Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

November 14, 2022
David Bautz, PhD
312-265-9471
dbautz@zacks.com

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

Soligenix, Inc.

(SNGX-NASDAQ)

SNGX: HyBryte™ NDA to be Submitted Before the End 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 (11/14/22)	$0.70
Valuation	**$4.00**

OUTLOOK

On November 10 2022, Soligenix, Inc. (SNGX) announced financial results for the third quarter of 2022 and provided a business update. We continue to anticipate the company filing a new drug application (NDA) for HyBryte™ with the U.S. FDA before the end of 2022. Soligenix also recently announced a $2.6 million orphan products development grant from the U.S. FDA to evaluate HyBryte in patients with early-stage cutaneous T cell lymphoma (CTCL), including its potential for use at home.

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	**$0.40**
One-Year Return (%)	**-23.14**
Beta	**1.76**
Average Daily Volume (sh)	**62,419**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$30**
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 (%)	**-38.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-2.3**
P/E using 2019 Estimate	**-1.5**

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

© Copyright 2022, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

HyBryte™ NDA Anticipated Before the End of 2022

Soligenix, Inc. (SNGX) 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 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.

Soligenix is now in a position to submit an NDA to the U.S. FDA for HyBryte before the end 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.

In July 2022, Soligenix announced that it has reached agreement with the U.S. FDA for an initial pediatric study (iPSP) plan for HyBryte™ for the treatment of CTCL. The iPSP stipulates that Soligenix intends to

request a full waiver of pediatric studies in the submission of the NDA for HyBryte™. The agreement with the FDA on the iPSP is a regulatory requirement that must be met prior to submitting the NDA.

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 should initiate in the fourth quarter of 2022.

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.

In October 2022, Soligenix announced the formation of a Medical Advisory Board (MAB) to provide guidance for the upcoming Phase 2a clinical trial as well as any future clinical trials in psoriasis. The members of the MAB include:

Neal Bhatia, MD – a board-certified dermatologist who serves as Director of Clinical Dermatology at Therapeutics Clinical Research in San Diego, CA.
George Han, MD, PhD – a board-certified dermatologist who serves as associate professor in the Department of Dermatology at the Donald and Barbara Zucker School of Medicine at Hofstra.
Jonathan S. Weiss, MD – a board-certified dermatologist who serves as adjunct assistant professor of Dermatology at the Emory University School of Medicine.
Paul S. Yamauchi, MD, PhD – a board-certified dermatologist who serves as Medical Director at both the Dermatology Institutue & Skin Care Center and Clinical Sciences Institute in Santa Monica, CA.

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).

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.

Financial Update

On November 10, 2022, Soligenix announced financial results for the third quarter of 2022. The company reported revenues of $0.2 million for the third quarter of 2022. The revenues are derived primarily from third party licensing and government contracts and grants to support the development of RiVax®, SGX943, ThermoVax®, and CiVax®. R&D expenses for the third quarter of 2022 were $1.9 million, compared to $2.2 million for the third quarter of 2021. The decrease was primarily due to the completion of the oral mucositis Phase 3 clinical trial. G&A expenses for the third quarter of 2022 were $1.2 million, compared to $1.1 million for the third quarter of 2021. The increase was primarily due to an increase in expenses associated with the 2022 Annual Shareholder Meeting along with increased expenses associated with the commercialization of HyBryte™.

Soligenix exited the third quarter of 2022 with approximately $16.9 million in cash and cash equivalents. As of November 3, 2022, Soligenix had approximately 43.2 million shares outstanding, and when factoring in stock options, warrants, and the potential convertible debt the fully diluted share count is approximately 47.9 million.

Conclusion

Soligenix has a very important milestone upcoming before the end of 2022 with the filing of the NDA for HyBryte™. In addition, we anticipate the initiation of the Phase 2a clinical trial of SGX302 in psoriasis in December 2022. With $16.9 million in cash, which does not include the non-dilutive government funding, the company is well funded through its near term milestones. With no changes to our model our valuation remains at $4.00 per share.

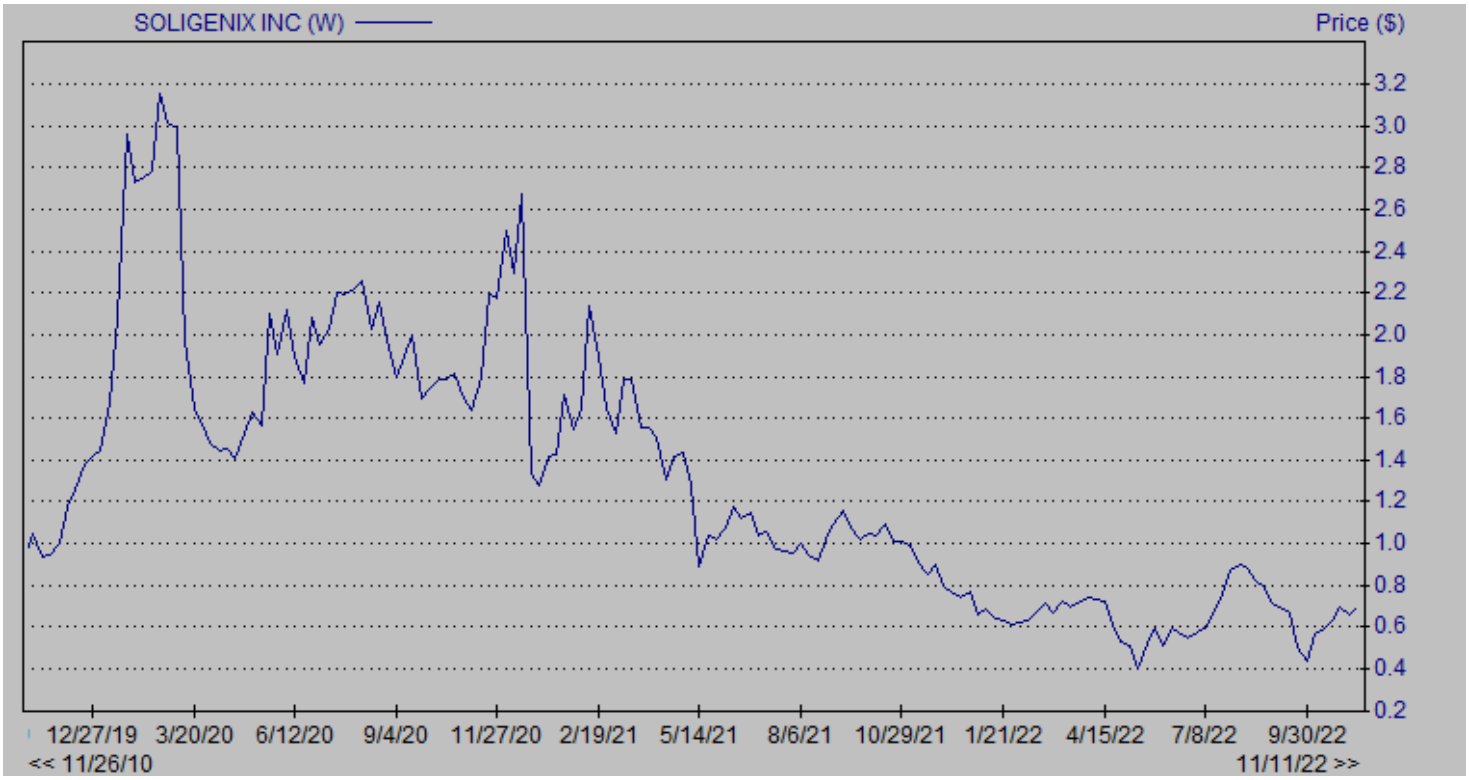
PROJECTED FINANCIALS

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*

© Copyright 2022, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

© Copyright 2022, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.