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Soligenix, Inc.

(SNGX-NASDAQ)

SNGX: DMC Reports No Safety Signals for Ongoing Phase 3 Trial in CTCL; Blinded Interim Efficacy Analysis in 1H26

Based on our probability adjusted DCF model that takes into account potential future revenues from HyBryte™, SGX302, and SGX945, SNGX is valued at $25.00 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 (11/10/25)	$1.37
Valuation	**$25.00**

OUTLOOK

On November 7, 2025, Soligenix, Inc. (SNGX) announced financial results for the third quarter of 2025 and provided a business update. Recently, the Data Monitoring Committee (DMC) for the ongoing confirmatory Phase 3 clinical trial of HyBryte™ in the treatment of cutaneous T cell lymphoma (CTCL) concluded that there were no safety concerns and that HyBryte has an acceptable safety profile consistent with the safety data from all previous clinical studies. We anticipate an update on enrollment from the company in the fourth quarter of 2025 and a pre-specified blinded interim efficacy analysis in the first half of 2026. In addition, we anticipate topline results from the Phase 2a clinical trial of SGX302 in mild-to-moderate psoriasis before the end of 2025.

SUMMARY DATA

52-Week High	**$4.96**
52-Week Low	**$1.11**
One-Year Return (%)	**-60.86**
Beta	**2.00**
Average Daily Volume (sh)	**348,355**
Shares Outstanding (mil)	**4**
Market Capitalization ($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	**-0.4**
P/E using 2026 Estimate	**-0.8**

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)
2024	0.1 A	0.0 A	0.0 A	0.0 A	0.1 A
2025	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2026					1.0 E
2027					1.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-$2.91 A	-$1.31 A	-$0.78 A	-$1.18 A	-$4.98 A
2025	-$1.06 A	-$0.82 A	-$0.58 A	-$0.27 E	-$2.15 E
2026					-$0.78 E
2027					-$0.66 E

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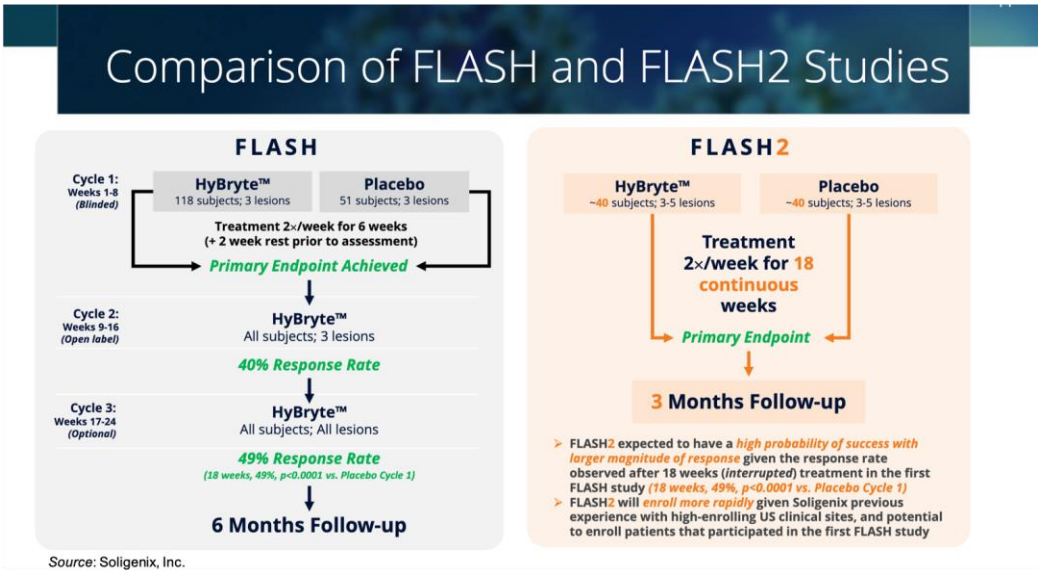
WHAT'S NEW

Business Update

DMC Confirms No Safety Concerns for Ongoing Phase 3 FLASH2 Trial

On October 7, 2025, Soligenix, Inc. (SNGX) announced that the Data Monitoring Committee (DMC) concluded there were no safety concerns with the ongoing Phase 3 FLASH2 Trial of HyBryte™ (SGX301 or synthetic hypericin) in the treatment of cutaneous T cell lymphoma (CTCL). We anticipate the company providing an enrollment update in the fourth quarter of 2025 as well as the DMC conducting a pre-specified blinded interim efficacy analysis in the first half of 2026. The possible outcomes of that analysis are to stop the trial early for efficacy, continue the trial with additional patients, continue the trial as planned, or to stop the trial for futility.

The Phase 3 FLASH2 Trial is evaluating HyBryte in 80 patients with early-stage cutaneous T cell lymphoma (CTCL). The FLASH2 trial is 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 from the FLASH trial, we believe the FLASH2 trial has a high probability of success.



Source: Soligenix, Inc.

Results from Phase 2a Psoriasis Trial Expected Before End of 2025

Soligenix is currently evaluating SGX302 (synthetic hypericin) as a treatment for mild to moderate psoriasis. The Phase 2a trial is a randomized, double blind, placebo controlled study this is enrolling patients with mild-to-moderate, stable psoriasis covering 2% to 30% of their body. Placebo or SGX302 is being administered twice weekly for up to 18 weeks, with each treatment consisting of application followed approximately 24 hours later with visible light activation. The efficacy endpoints include lesion clearance along with patient quality of life indices. We anticipate topline results from the study before the end of 2025.

Following evaluation of the first five subjects enrolled in the trial, a clear biological signal was seen as evidenced by an improvement in PASI (psoriasis area and severity index) score. In Cohort 2, five additional patients were treated with a more rapid escalation and higher final dose level of light to more closely match how the drug will be utilized in the "real world" clinical setting. The results from Cohort 2 showed that there were no drug-related adverse events reported. Four of the patients were evaluable (one patient withdrew early in the study for personal reasons unrelated to the study), with two of them achieving an Investigator Global Assessment (IGA) score of 1 ("Almost

Clear"), a standard clinical measure for treatment success in psoriasis. In addition, the patients in Cohort 2 had a mean drop of approximately 50% in the PASI score.

The company is continuing to test different light levels and light intensity/duration to optimize the conditions for psoriasis patients and we anticipate results from the next cohort of patients before the end of 2025. Once the optimized conditions are established, the ultimate goal is to transition to "at home" use prior to initiating a Phase 3 trial. The ability for patients to treat themselves at home would be a clear differentiator from other psoriasis treatments on the market.

Updates United States Medical Advisory Board for CTCL

On October 14, 2025, Soligenix announced the update for its U.S. Medical Advisory Board (MAB) for CTCL to provide medical/clinical strategic guidance as it advances the Phase 3 development of HyBryte for the treatment of CTCL. The members of the MAB include:

Jennifer DeSimone, MD: Dr. DeSimone is an Associate Professor of Dermatology at the University of Virginia INOVA Fairfax Campus. She is the Director of Cutaneous Lymphoma at the Inova Schar Cancer Institute where she treats >1,000 lymphoma patients. Dr. DeSimone is a member of the International Society for Cutaneous Lymphomas, a medical advisor for the Cutaneous Lymphoma Foundation, and a member of the U.S. Cutaneous Lymphoma Consortium.

Youn Kim, MD: Dr. Kim is the Joanne and Peter Haas Jr. Professor for Cutaneous Lymphoma Research at Stanford University School of Medicine and at Stanford Cancer Institute. She is the Director of the Multidisciplinary Cutaneous Lymphoma Clinic and Research Program at Stanford. Dr. Kim is a member of the Non-Hodgkin's Lymphoma Panel of the National Comprehensive Cancer Network. She serves on the Board of Directors and has served as the President of the International Society for Cutaneous Lymphomas. Her extensive publication record includes over 350 publications to her name.

Aaron Mangold, MD: Dr. Mangold is a dermatologist with expertise in cutaneous lymphoma and complex medical dermatology. He directs the Multi-disciplinary Cutaneous Lymphoma Clinic and is the Chair of Dermatology Research. In addition, Dr. Mangold is the Vice Chair of Research Operations Management Team and Medical Director of the Clinical Trial Office at Mayo Clinic Arizona. He serves on the board of the U.S. Cutaneous Lymphoma Consortium and was on the board of the Arizona Medical Association and President of the Arizona Dermatology Surgery Society.

Brian Poligone, MD, PhD – Chair: Dr. Poligone is the founder and Medical Director of the Rochester Skin Lymphoma Medical Group and the Director of Cancer Biology Research for the Rochester General Hospital Research Institute. He has over 50 publications in his specialty and has been invited to speak at more than 100 meetings on both his scientific studies and clinical knowledge in the field of lymphoma and skin cancer. He has enrolled over 40 patients while participating in 4 clinical trials evaluating HyBryte.

Financial Update

On November 7, 2025, Soligenix announced financial results for the third quarter of 2025. The company reported no revenue for the third quarters of 2025 and 2024. R&D expenses for the third quarter of 2025 were $1.6 million, compared to $1.0 million for the third quarter of 2024. The increase was primarily due to costs associated with the confirmatory Phase 3 CTCL trial along with third-party manufacturing costs. G&A expenses for the third quarter of 2025 were $1.0 million, compared to $0.9 million for the third quarter of 2024. The increase was primarily due to increases in professional expenses.

Soligenix exited the third quarter of 2025 with approximately $10.5 million in cash and cash equivalents. We estimate this is sufficient to fund operations through 2026. As of October 31, 2025, Soligenix had approximately 10.1 million shares outstanding, and when factoring in stock options and warrants, a fully diluted share count of approximately 17.0 million.

Conclusion

We look forward to the enrollment update for the FLASH2 Phase 3 trial of HyBryte in CTCL along with the topline results for the Phase 2a trial of SGX302 before the end of 2025. In addition, we anticipate the results from a blinded interim efficacy analysis for the FLASH2 trial in the first half of 2026. With no changes to our model our valuation remains at $25 per share.

PROJECTED FINANCIALS

Soligenix, Inc.	2024 A	Q1 A	Q2 A	Q3 A	Q4 E	2025 E	2026 E	2027 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$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	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$1.0**	**$1.0**
Cost of Revenue	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.8	$0.8
Gross Income	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.2**	**$0.2**
Gross Margin	*0.0%*	*#DIV/0!*	*100.0%*	*#DIV/0!*	*#DIV/0!*	*100.0%*	*20.0%*	*20.0%*
Research & Development	$5.2	$2.2	$1.7	$1.6	$1.5	$7.0	$5.3	$5.5
General & Administrative	$4.2	$1.1	$1.1	$1.0	$1.2	$4.4	$5.0	$5.2
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($9.4)	($3.3)	($2.8)	($2.6)	($2.7)	($11.4)	($10.1)	($10.5)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.8	$0.1	$0.1	$0.0	$0.0	$0.2	$0.0	$0.0
Pre-Tax Income	**($8.7)**	**($3.2)**	**($2.7)**	**($2.5)**	**($2.7)**	**($11.2)**	**($10.1)**	**($10.5)**
Net Taxes (benefit)	$0.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*4.7%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($8.3)**	**($3.2)**	**($2.7)**	**($2.5)**	**($2.7)**	**($11.2)**	**($10.1)**	**($10.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($4.98)**	**($1.06)**	**($0.82)**	**($0.58)**	**($0.27)**	**($2.15)**	**($0.78)**	**($0.66)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	1.7	3.0	3.3	4.3	10.1	5.2	13.0	16.0

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

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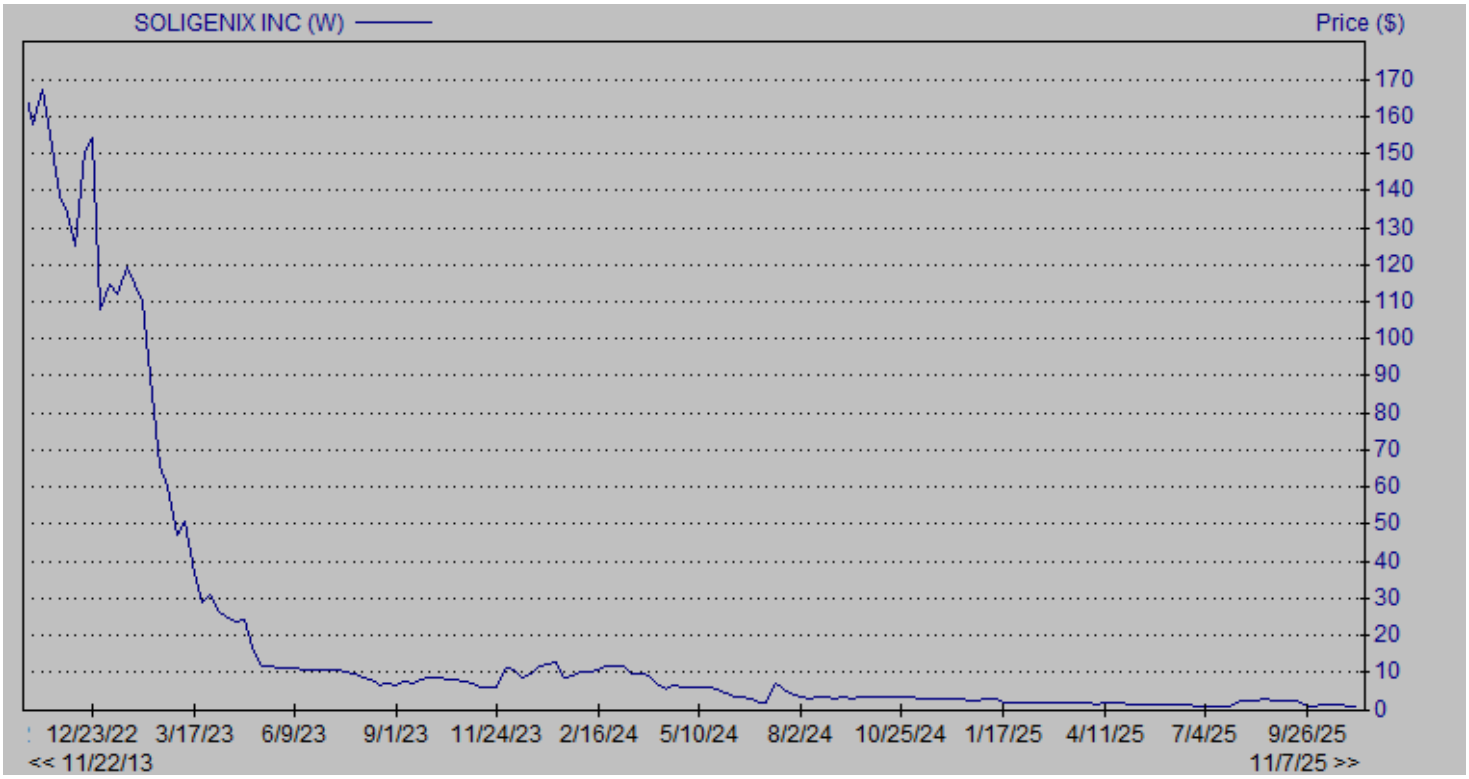

Source: Zacks Small Cap Research

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