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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: One Positive Phase 3 Clinical Trial; One More to Readout Before End of 2020…

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 (11/16/20)	$1.80
Valuation	**$15.00**

OUTLOOK

On November 12, 2020, Soligenix, Inc. (SNGX) announced financial results for the third quarter of 2020 and provided a business update. During the third quarter, the company announced results from Cycle 3 of the Phase 3 clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL). The results showed that treatment with SGX301 up to 18 weeks continues to have a positive effect, and there is an equally positive effect for both patch and plaque lesions. We anticipate the company filing a New Drug Application (NDA) for SGX301 in the first half of 2021. In the fourth quarter of 2020, we anticipate topline results from the Phase 3 clinical trial of SGX942 for the treatment of oral mucositis in patients with squamous cell carcinoma of the oral cavity.

SUMMARY DATA

52-Week High	**$3.34**
52-Week Low	**$0.92**
One-Year Return (%)	**92.21**
Beta	**1.29**
Average Daily Volume (sh)	**590,562**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$54**
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	**-3.1**
P/E using 2019 Estimate	**-5.2**

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	0.9 A	0.5 A	0.6 A	1.1 E	3.1 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	-$0.06 A	-$0.11 E	-$0.56 E
2021					-$0.58 E
2022					-$0.34 E

WHAT'S NEW

Business Update

Topline Results for SGX942 in 4Q20

Soligenix, Inc. (SNGX) is currently conducting the Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) trial of SGX942 in the treatment of oral mucositis (OM) in patients with squamous cell carcinoma of the oral cavity and oropharynx undergoing chemoradiation therapy. In June 2020, the company announced that the trial was fully enrolled with 268 patients. For an overview of the DOM-INNATE trial, please see our previous Q&A with Dr. Richard Straube, Soligenix's Chief Medical Officer.

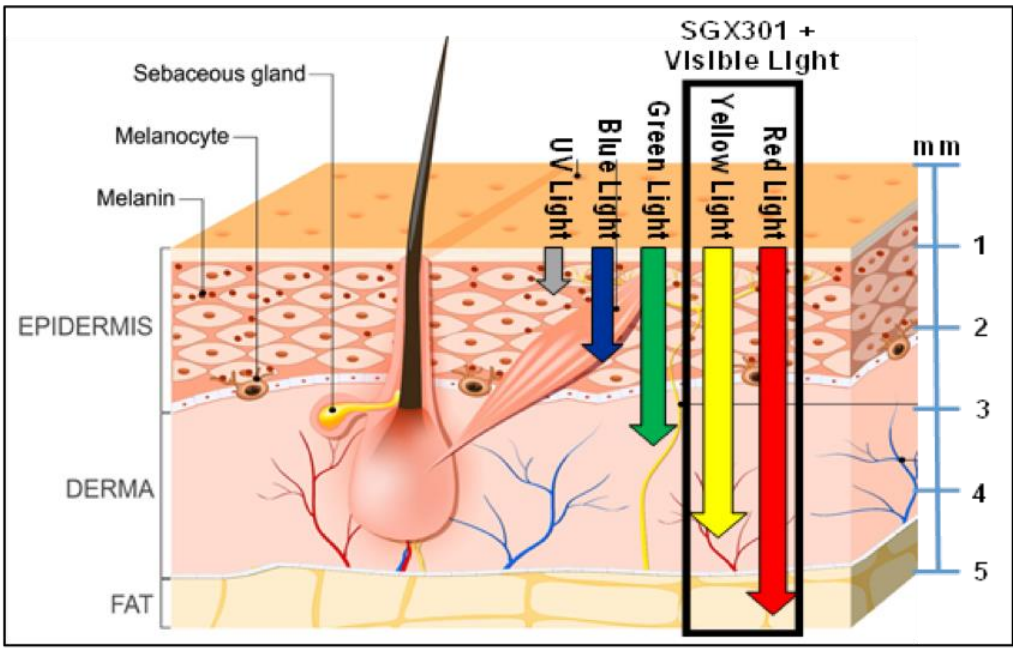
The company had previously received a positive recommendation from the Independent Data Monitoring Committee (DMC) in Aug. 2019 to continue enrollment in the trial and that approximately 70 additional subjects be randomized into the trial to maintain the 90% statistical power for the primary outcome. We anticipate topline results from the trial in the fourth quarter of 2020.

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

In October 2020, Soligenix 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.

Initial COVID-19 Vaccines Face Logistical Issues

On November 9, 2020, Pfizer, Inc. (PFE) and BioNTech SE (BNTX) announced their mRNA-based SARS-CoV-2 vaccine candidate (BNT162b2) showed efficacy against COVID-19 based on the first interim efficacy analysis conducted on Nov. 8, 2020. The first interim efficacy analysis was performed after the evaluable case count reached 94, with the case split between vaccinated and those receiving placebo indicating a vaccine efficacy rate >90% at seven days after the first dose. There have been no serious safety concerns and the trial will continue to collect additional safety and efficacy data as planned.

While the data presented by Pfizer and BioNTech is certainly encouraging, the vaccine's storage requirements are going to be an obstacle for widespread distribution, at least initially. The problem is that the vaccine is required to be stored at -70ºC or below and it can only be kept at 4ºC for up to five days. Those type of storage facilities are not widespread, even at leading medical institutions in the U.S., let alone in poorer countries.

In contrast to BNT162b2 and other COVID-19 vaccines in development, one of the biggest advantages of CiVax™, Soligenix's COVID-19 vaccine candidate, is that it can be shipped at ambient temperature and stored at temperatures as high as 40ºC (104ºF). CiVax consists of a recombinant spike protein from the SARS-CoV-2 virus that is expressed in an insect cell expression system to ensure stable glycosylation patterns. Protein vaccines have been used successfully for a long time and have a strong safety record. CiVax includes the CoVaccine HT™ adjuvant, which Soligenix licensed from BTG-Boston Scientific. CoVaccine HT has previously been shown to induce both humoral (antibody) and cell-mediated immunity. Lastly, Soligenix's

thermostabilization platform, ThermoVax®, allows for individually lyophilized samples to be prepared that can be reconstituted with sterile water immediately prior to administration.

As the world continues to battle the ongoing pandemic and attention now turns to vaccine development, we believe the advantages of CiVax offer a compelling opportunity should the initial vaccines and their limitations on storage and stability prove too difficult to result in widespread deployment.

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 A	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	$0.6	$1.1	$3.1	$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**	**$0.6**	**$1.1**	**$3.1**	**$4.5**	**$25.5**
Cost of Revenue	$3.6	$0.8	$0.4	$0.4	$0.9	$2.5	$3.7	$8.0
Gross Income	**$1.1**	**$0.1**	**$0.1**	**$0.2**	**$0.2**	**$0.7**	**$0.8**	**$17.5**
Gross Margin	*22.9%*	*10.3%*	*28.1%*	*36.5%*	*18.2%*	*21.0%*	*17.8%*	*68.6%*
Research & Development	$8.1	$2.7	$2.2	$1.3	$2.5	$8.6	$10.0	$12.0
General & Administrative	$3.5	$0.9	$0.8	$0.8	$1.0	$3.4	$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)	($1.8)	($3.3)	($16.4)	($19.2)	($12.5)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.6	$0.1	$0.0	$0.0	$0.1	$0.2	$0.2	$0.2
Pre-Tax Income	**($10.0)**	**($8.4)**	**($2.8)**	**($1.8)**	**($3.3)**	**($16.2)**	**($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%*	*5.2%*	*0.0%*	*0.0%*
Reported Net Income	**($9.4)**	**($7.6)**	**($2.8)**	**($1.8)**	**($3.3)**	**($15.4)**	**($19.0)**	**($12.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.48)**	**($0.32)**	**($0.10)**	**($0.06)**	**($0.11)**	**($0.56)**	**($0.58)**	**($0.34)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	19.4	23.4	26.9	29.6	30.0	27.5	33.0	36.0

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

HISTORICAL STOCK PRICE

Source: Zacks Small Cap Research

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