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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Soligenix, Inc.

(SNGX-NASDAQ)

SNGX: Phase 2a Trial of SGX302 in Psoriasis to Initiate in Second Half of 2022…

Based on our probability adjusted DCF model that takes into account potential future revenues from HyBryte™ and CiVax™, SNGX is valued at $4.00 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 (05/19/22)	$0.44
Valuation	**$4.00**

OUTLOOK

On May 13, 2022, Soligenix, Inc. (SNGX) announced financial results for the first quarter of 2022 and provided a business update. We continue to anticipate the company submitting a new drug application (NDA) to the U.S. FDA for HyBryte™ (SGX301) for the treatment of cutaneous T cell lymphoma (CTCL) in the second half of 2022. In addition, the company is expected to initiate a Phase 2a clinical trial in mild-to-moderate psoriasis with SGX302 (synthetic hypericin). Soligenix will also be evaluating the best way to advance SGX942, which may include a partnership to perform a second Phase 3 study in oral mucositis along with its potential use in oncology based on positive pre-clinical xenograft studies.

SUMMARY DATA

52-Week High	**$1.31**
52-Week Low	**$0.40**
One-Year Return (%)	**-53.93**
Beta	**1.28**
Average Daily Volume (sh)	**158,807**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$19**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-35.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-1.3**
P/E using 2019 Estimate	**-1.3**

Risk Level	**Above Avg.**
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)
2021	0.1 A	0.2 A	0.2 A	0.3 A	0.8 A
2022	0.2 A	0.2 E	0.2 E	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	-$0.07 E	-$0.08 E	-$0.08 E	-$0.33 E
2023					-$0.48 E
2023					-$0.39 E

WHAT'S NEW

Business Update

SGX302 for Psoriasis

Soligenix, Inc. (SNGX) will be developing synthetic hypericin (the active ingredient in HyBryte) as part of a photodynamic therapy in mild-to-moderate psoriasis patients under the research name SGX302. Psoriasis is a common, chronic, noncontagious, multisystem inflammatory condition that most commonly presents on the skin of the elbows, knees, scalp, back, and thighs. There are multiple types of psoriasis, with plaque psoriasis, being the most common and affecting 80-90% of all individuals with psoriasis. Plaque psoriasis involves the hyperproliferation of epidermal keratinocytes that results in red or white, scaly, and typically itchy skin lesions. In addition, approximately 20% of psoriasis patients suffer from psoriatic arthritis, an inflammatory joint disease associated with psoriasis (Zacharlae, 2003). There is no known cure for the disease, thus depending upon the severity of the condition and how responsive it is to treatment, some patients are on therapy for life.

While psoriasis itself is not life-threatening, there are several conditions that are associated with the disease, including cardiovascular disease (Shlyankevich *et al*., 2014) and hypertension (Armstrong *et al*., 2013). In addition, patients with psoriasis have an increased risk for a number of non-skin cancers, including cancer of the lung, upper gastrointestinal tract, urinary tract, liver, and pancreas (Richard *et al*., 2013).

The severity of psoriasis is dependent on how much of a person's body surface area (BSA) is affected by the condition. Mild psoriasis typically covers <3%, moderate covers between 3-10%, and severe covers more than 10% (National Psoriasis Foundation). However, the severity of the disease also takes into account how it affects a patient's daily life, with even small psoriatic lesions on the palms or soles of the feet capable of having a severely negative impact on an individual's quality of life.

Soligenix previously tested synthetic hypericin in a small Phase 1/2 trial involving 13 patients with psoriasis (Rook *et al*., 2010). Results showed that of the 11 evaluable patients, six responded to treatment with hypericin. There were no deaths or serious adverse events and the only reported adverse events were mild to moderate and included itching, burning, erythema, and pruritis at that application site.

The company is currently evaluating different topical formulations of synthetic hypericin while at the same time working with psoriasis experts to finalize a clinical trial protocol. We anticipate a Phase 2a study initiating in the second half of 2022. We estimate that the company has sufficient capital to conduct the trial without the need to raise additional capital.

HyBryte™ NDA Anticipated in Second Half of 2022

Soligenix previously completed a Phase 3 clinical trial of HyBryte™ (SGX301, synthetic hypericin) in patients with cutaneous T cell lymphoma (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 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.

Soligenix is now in a position to submit an NDA to the U.S. FDA for HyBryte in the second half of 2022. HyBryte has received both Orphan Drug and Fast Track designations from the U.S. FDA as well as Orphan Drug designation from the European Medicines Agency (EMA).

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.

Arbitration with Emergent BioSolutions Offers Potential Upside

Soligenix is currently involved in an arbitration dispute with Emergent BioSolutions, Inc. (EBS) in which Soligenix alleges that EBS fraudulently induced the company into entering into contracts with its subsidiaries and that the subsidiaries breached agreements with Soligenix. The disputed agreements pertain to the manufacture of RiVax bulk drug substance (BDS) that Emergent released despite the BDS being out-of-specification. This resulted in Soligenix having to suspend the Phase 1c trial evaluating RiVax in healthy adults. Soligenix presented its case at an arbitration hearing in January 2022 and we anticipate a decision on the case this summer. Manufacturing issues have been a problem for EBS in other circumstances, as shown in the report from the House Select Subcommittee on the Coronavirus Crisis titled "The Coronavirus Vaccine Manufacturing Failures of Emergent BioSolutions" from May 2022. While difficult to predict how the arbitration may be decided, the fact that EBS has a history of poor manufacturing practices likely bodes well for Soligenix, which is seeking in excess of $19 million from EBS.

Financial Update

On May 13, 2022, Soligenix announced financial results for the first quarter of 2022. The company reported revenues of $0.2 million for the first quarter of 2022, compared to $0.1 million for the first quarter of 2021. 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 2022 were $1.7 million, compared to $1.3 million for the first quarter of 2021. The increase was primarily due to increased expenses associated with the preparation of the upcoming HyBryte NDA filing. G&A expenses for the first quarter of 2022 were $2.6 million, compared to $1.0 million for the first quarter of 2021. The increase was primarily due to an increase in legal and consulting services associated with the arbitration against Emergent BioSolutions, Inc.

Soligenix exited the first quarter of 2022 with approximately $22.9 million in cash and cash equivalents. As of May 6, 2022, Soligenix had approximately 43.1 million shares outstanding, and when factoring in stock options, warrants, and the potential convertible debt the fully diluted share count is approximately 47.6 million.

Conclusion

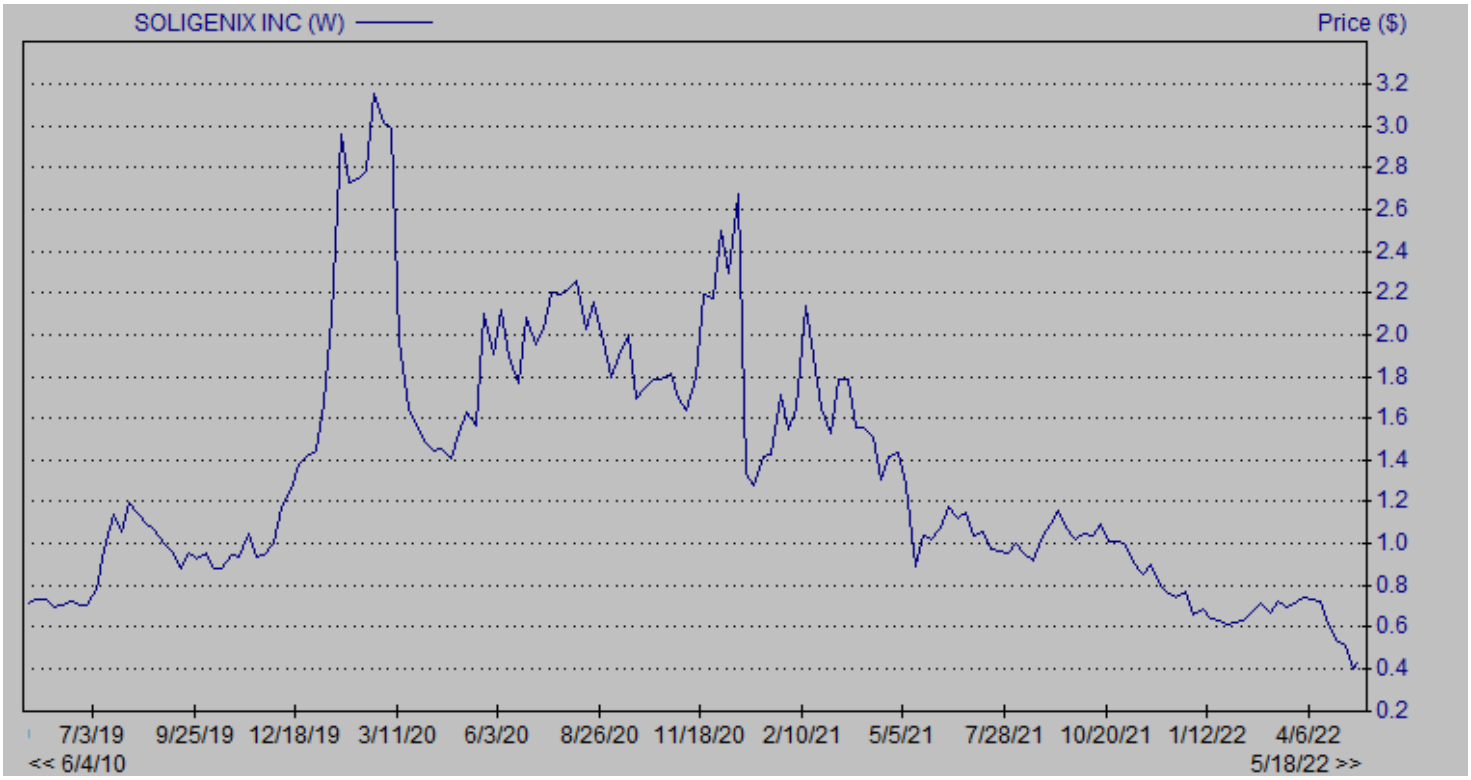
Soligenix has a number of important milestones/events upcoming in 2022, including the NDA filing for HyBryte and the initiation of a psoriasis clinical trial for SGX302, both of which we anticipate in the second half of 2022. The current cash position, along with additional financial instruments available to the company, should provide funding into 2023, and the arbitration outcome with EBS provides potential upside to the company's cash position. We have removed CiVax from our model as the current COVID-19 vaccines are seeing oversupply issues and we believe there is not likely to be a follow up vaccine market. With this change our valuation decreased to $4.00 per share.

PROJECTED FINANCIALS

Soligenix, Inc.	2021 A	Q1 A	Q2 E	Q3 E	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	$0.2	$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%*	*10.0%*	*10.0%*	*10.0%*	*19.8%*	*33.3%*	*41.2%*
Research & Development	$8.4	$1.7	$2.0	$2.2	$2.5	$8.4	$9.0	$10.0
General & Administrative	$4.8	$2.6	$1.0	$1.0	$1.1	$5.7	$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)	($3.0)	($3.2)	($3.6)	($13.9)	($21.0)	($19.0)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.3	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.5
Pre-Tax Income	**($13.4)**	**($4.3)**	**($3.1)**	**($3.3)**	**($3.7)**	**($14.4)**	**($21.5)**	**($19.5)**
Net Taxes (benefit)	$0.9	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*6.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($12.6)**	**($4.3)**	**($3.1)**	**($3.3)**	**($3.7)**	**($14.4)**	**($21.5)**	**($19.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.32)**	**($0.10)**	**($0.07)**	**($0.08)**	**($0.08)**	**($0.33)**	**($0.48)**	**($0.39)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	39.6	42.9	43.2	43.7	44.0	43.5	45.0	50.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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