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Soligenix, Inc.

(SNGX-NASDAQ)

SNGX: Positive Results for Compatibility Study of HyBryte in CTCL…

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 (05/30/23)	$0.73
Valuation	**$3.50**

OUTLOOK

On May 15, 2023, Soligenix, Inc. financial results for the first quarter of 2023 and provided a business update. The company recently announced positive results from a compatibility study of HyBryte in the treatment of cutaneous T cell lymphoma (CTCL) using the commercially ready Daavlin Series 7 visible light device, which recently received 510(k) clearance from the FDA. The results of the study showed that a device capable of producing an appropriate and consistent wavelength of light (500 to 600 nm) is suitable for use with HyBryte, and the treatment response rate of 22% following eight weeks of twice weekly treatment recapitulated the results of the FLASH trial. The FDA recently granted a Type A meeting request to discuss the design of a second Phase 3 study evaluating HyBryte in the treatment of CTCL. We anticipate the company releasing details about that study when they have more clarity on next steps.

SUMMARY DATA

52-Week High	**$14.06**
52-Week Low	**$0.71**
One-Year Return (%)	**-91.93**
Beta	**1.74**
Average Daily Volume (sh)	**2,672,254**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$2**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**4**
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	**-0.2**

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)
2022	0.2 A	0.2 A	0.2 A	0.4 A	0.9 A
2023	0.3 A	0.2 E	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	-$0.49 E	-$0.54 E	-$0.57 E	-$2.05 E
2024					-$1.74 E
2025					-$2.01 E

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WHAT'S NEW

Business Update

Positive Results from Compatibility Study of HyBryte™ in CTCL

On May 4, 2023, Soligenix, Inc. (SNGX) announced positive results from a compatibility study of HyBryte in the treatment of cutaneous T cell lymphoma (CTCL) using the commercially ready Daavlin Series 7 visible light device. The purpose of the study was to establish that any light device capable of producing visible light (500 to 650 nm) was suitable for use with HyBryte and to extend the pharmacokinetic profile using a recently developed, more sensitive hypericin assay. Both of those objectives were met in the study. In addition, the treatment response rate of 22% following eight weeks of twice-weekly treatment recapitulated the results of the Phase 3 FLASH study. Additional results include:

- All study participants had improvements in their cumulative CAILS score (average = 36.4%, range = 8 to 100)
- 7 of 27 (25.9%) index lesions had at least a 50% improvement in CAILS score and 4 of 27 (14.8%) index lesions were completely resolved following eights weeks of treatment
- There were extremely low and limited levels of systemic hypericin (plateau concentration of ~ 0.00013 μg/mL) and no observable impact to normal sinus rhythm

These results support the positive data for HyBryte seen in the Phase 3 FLASH trial and show that any light source capable of producing visible light in an appropriate and consistent wavelength can be utilized to activate the drug product.

FDA Grants Type A Meeting to Discuss Design of Second Phase 3 CTCL Study

On May 11, 2023, Soligenix announced that the U.S. FDA has granted a Type A meeting to discuss the design of a second Phase 3 trial evaluate HyBryte in the treatment of CTCL. This will be a following up meeting to the Type A meeting conducted earlier this year to discuss the refusal to file (RTF) letter previously issued in regards to the company's new drug application (NDA) for HyBryte for the treatment of early stage CTCL. At that meeting, the FDA stated it is going to require positive results from a second clinical trial in addition to the positive results from the Phase 3 FLASH study in order to accept an NDA filing. We anticipate the company announcing details of the second Phase 3 trial when the company has greater clarity on next steps.

Exclusive Option Agreement for Behçet's Disease Treatment

On May 1, 2023, Soligenix announced it has entered into an exclusive option agreement with Silk Road Therapeutics, which grants the company the right to acquire a novel topical formulation of pentoxifylline (PTX), a non-biological anti-TNF-alpha inhibitor, for the treatment of mucocutaneous ulcers in patients suffering from Behçet's Disease (BD). Subsequently, the company announced the appointment of Dr. Timothy Coté to its Board of Directors. Dr. Cote worked at the NIH, CDC and FDA for 23 years, including as the Director of the FDA Office of Orphan Products Development, in which he implemented the U.S. Orphan Drug Act and personally signed decisions on more than 1,400 orphan drug designation applications. Following his tenure at the FDA, Dr. Coté served as CEO of Cote Orphan, a consultancy firm that was sold to IQVIA in 2017. He is currently the CEO of Silk Road Therapeutics, from which Soligenix signed the exclusive option to purchase the novel topical formulation of pentoxyfilline (PTX).

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.

Pentoxifylline (PTX) is a methylated xanthine that nonselectively inhibits phosphodiesterase, which in turn leads to TNF inhibition (Marques *et al*., 1999). An open label, randomized, parallel group study was performed that compared PTX gel in addition to cochicine (PTX-COL) with cochicine alone (COL) (Hatemi *et al*., 2019). Patients with BD who were treated with COL and not using other systemic medications and having at least one oral ulcer that appeared during the last 48 hours were included. PTX 5% gel (1000 mg/day) was applied in four divided doses per day for 14 days. A total of 39 patients were included in the trial, 18 in the PTX-COL group and 21 in the COL group. Results showed that 83% of patients receiving PTX had index ulcer area shrinkage by Day 2 compared to 19% of patients receiving COL ($P<0.0001$). On Day 4, the percentage of patients who had an undetectable index mouth ulcer was 72% in the PTX-COL group compared to 29% in the COL group ($P<0.0001$). Pain scores were also found to decrease in the PTX-COL group. Lastly, no serious adverse events were reported.

Soligenix has 120 days to exercise its option to purchase PTX. The compound is Phase 3 ready with only minor CMC work needed, including standardization of the formulation and production of cGMP material for use in the Phase 3 clinical trial.

Financial Update

On May 15, 2023, Soligenix announced financial results for the first quarter of 2023. The company reported revenues of $0.3 million for the first quarter of 2023, compared to $0.2 million for the first quarter of 2022. The revenues are derived from government contracts and grants to support the development of RiVax® along with grants to support the development of SGX943, ThermoVax®, and CiVax®. R&D expenses for the first quarter of 2023 were $1.0 million, compared to $1.7 million for the first quarter of 2022. The decrease was primarily due to decreased expenses associated with the oral mucositis Phase 3 clinical trial along with a decrease in manufacturing costs associated with the HyBryte NDA filing. G&A expenses for the first quarter of 2023 were $1.2 million, compared to $2.5 million for the first quarter of 2022. The decrease was primarily due to an decrease in legal and consulting services associated with the arbitration against Emergent BioSolutions, Inc.

Soligenix exited the first quarter of 2023 with approximately $10.3 million in cash and cash equivalents. Subsequent to the end of the quarter, the company raised gross proceeds of $8.5 million through the sale of 6.5385 million shares of common stock (or common stock equivalents in lieu thereof) 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 May 9, 2023, Soligenix had approximately 8.1 million shares outstanding, and when factoring in stock options, warrants, and the potential convertible debt the fully diluted share count is approximately 19.1 million.

Conclusion

The new clinical data for HyBryte is encouraging as it recapitulates what was seen in the Phase 3 FLASH trial while also showing that any light generating device will be capable of being used with synthetic hypericin. We look forward to details regarding the second Phase 3 clinical trial for HyBryte in CTCL following the receipt of the Type A meeting minutes. The company's expansion into BD looks promising and we will be interested to hear more about the development pathway for PTX as the year progresses. We have added PTX to our model, and having adjusting for the recent financing our valuation now stands at $3.50 per share.

PROJECTED FINANCIALS

Soligenix, Inc.	2022 A	Q1 A	Q2 E	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	$0.1	$0.1	$0.1	$0.6	$0.6	$0.6
Gross Income	**$0.4**	**$0.0**	**$0.1**	**$0.1**	**$0.1**	**$0.3**	**$0.4**	**$0.4**
Gross Margin	*42.0%*	*12.1%*	*45.0%*	*40.0%*	*40.0%*	*32.8%*	*40.0%*	*40.0%*
Research & Development	$7.9	$0.9	$2.0	$2.2	$2.5	$7.7	$9.0	$10.0
General & Administrative	$6.7	$1.2	$1.8	$2.0	$2.1	$7.1	$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)**	**($3.8)**	**($4.1)**	**($4.5)**	**($14.5)**	**($18.6)**	**($25.6)**
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.7	$0.1	$0.1	$0.2	$0.1	$0.5	$0.5	$0.5
Pre-Tax Income	**($15.0)**	**($2.2)**	**($3.9)**	**($4.3)**	**($4.6)**	**($15.1)**	**($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%*	*7.7%*	*0.0%*	*0.0%*
Reported Net Income	**($13.8)**	**($1.0)**	**($3.9)**	**($4.3)**	**($4.6)**	**($13.9)**	**($19.1)**	**($26.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($4.81)**	**($0.36)**	**($0.49)**	**($0.54)**	**($0.57)**	**($2.05)**	**($1.74)**	**($2.01)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.9	2.9	8.0	8.1	8.1	6.8	11.0	13.0

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

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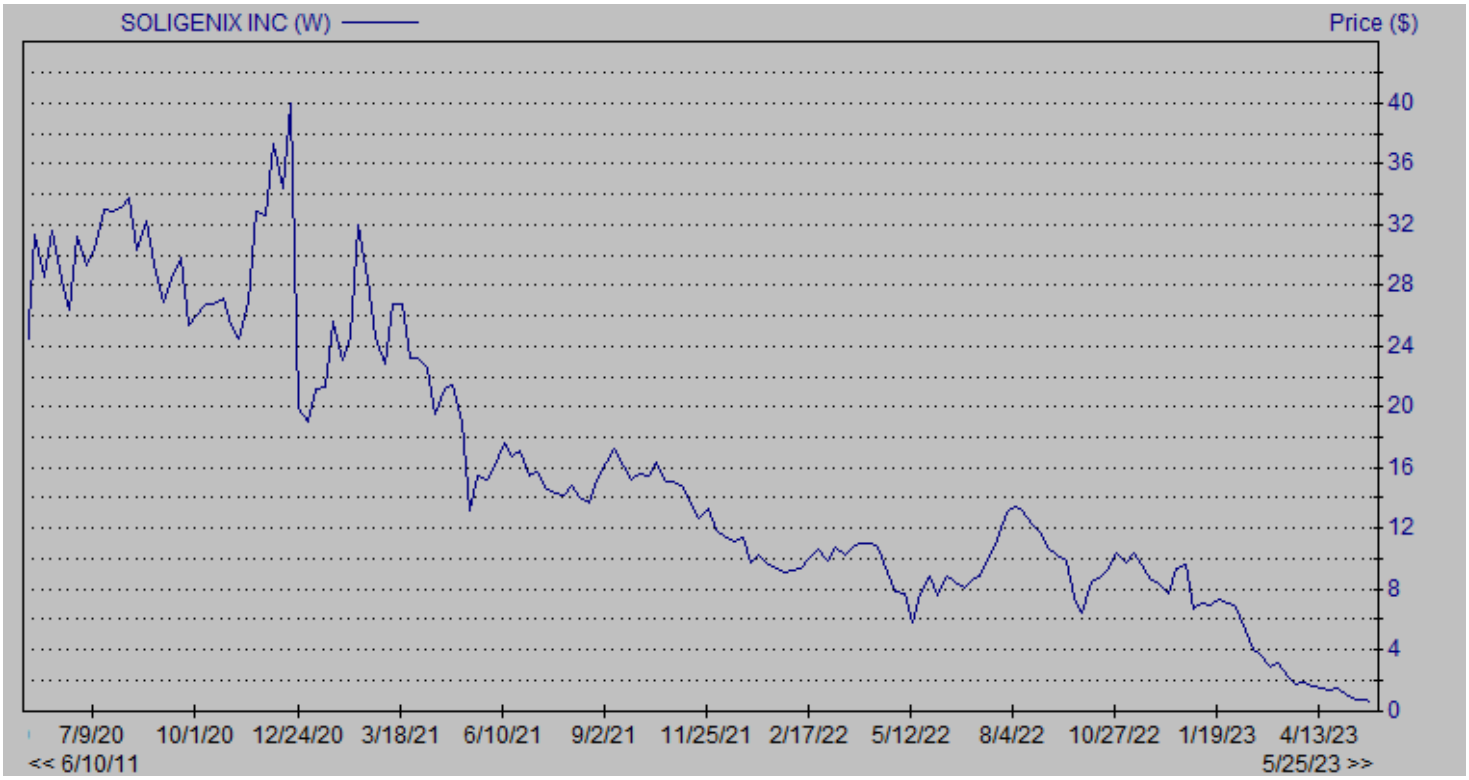

Source: Zacks Small Cap Research

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