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December 16, 2022
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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: HyBryte™ NDA Submitted…

Based on our probability adjusted DCF model that takes into account potential future revenues from HyBryte™ and CiVax™, SNGX is valued at $4.50 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 (12/16/22)	$0.61
Valuation	**$4.50**

OUTLOOK

On December 15, 2022, Soligenix, Inc. (SNGX) announced the filing of a new drug application (NDA) for HyBryte™ with the U.S. FDA for the treatment of cutaneous T cell lymphoma (CTCL). With an expected approval in the second half of 2023, we anticipate the commercial launch of HyBryte in the first quarter of 2024.

We continue to anticipate the initiation of a Phase 2a clinical trial of SGX302 (synthetic hypericin) in psoriasis in December 2022. In support of this, Soligenix recently announced the formation of a psoriasis medical advisory board, which will play an important advisory role in the upcoming trial as well as any future clinical studies.

SUMMARY DATA

52-Week High	**$0.94**
52-Week Low	**$0.40**
One-Year Return (%)	**-14.66**
Beta	**1.69**
Average Daily Volume (sh)	**69,067**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$26**
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 (%)	**-39.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-2.0**
P/E using 2019 Estimate	**-1.3**

Risk Level	**Above Avg.**
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)
2021	0.1 A	0.2 A	0.2 A	0.3 A	0.8 A
2022	0.2 A	0.2 A	0.2 A	0.2 E	0.8 E
2023					6.0 E
2024					17.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.06 A	-$0.05 A	-$0.09 A	-$0.09 A	-$0.32 A
2022	-$0.10 A	-$0.06 A	-$0.08 A	-$0.08 E	-$0.34 E
2023					-$0.48 E
2023					-$0.39 E

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WHAT'S NEW

Business Update

HyBryte™ NDA Submitted

On December 15, 2022, Soligenix, Inc. (SNGX) announced the filing of a New Drug Application (NDA) with the U.S. FDA for HyBryte™ (SGX301, synthetic hypericin) for the treatment of cutaneous T cell lymphoma (CTCL). The company had previously completed a Phase 3 clinical trial of HyBryte™ in patients with CTCL. The FLASH (Fluorescent Light Activated Synthetic Hypericin) trial was a randomized, double blind, placebo controlled study that enrolled 169 patients with either Stage IA, IB, or IIA mycosis fungoides (the most common type of CTCL) (NCT02448381). The results of the trial were recently published in the *Journal of the American Medical Association (JAMA) Dermatology* (Kim *et al*., 2022).

The trial consisted of three treatment cycles, with each cycle lasting eight weeks. Each study subject had three target lesions treated during the trial. In Cycle 1, patients were randomized 2:1 (n=116 for SGX301; n=50 for placebo) to receive twice weekly treatment of either 0.25% SGX301 or placebo (an ointment with the same light exposure as for SGX301) for six weeks, with treatment response determined at the end of the eighth week. In Cycle 2, all subjects received 0.25% SGX301 on their target lesions, and for those that decided to continue in the trial there was a third treatment cycle where 0.25% SGX301 was applied to all of the patient's lesions.

The results for Cycle 1 showed a statistically significant treatment response in the Composite Assessment of Index Lesion Score (CAILS) primary endpoint assessed at 8 weeks with 16% of patients receiving SGX301 responding compared to only 4% receiving placebo responding (P=0.04).

In Cycle 2, a total of 155 patients received 0.25% SGX301 on their target lesions (110 receiving 12 weeks of SGX301 and 45 receiving six weeks of placebo treatment followed by six weeks of SGX301 treatment). The results of Cycle 2 showed that continued treatment out to 12 weeks resulted in increased efficacy as shown by a 40% responder rate (P<0.0001 compared to both placebo and six-week treatment data). Response rates further improved in Cycle 3 with 49% of patients electing to receive SGX301 for 18 weeks demonstrating a 50% or greater reduction in the combined CAILS. (P<0.0001 compared to the end of Cycle 1).

Importantly, after 12 weeks of treatment with HyBryte, there is a similar response on both patch (37% response; P=0.0009) and plaque (42% response; P<0.001) lesions when compared to Cycle 1 placebo lesion responses.

HyBryte is a safe and well tolerated CTCL treatment that shows positive effects in a relatively short period of time and has increasing efficacy with continued use. Since CTCL is a long-lasting condition, safety and tolerability are at the forefront of prescribing physicians concerns when treating patients, and many other CTCL therapies have a number of potential serious side effects, particularly with extended use. We believe the data that Soligenix has compiled for SGX301 in treating CTCL positions it as a promising front-line therapy for a large percentage of patients.

The company is planning to commercialize HyBryte in the U.S. in lieu of seeking a commercialization partnership. Since the CTCL market is a specialized market, Soligenix can cost effectively market the drug with a launch cost of less than $10 million. This way, the company is able to keep 100% of the drug's value. For overseas markets, we anticipate a commercial partnership and the company is currently in discussions with potential partners. Approval will be sought first in the U.S. followed by other key markets worldwide.

In September 2022, Soligenix announced a $2.6 million Orphan Products Development grant by the U.S. FDA was awarded to an academic institution that was a leading enroller in the FLASH study. The purpose of the grant is to evaluate HyBryte™ for the expanded treatment of patients with early-stage CTCL, including its potential for at-home use. The clinical study will be an open label, multicenter trial that will enroll approximately 50 patients that participated in the Phase 3 FLASH study. Patients have the potential to be treated for up to 12

months with twice a week dosing. The primary endpoint for the study will be evaluating the number of treatment successes, which are defined as ≥50% reduction in the cumulative CAILS score from baseline to the end of treatment. The trial is likely to initiate in the first half of 2023.

Phase 2 Trial in Psoriasis to Initiate in December 2022

In June 2022, Soligenix, Inc. (SNGX) announced that the U.S. Food and Drug Administration (FDA) had cleared the Investigational New Drug (IND) application for a Phase 2a clinical trial in psoriasis. The trial, titled "Phase 2 Study Evaluating SGX302 in the Treatment of Mild-to-Moderate Psoriasis", will be a randomized, double blind, placebo controlled study that will enroll up to 32 patients age 18 years or older with mild to moderate, stable psoriasis covering 2% to 30% of their body. Placebo or SGX302 (randomized 1:1) will be administered twice weekly for up to 18 weeks, with each treatment consisting of application of therapy followed approximately 24 hours later with visible light activation. The efficacy endpoints for the trial will include lesion clearance along with patient quality of life indices. We anticipate the trial initiating in December 2022.

Conclusion

The filing of the NDA for HyBryte™ is a very important milestone for the company and moves Soligenix one step closer to becoming a commercial stage organization. We look forward to updates from the company in regards to a PDUFA date as well as updates regarding the preparation for commercializing the drug. In addition, we anticipate the initiation of the Phase 2a clinical trial of SGX302 in psoriasis in December 2022. We have advanced the DCF model ahead one year and slightly increased the probability of approval for HyBryte™, and our valuation now stands at $4.50.

PROJECTED FINANCIALS

Soligenix, Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$0.8	$0.2	$0.2	$0.2	$0.2	$0.8	$1.0	$1.0
SGX301	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$5.0	$16.0
Public Health Solutions	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.8**	**$0.2**	**$0.2**	**$0.2**	**$0.2**	**$0.8**	**$6.0**	**$17.0**
Cost of Revenue	$0.7	$0.1	$0.2	$0.1	$0.2	$0.6	$4.0	$10.0
Gross Income	**$0.1**	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.2**	**$2.0**	**$7.0**
Gross Margin	*11.6%*	*51.0%*	*15.5%*	*22.1%*	*10.0%*	*24.0%*	*33.3%*	*41.2%*
Research & Development	$8.4	$1.7	$2.0	$1.8	$2.5	$8.1	$9.0	$10.0
General & Administrative	$4.8	$2.6	$1.4	$1.3	$1.1	$6.4	$14.0	$16.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($13.1)	($4.2)	($3.4)	($3.1)	($3.6)	($14.3)	($21.0)	($19.0)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.3	$0.1	$0.1	$0.2	$0.1	$0.6	$0.5	$0.5
Pre-Tax Income	**($13.4)**	**($4.3)**	**($3.5)**	**($3.3)**	**($3.7)**	**($14.9)**	**($21.5)**	**($19.5)**
Net Taxes (benefit)	$0.9	$0.0	($1.2)	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*6.4%*	*0.0%*	*32.6%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($12.6)**	**($4.3)**	**($2.4)**	**($3.3)**	**($3.7)**	**($14.9)**	**($21.5)**	**($19.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.32)**	**($0.10)**	**($0.06)**	**($0.08)**	**($0.08)**	**($0.34)**	**($0.48)**	**($0.39)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	39.6	42.9	43.0	43.1	44.0	43.3	45.0	50.0

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

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