.0	$0.0
Pre-Tax Income	**($7.9)**	**($1.9)**	**($2.1)**	**($2.2)**	**($2.2)**	**($8.4)**	**($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)**	**($2.1)**	**($2.2)**	**($2.2)**	**($8.4)**	**($8.8)**	**($9.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($12.66)**	**($2.91)**	**($2.11)**	**($2.21)**	**($2.18)**	**($9.20)**	**($7.04)**	**($6.20)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	0.5	0.7	1.0	1.0	1.0	0.9	1.3	1.5

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

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