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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Phase 3 Trial of SGX942 Does Not Meet Primary Endpoint…

Based on our probability adjusted DCF model that takes into account potential future revenues from SGX301, and CiVax, SNGX is valued at $7.00 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 (12/23/20)	$1.39
Valuation	**$7.00**

OUTLOOK

On December 22, 2020, Soligenix, Inc. (SNGX) announced topline results for the Phase 3 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer patients. Despite a 56% reduction in the median duration of serious oral mucositis (SOM), 18 days in the placebo group compared to 8 days in the SGX942 group, the primary endpoint did not achieve statistical significance. The biological activity of dusquetide was supported by secondary endpoints, including a 50% reduction in the duration of SOM in the per protocol population (*P*=0.049). The company will further evaluate the data set to determine what led to the lack of a statistically significant outcome in the primary endpoint. In the meantime, Soligenix continues work on an NDA for SGX301 in CTCL, which they anticipate being filed in 2021.

SUMMARY DATA

52-Week High	**$3.34**
52-Week Low	**$1.36**
One-Year Return (%)	**0.00**
Beta	**1.47**
Average Daily Volume (sh)	**1,375,906**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$41**
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 (%)	**-23.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-2.4**
P/E using 2019 Estimate	**-4.5**

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)
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

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WHAT'S NEW

Business Update

Phase 3 Clinical Trial of SGX942 Does Not Meet Primary Endpoint

On December 22, 2020, Soligenix, Inc. (SNGX) announced topline results from 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. A total of 268 patients were randomized 1:1 to receive either SGX942 or placebo. Despite a 56% decrease in the median duration of serious OM (SOM) from 18 days in the placebo cohort to 8 days in the SGX942 cohort, the primary endpoint did not achieve statistical significance, defined as a P value ≤0.05.

While the primary endpoint did not achieve statistical significance, certain secondary endpoints helped to support the biological activity of SGX942, including a statistically significant 50% reduction in the duration of SOM in the per-protocol population (defined as the population receiving a minimum of 55 Gy radiation and at least 10 doses of study drug through the intended treatment period with no major protocol deviations) and a 16% decrease in the incidence of SOM in the SGX942 cohort compared to the placebo group.

During a conference call to discuss the results, management answered a number of questions regarding the results. A few of the questions and their answers are indicated below.

- **If SGX942 didn't work for OM, do you think it still might work in other indications?**
  Dr. Richard Straube, Soligenix's Chief Medical Officer, explained that he felt the drug did in fact "work" in OM by demonstrating consistent reductions in the duration and severity of OM in two clinical studies, however it unfortunately did not cross the statistical threshold of a P value ≤0.05 to declare it a success. In regards to other potential indications, there is preclinical and Phase 1 data showing control of inflammation while increasing the host's ability to clear bacteria and enhance wound healing, thus the drug could be tested for anti-inflammatory or antibacterial indications.
- **How do you explain the failure of the Phase 3 trial in light of the success and magnitude of the response observed in the Phase 2 trial?**
  Dr. Straube indicated that since the data set has not been fully analyzed it is difficult to say, however there are a number of potential confounding factors, such as the smaller size of the Phase 2 trial, the possibility of having responding and non-responding sub-populations in the Phase 3 trial, and the potential variability in the placebo population. The company intends to explore these possibilities along with other aspects of patient demographics and the outcomes of other secondary endpoints over the next few months to determine if there is a path forward for the program in consultation with the FDA and EMA.
- **In the Phase 2 trial and your preclinical data you saw a significant anti-infective signal. Did you see that in the Phase 3 trial? What you think this says about the mechanism of action of your compound?**
  Dr. Oreola Donini, Soligenix's Chief Scientific Officer, stated that in the Phase 2 study a reduction in the rate of infection was noted, most prominently in the 6 mg/kg dose group but also in the 1.5 mg/kg dose group. In the Phase 3 study, where the more anti-inflammatory 1.5 mg/kg dose was used, there was not a strong anti-infective signal. This is consistent with the underlying mechanism of dusquetide, in which the anti-infective and anti-inflammatory signals peak at different dose levels. The company had been hopeful that an anti-infective signal would be observed, however none was observed in the study.

- **Given the interim analysis you conducted, which advised enrolling an additional 70 subjects, it is surprising that the patient numbers were still not sufficient to see a statistically significant response. What do you think caused this?**
  Dr. Donini stated that the company was surprised as well that the additional patients did not result in a statistically significant outcome. However, there is a high degree of variability in an OM patient population, and group comparisons had to be done with a comparison of distributions, which is also more susceptible to variability. While the company is still investigating this, the initial thought is that the variability changed between the first approximately 100 subjects and the final 160 subjects in the trial.
- **If there is a potential path forward, I don't think investors would have any confidence in the program (SGX942) being successful the second time around, so how would you be able to fund it? I would think a strategic partnership or sale of the asset is the only logical path.**
  Dr. Chris Schaber (Soligenix's CEO) stated that it was difficult to say anything further at this time without seeing all the data from the study, however the questioner was correct that the company will need to look at all possible strategic options moving forward, which may include, for example, a co-development partnership. However, Dr. Schaber reiterated that dusquetide is a platform technology and there is applicability in other indications which the company will also evaluate, such as infectious diseases.

As mentioned during the Q&A, Soligenix will be further evaluating the data set to better determine why the primary endpoint did not reach statistical significance. Until this analysis is complete, we are unsure of the path forward for SGX942. We anticipate updates from the company in the coming months when there is additional clarity.

Conclusion

We are disappointed by the results of the Phase 3 trial of SGX942 in OM and look forward to updates from the company regarding additional analyses of the data set and a potential path forward for the drug. In the meantime, the company is focused on preparing the New Drug Application for SGX301 in the treatment CTCL along with pre-commercialization activities for a U.S. launch following approval.

Until we receive additional clarity on the path forward for SGX942 we have removed it from our model, which has decreased our valuation to $7.00.

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*

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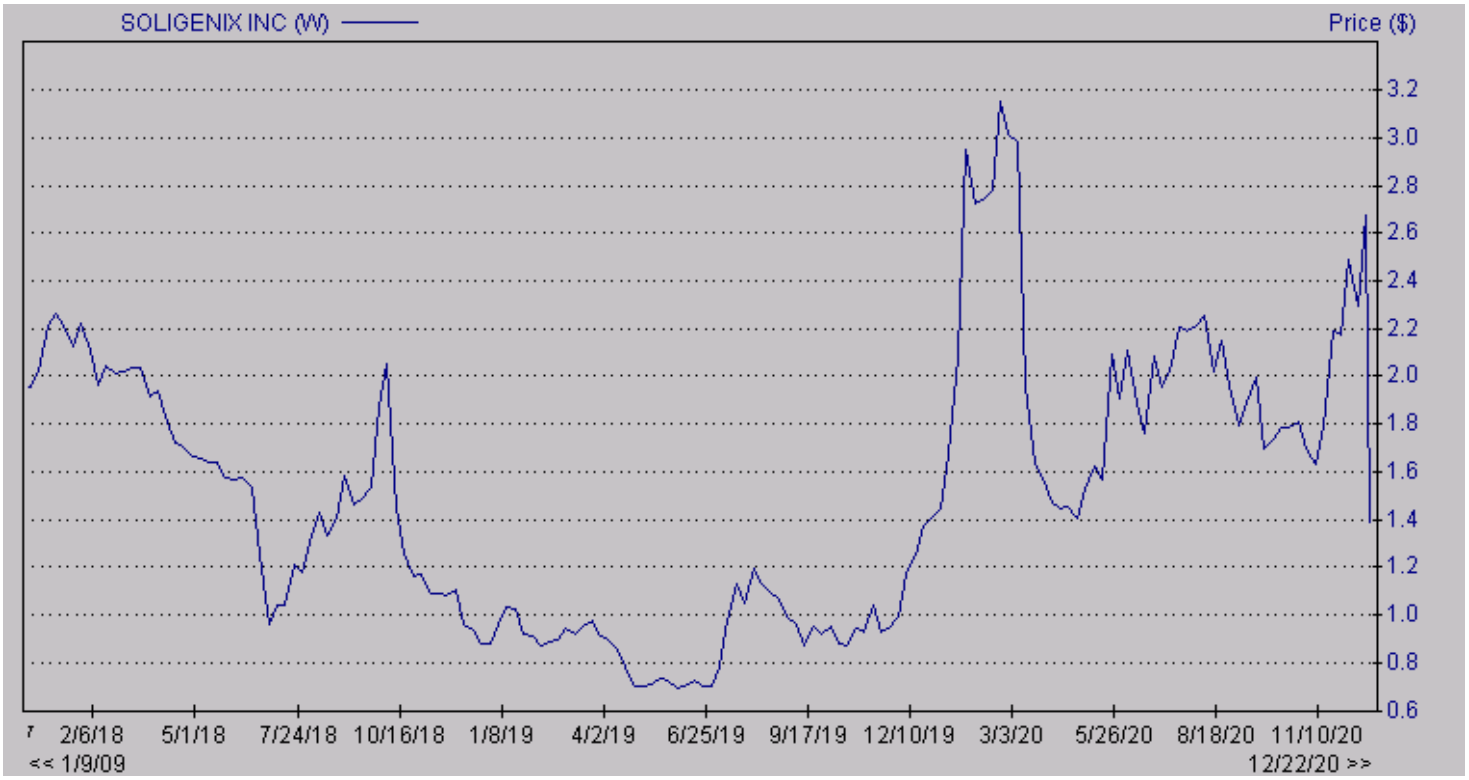

Source: Zacks Small Cap Research

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