Zacks Small-Cap Research
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Soligenix, Inc.

(SNGX-NASDAQ)

SNGX: HyBryte™ Expanded Treatment Trial Underway…

Based on our probability adjusted DCF model that takes into account potential future revenues from HyBryte™, SNGX is valued at $3.50 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 (08/24/23)	$0.46
Valuation	**$3.50**

OUTLOOK

On August 21, 2023, Soligenix, Inc. announced financial results for the second quarter of 2023 and provided a business update. The company recently announced the initiation of the HyBryte expanded treatment trial. This investigator-initiated study is designed to evaluate the expanded treatment (including up to 12 months of treatment) with HyBryte of early-stage cutaneous T cell lymphoma (CTCL) patients. Approximately 50 patients are expected to enroll with the potential to be treated for up to 12 months. The study will also allow for potential transition to the home-use setting. The primary endpoint of the study is defined as ≥50% reduction in the cumulative CAILS (Composite Assessment of Index Lesion Severity) from baseline to the end of treatment. The study is being supported by a $2.6 million Orphan Products Development grant from the FDA.

SUMMARY DATA

52-Week High	**$12.44**
52-Week Low	**$0.44**
One-Year Return (%)	**-96.30**
Beta	**1.67**
Average Daily Volume (sh)	**241,720**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
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 2018 Estimate	**-0.2**
P/E using 2019 Estimate	**-0.3**

Risk Level	**High**
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)
2022	0.2 A	0.2 A	0.2 A	0.4 A	0.9 A
2023	0.3 A	0.2 A	0.2 E	0.2 E	0.9 E
2024					1.0 E
2025					1.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$1.52 A	-$0.83 A	-$1.15 A	-$1.28 A	-$4.81 A
2023	-$0.36 A	-$0.22 A	-$0.44 E	-$0.47 E	-$1.56 E
2024					-$1.74 E
2025					-$2.01 E

WHAT'S NEW

Business Update

HyBryte™ Expanded Treatment Trial Underway

On August 10, 2023, Soligenix, Inc. (SNGX) announced the start of the investigator-initiated study that is designed to examine the expanded treatment, including up to 12 months of treatment, with HyBryte in patients with early-stage cutaneous T cell lymphoma (CTCL). It is an open label, multicenter trial that will enroll approximately 50 patients. Each patient has the potential to be treated for up to 12 months with twice a week dosing (visible light activation to follow ointment application by 24 ± 6 hours. The study also allows for the potential transition to the home-use setting. The primary endpoint of the trial is the number of treatment successes (defined as ≥50% reduction in the cumulative CAILS (Composite Assessment of Index Lesion-Severity). The study is being funded through a $2.6 million Orphan Products Development grant awarded by the U.S. FDA.

Expanding SGX302 Phase 2a Study in Mild-to-Moderate Psoriasis

In July 2023, Soligenix, announced that the company will be expanding the ongoing Phase 2a clinical trial of SGX302 (synthetic hypericin) in patients with mild-to-moderate psoriasis. A clear biological signal was seen following evaluation of the first five subjects enrolled in the trial as evidenced by an improvement in the PASI (psoriasis area and severity index) score. At least an additional five patients will now be enrolled into the trial, which will allow Soligenix to evaluate SGX302 in the context of accelerated light treatment and additional adjunct treatment. We anticipate results from the Phase 2a trial before the end of 2023.

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.

Update on FDA Interactions for HyBryte

In April 2023, Soligenix conducted a Type A meeting with the FDA regarding the design of a second Phase 3 clinical trial for HyBryte in the treatment of cutaneous T cell lymphoma (CTCL). The FDA will require a second, confirmatory study with a longer comparative treatment duration than was conducted in the FLASH study to support an NDA filing for HyBryte in CTCL. We spoke with Soligenix management and learned that while they do not have a final FDA agreement as yet, they remain in active discussions with the FDA and will be communicating the outcome of these interactions as soon as possible once they have definitive clarity. Dr. Schaber noted that, while he had hoped the process would have moved a bit quicker, it's important to maintain positive and productive dialogue when working to gain potential agreement on a feasible and highly executable clinical trial design. The company anticipates having that clarity before the end of the year and will update investors as soon as possible.

Financial Update

On August 21, 2023, Soligenix announced financial results for the second quarter of 2023. The company reported revenues of $0.21 million for the second quarter of 2023, compared to $0.23 million for the second quarter of 2022. The decrease was primarily due to the conclusion of the grant associated with the development of SGX943 during the most recent quarter. R&D expenses for the second quarter of 2023 were $0.8 million, compared to $2.0 million for the second quarter of 2022. The decrease was primarily due to a decrease in manufacturing costs associated with the HyBryte NDA filing. G&A expenses for the second quarter of 2023 were $0.9 million, compared to $1.4 million for the second quarter of 2022. The decrease was primarily due to a decrease in legal and consulting services associated with the arbitration against Emergent BioSolutions, Inc.

Soligenix exited the second quarter of 2023 with approximately $13.2 million in cash and cash equivalents due in part to a public offering during the second quarter of 2023 that raised gross proceeds of $8.5 million through the sale of 6.5385 million shares at $1.30 per share along with 6.5385 million warrants with an exercise price of $1.50 per share and a five year expiration date. As of August 14, 2023, Soligenix had approximately 9.8 million shares outstanding, and when factoring in stock options, warrants, and the potential convertible debt the fully diluted share count is approximately 18.7 million.

Conclusion

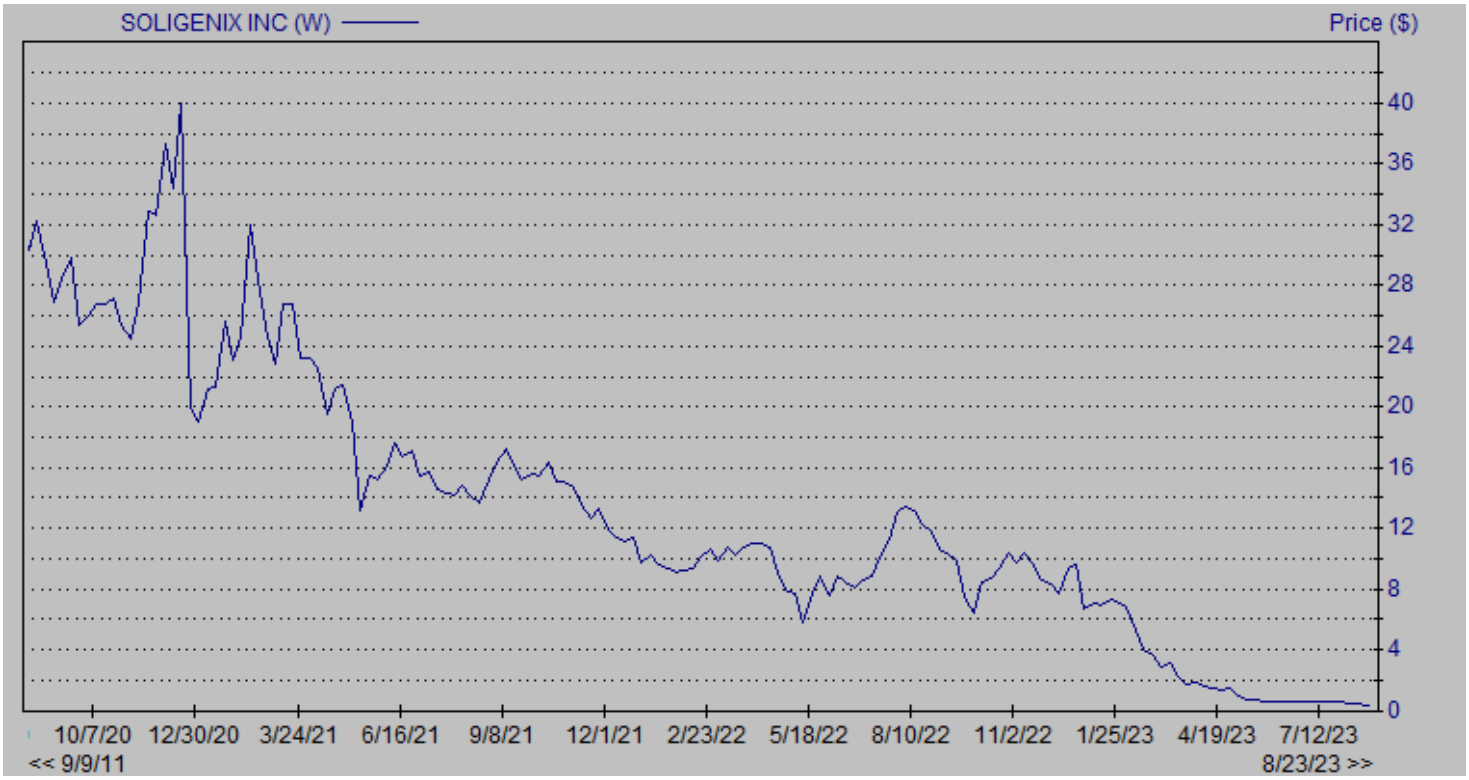
We're glad to see the expanded treatment trial for HyBryte is underway and we look forward to updates from that trial in the future. The company is continuing to work with the FDA regarding the registrational pathway for HyBryte in CTCL, and we are hopeful that an update will be provided before the end of the year. With no changes to our model our valuation remains at $3.50 per share.

PROJECTED FINANCIALS

Soligenix, Inc.	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
License Revenue	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$0.7	$0.3	$0.2	$0.2	$0.2	$0.9	$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	**$0.9**	**$0.3**	**$0.2**	**$0.2**	**$0.2**	**$0.9**	**$1.0**	**$1.0**
Cost of Revenue	$0.6	$0.2	$0.2	$0.1	$0.1	$0.7	$0.6	$0.6
Gross Income	**$0.4**	**$0.0**	**$0.0**	**$0.1**	**$0.1**	**$0.2**	**$0.4**	**$0.4**
Gross Margin	*42.0%*	*12.1%*	*11.1%*	*40.0%*	*40.0%*	*24.8%*	*40.0%*	*40.0%*
Research & Development	$7.9	$0.9	$0.8	$2.2	$2.5	$6.4	$9.0	$10.0
General & Administrative	$6.7	$1.2	$0.9	$2.0	$2.1	$6.2	$10.0	$16.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($14.2)	($2.2)	($1.6)	($4.1)	($4.5)	($12.4)	($18.6)	($25.6)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.7	$0.1	$0.0	$0.2	$0.1	$0.4	$0.5	$0.5
Pre-Tax Income	**($15.0)**	**($2.2)**	**($1.6)**	**($4.3)**	**($4.6)**	**($12.8)**	**($19.1)**	**($26.1)**
Net Taxes (benefit)	$1.2	($1.2)	$0.0	$0.0	$0.0	$1.2	$0.0	$0.0
Tax Rate	*7.7%*	*52.6%*	*0.0%*	*0.0%*	*0.0%*	*9.1%*	*0.0%*	*0.0%*
Reported Net Income	**($13.8)**	**($1.0)**	**($1.6)**	**($4.3)**	**($4.6)**	**($11.6)**	**($19.1)**	**($26.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($4.81)**	**($0.36)**	**($0.22)**	**($0.44)**	**($0.47)**	**($1.56)**	**($1.74)**	**($2.01)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.9	2.9	7.2	9.8	9.9	7.5	11.0	13.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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