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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Continued Treatment with SGX301 Leads to Increased Efficacy in CTCL…

Based on our probability adjusted DCF model that takes into account potential future revenues from SGX301 and SGX942, SNGX is valued at $12.00 per share. This model is highly dependent upon continued clinical success of SGX301 and SGX942 and will be adjusted accordingly based upon future clinical results.

Current Price (05/05/20)	$1.58
Valuation	**$12.00**

OUTLOOK

On April 30, 2020, Soligenix, Inc. (SNGX) announced additional data from the Phase 3 clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL) showing that continued treatment out to 12 weeks increased the positive response rate to 40% (P<0.0001 compared to both placebo and six weeks of treatment). These data confirm the benefit that CTCL patients receive from SGX301 treatment. Study investigators have been very pleased with the results and we have been told a number of patients have requested continued access to the drug following the end of the treatment protocol for the Phase 3 trial. We believe the data that the company has compiled thus far is very compelling and will likely make SGX301 a front-line therapy option for a large percentage of CTCL patients.

SUMMARY DATA

52-Week High	**$3.34**
52-Week Low	**$0.67**
One-Year Return (%)	**127.04**
Beta	**1.10**
Average Daily Volume (sh)	**1,747,356**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$41**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-14.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-3.2**
P/E using 2019 Estimate	**-3.2**

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	1.1 E	1.1 E	1.1 E	1.1 E	4.4 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	-$0.11 E	-$0.11 E	-$0.12 E	-$0.12 E	-$0.45 E
2021					-$0.63 E
2022					-$0.37 E

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WHAT'S NEW

Business Update

Increased Efficacy with Continued Treatment in Phase 3 Trial of SGX301

On April 30, 2020, Soligenix, Inc. (SNGX) announced positive results for Cycle 2 of the Phase 3 FLASH clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL) showing that continued treatment out to 12 weeks results in increased efficacy as shown by a 40% responder rate (P<0.0001 compared to both placebo and six-week treatment data). These data show that treatment with SGX301 is efficacious when compared to a placebo treatment, and that continued treatment results in better outcomes. The safety profile of SGX301 continues to show that the drug is safe and well tolerated.

The FLASH (Fluorescent Light Activated Synthetic Hypericin) trial is 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.

The company previously reported a statistically significant treatment response in the Composite Assessment of Index Lesion Score (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). The increased responder rate along with a highly significant P value for Cycle 2 is a very encouraging sign, and we believe this sets up SGX301 to be a front-line therapy for a number of CTCL patients.

The most important takeaways for investors regarding the use of SGX301 in CTCL is that the treatment is clearly having a positive effect in terms of reducing lesion severity (any by extension, lesion symptoms), and that these positive effects are being seen in a relatively short period of time (as early as six weeks) with continued improvement with ongoing treatment. In addition, SGX301 is safe and well tolerated, which is in stark contrast to a number of other CTCL therapies (see our previous report on the Cycle 1 data for an overview of other CTCL treatments). We believe these data position SGX301 to be a likely front-line therapy option for a large percentage of CTCL patients.

Licenses Novel Adjuvant for Coronavirus Vaccine

On Apr. 16, 2020, Soligenix announced that it has licensed CoVaccine HT™, a novel vaccine adjuvant, from BTG Specialty Pharmaceuticals (a division of Boston Scientific) for use in vaccines against SARS-CoV-2, the cause of COVID-19, and pandemic influenza. CoVaccine HT enhances both cell-mediated and humoral (antibody-mediated) immunity. It has also been shown to target a Th1 response, which is considered important for coronaviruses.

Soligenix has previously shown the utility of CoVaccine HT in its filovirus vaccine program to develop vaccines against Ebola and Marburg viruses. Using CoVaccine HT, the company reported 100% efficacy in protecting rhesus macaques from Ebola, a model in which other adjuvants fail completely.

Soligenix's vaccine technology is based on using protein subunits combined with an adjuvant to increase the immune response. In addition, Soligenix has technology that allows for the thermostabilization of subunit protein vaccines to allow them to be stored and shipped at ambient temperatures. Since

population-wide vaccination may be necessary to prevent extended economic disruption from COVID-19, the ability to not need refrigeration is likely to be a big advantage.

Since the company has previously produced other vaccines for different virus targets, the manufacturing platform is already in place. Importantly, this expression system produces a stable pattern of glycosylation, which is vital to eliciting a proper immune response. Initial immunogenicity studies are ongoing and we expect manufacturing protocols to be implemented to produce sufficient quantities of antigen for the vaccine. Since protein subunit vaccines are relatively safe, human clinical trials should be able to commence relatively quickly. We expect additional guidance on timelines over the next few months.

Conclusion

The additional data for SGX301 is very encouraging and shows that the compound is likely to be an effective treatment option for patients with CTCL. The fact that efficacy continues to increase with extended treatment is likely going to be an important point for prescribing physicians and patients, and thus we believe a high percentage of CTCL patients will use SGX301 as front-line treatment. The stock continues to be inexplicably held back, which is surprising given the strong data in CTCL and expected results in the Phase 3 oral mucositis (OM) trial of SGX942 due in the fourth quarter of 2020, and we view the current stock price as an excellent entry point for investors. Our current valuation remains at $12 per share.

PROJECTED FINANCIALS

Soligenix, Inc.	2019 A	Q1 E	Q2 E	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	$1.1	$1.1	$1.1	$1.1	$4.4	$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**	**$1.1**	**$1.1**	**$1.1**	**$1.1**	**$4.4**	**$4.5**	**$25.5**
Cost of Revenue	$3.6	$0.9	$0.9	$0.9	$0.9	$3.6	$3.7	$8.0
Gross Income	**$1.1**	**$0.2**	**$0.2**	**$0.2**	**$0.2**	**$0.8**	**$0.8**	**$17.5**
Gross Margin	*22.9%*	*18.9%*	*18.2%*	*18.2%*	*18.2%*	*18.4%*	*17.8%*	*68.6%*
Research & Development	$8.1	$2.0	$2.2	$2.4	$2.5	$9.1	$10.0	$12.0
General & Administrative	$3.5	$0.9	$0.9	$0.9	$1.0	$3.7	$10.0	$18.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($10.5)	($2.7)	($2.9)	($3.1)	($3.3)	($12.0)	($19.2)	($12.5)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.6	$0.1	$0.1	$0.1	$0.1	$0.2	$0.2	$0.2
Pre-Tax Income	**($10.0)**	**($2.6)**	**($2.9)**	**($3.1)**	**($3.3)**	**($11.8)**	**($19.0)**	**($12.3)**
Net Taxes (benefit)	$0.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*6.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($9.4)**	**($2.6)**	**($2.9)**	**($3.1)**	**($3.3)**	**($11.8)**	**($19.0)**	**($12.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.48)**	**($0.11)**	**($0.11)**	**($0.12)**	**($0.12)**	**($0.45)**	**($0.63)**	**($0.37)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	19.4	25.0	26.0	26.0	27.0	26.0	30.0	33.0

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

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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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