Zacks Small-Cap Research
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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Cycle 3 Data for SGX301 Phase 3 Trial in CTCL Shows Continued Positive Effects…

Based on our probability adjusted DCF model that takes into account potential future revenues from SGX301, SGX942, and CiVax, SNGX is valued at $15.00 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 (10/23/20)	$1.65
Valuation	**$15.00**

OUTLOOK

On October 22, 2020, Soligenix, Inc. (SNGX) announced Cycle 3 data for the Phase 3 clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL). Approximately 50% of patients in the trial continue to see improvement in response rates through 18 weeks of treatment (3 cycles total). Importantly, SGX301 continues to be safe and well tolerated with no systemic exposure noted through six months of treatment. Additional analysis of Cycle 1 and 2 data shows that following 12 weeks of treatment there is an equally effective response to SGX301 for both patches (37% response; *P*=0.0009) and plaque (42% response; *P*<0.0001) lesions when compared to cycle 1 placebo lesion responses. We believe the equal response to patches and plaques could be another differentiator, that along with the strong safety profile will lead to commercial success for SGX301 in CTCL.

SUMMARY DATA

52-Week High	**$3.34**
52-Week Low	**$0.88**
One-Year Return (%)	**84.98**
Beta	**1.17**
Average Daily Volume (sh)	**230,551**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$49**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-19.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-2.6**
P/E using 2019 Estimate	**-4.8**

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)
2019	1.1 A	1.5 A	1.3 A	0.7 A	4.6 A
2020	0.9 A	0.5 A	1.1 E	1.1 E	3.6 E
2021					4.5 E
2022					25.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.09 A	-$0.12 E	-$0.14 A	-$0.16 A	-$0.48 A
2020	-$0.32 A	-$0.10 A	-$0.10 E	-$0.11 E	-$0.60 E
2021					-$0.58 E
2022					-$0.34 E

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WHAT'S NEW

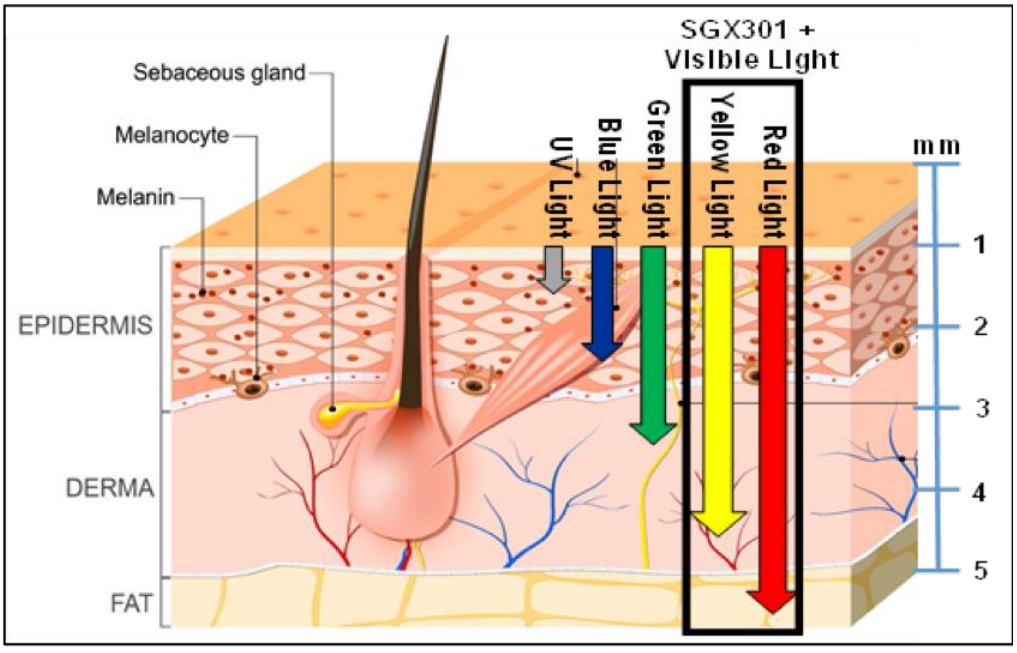
Business Update

Cycle 3 Data Shows Continued Efficacy for SGX301 in Phase 3 CTCL Trial

On October 22, 2020, Soligenix, Inc. (SNGX) announced data from Cycle 3 of the Phase 3 FLASH clinical trial of SGX301 in cutaneous T cell lymphoma (CTCL) shows continued efficacy for the product along with being safe and well tolerated. 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). 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, 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), 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.

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 (Composite Assessment of Index Lesion Score). This compares to 40% of patients demonstrating a similar reduction after completing 12 weeks of treatment (*P*=0.046). The company had previously reported a statistically significant treatment response in the CAILS primary endpoint assessed at 8 weeks for Cycle 1 with 16% of patients receiving SGX301 responding compared to only 4% receiving placebo responding (*P*=0.04). We are very encouraged by the robust increased response to treatment over time.

Continued analysis of Cycle 1 and 2 data shows that following 12 weeks of treatment with SGX301, 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. This is likely due to the wavelength of light used for SGX301, which penetrates deeper into the skin compared to UV light, as shown in the following image. In addition, the ability of SGX301 to be effective against harder to treat plaque lesions could have positive implications for its potential use in treating psoriasis.



Source: Soligenix, Inc.

The important takeaways for investors are that SGX301 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.

Now that the trial is concluded, the company will turn its attention to identifying a suitable commercialization partner and preparing a New Drug Application, which we anticipate occurring in the first half of 2021.

Conclusion

We remind investors that the company will be announcing Phase 3 clinical data for SGX942 in oral mucositis (OM) before the end of 2020. Thus far, the stock has not responded favorably to the positive data for SGX301 in CTCL, which may indicate that investors are waiting on the OM data. However, we believe the stock is exceptionally undervalued at its current price, even if SGX301 was the only product in development. Our current valuation is $15 and at the current depressed price we view an investment in Soligenix as offering a very positive risk/reward profile.

PROJECTED FINANCIALS

Soligenix, Inc.	2019 A	Q1 A	Q2 A	Q3 E	Q4 E	2020 E	2021 E	2022 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$4.6	$0.9	$0.5	$1.1	$1.1	$3.6	$4.5	$4.5
SGX301	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$21.0
SGX942	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$4.6**	**$0.9**	**$0.5**	**$1.1**	**$1.1**	**$3.6**	**$4.5**	**$25.5**
Cost of Revenue	$3.6	$0.8	$0.4	$0.9	$0.9	$3.0	$3.7	$8.0
Gross Income	**$1.1**	**$0.1**	**$0.1**	**$0.2**	**$0.2**	**$0.6**	**$0.8**	**$17.5**
Gross Margin	*22.9%*	*10.3%*	*28.1%*	*18.2%*	*18.2%*	*17.5%*	*17.8%*	*68.6%*
Research & Development	$8.1	$2.7	$2.2	$2.4	$2.5	$9.8	$10.0	$12.0
General & Administrative	$3.5	$0.9	$0.8	$0.9	$1.0	$3.6	$10.0	$18.0
Other Expenses	$0.0	$5.0	$0.0	$0.0	$0.0	$5.0	$0.0	$0.0
Operating Income	($10.5)	($8.5)	($2.8)	($3.1)	($3.3)	($17.7)	($19.2)	($12.5)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.6	$0.1	$0.0	$0.1	$0.1	$0.2	$0.2	$0.2
Pre-Tax Income	**($10.0)**	**($8.4)**	**($2.8)**	**($3.1)**	**($3.3)**	**($17.5)**	**($19.0)**	**($12.3)**
Net Taxes (benefit)	$0.6	($0.8)	$0.0	$0.0	$0.0	$0.8	$0.0	$0.0
Tax Rate	*6.1%*	*9.9%*	*0.0%*	*0.0%*	*0.0%*	*4.8%*	*0.0%*	*0.0%*
Reported Net Income	**($9.4)**	**($7.6)**	**($2.8)**	**($3.1)**	**($3.3)**	**($16.7)**	**($19.0)**	**($12.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.48)**	**($0.32)**	**($0.10)**	**($0.10)**	**($0.11)**	**($0.60)**	**($0.58)**	**($0.34)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	19.4	23.4	26.9	30.0	30.0	27.6	33.0	36.0

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

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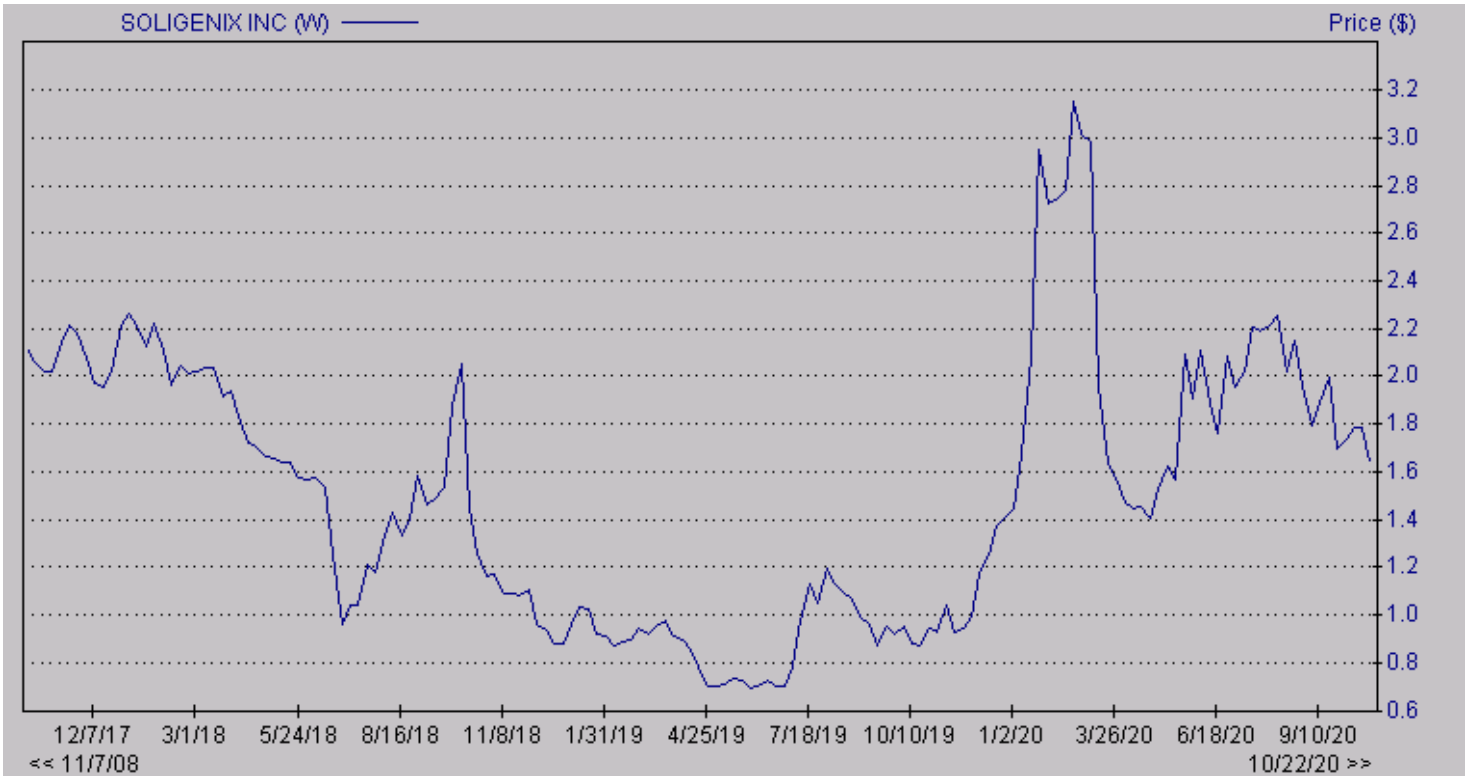
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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