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Soligenix, Inc.

(SNGX-NASDAQ)

SNGX: Q&A with Dr. Straube Regarding the Phase 3 OM Trial…

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 (06/30/20)	$2.22
Valuation	**$12.00**

OUTLOOK

Soligenix, Inc. (SNGX) is currently conducting the Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) clinical trial of SGX942 (dusquetide) for the treatment of severe oral mucositis (OM) in patients with squamous cell carcinoma of the oral cavity and oropharynx undergoing chemoradiation therapy. Following the company's announcement that it has completed enrollment for the trial we asked Dr. Richard Straube, Soligenix's Chief Medical Officer, a few questions to get an overview of SGX942, OM, and the Phase 3 trial.

SUMMARY DATA

52-Week High	**$3.34**
52-Week Low	**$0.71**
One-Year Return (%)	**208.33**
Beta	**1.17**
Average Daily Volume (sh)	**911,285**
Shares Outstanding (mil)	**27**
Market Capitalization ($mil)	**$59**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-16.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-2.7**
P/E using 2019 Estimate	**-7.8**

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	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	-$0.32 A	-$0.11 E	-$0.12 E	-$0.12 E	-$0.65 E
2021					-$0.63 E
2022					-$0.37 E

WHAT'S NEW

Business Update

Phase 3 DOM-INNATE Trial Fully Enrolled

On June 24, 2020, Soligenix, Inc. (SNGX) announced that enrollment has completed in 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. The study enrolled 268 patients following the interim analysis by the independent Data Monitoring Committee (DMC).

To get an overview of SGX942, OM, and the Phase 3 trial we asked Dr. Richard Straube, Soligenix's Chief Medical Officer, a few questions, with his answers provided below. Highlights from the interview, which we think are important details for investors, are given below with the full interview following.

- "We expect the topline primary endpoint data to be available in the fourth quarter of 2020."
- "There is currently **NO approved drug** for the treatment of oral mucositis in patients that have solid tumors."
- "We therefore estimate the worldwide market potential of oral mucositis in head and neck cancer to be greater than $500M."
- "The DMC recommendation to enroll additional subjects actually implies that they saw a meaningful difference with treatment and that there were no concerning safety signals."
- "Assuming clinical success, we therefore expect SGX942 potentially to be first to market with a very clinically convenient product with significant ancillary benefits."

DB: On the heels of announcing the success of your Phase 3 study in CTCL, you have now announced that enrollment was successfully completed in your SGX942 Phase 3 study for the treatment of oral mucositis in head and neck cancer. When should we expect topline results?

RS: Yes – 2020 is a big year for Soligenix! We expect the topline primary endpoint data to be available in the fourth quarter of 2020.

DB: As you know, many companies have had to suspend their clinical studies due to the COVID-19 pandemic. Can you tell me how it affected the SGX942 trial?

RS: As you know, COVID-19 spread across the world, including Europe and the U.S. where our sites are located. As COVID was spreading, we had met our initial enrollment target of 260 subjects, but were unsure how COVID might impact the subjects in the trial who were still receiving treatment. We therefore took a very cautious approach while we worked with the subjects and their caregivers to be sure that they got their needed treatments and that we obtained the necessary data with high quality. This was all done with the primary objective of ensuring subject, as well as Soligenix and site personnel, safety. I'm happy to report that this went better than expected. We enrolled a total of 268 subjects and enough of them have now completed the treatment phase of the study that we are confident we can complete the study while maintaining our high statistical power. And as I noted previously, we expect to have topline data by the end of this year.

DB: Can you provide a little background on oral mucositis and why it is an area of unmet medical need?

RS: Oral mucositis is a debilitating side effect of many tumor treatment regimens. Initially thought to be solely due to the death of normal but rapidly dividing cells inadvertently targeted by the chemotherapy and radiation treatment, it is now understood that the cell death of either the tumor cells or normal cells sends a signal to the innate immune system that repair systems are needed. Unfortunately, the first step

in the repair process is enhanced inflammation – which tends to amplify the underlying damage and exacerbates the existing oral mucositis.

At its worst, the pain can be so bad for patients that simply breathing through their open mouth hurts. This can be a truly debilitating condition. Severe oral mucositis is defined as pain so severe that it prevents patients from eating and/or drinking. The longer this persists, the more the patient is at risk for dehydration, malnutrition, and then subsequently infection and hospitalization. Oral mucositis affects a patient's quality of life, their willingness to comply with tumor treatment and therefore tumor outcomes, and their need for hospitalization (and concomitant pharmacoeconomic costs). As such, treatment/prevention of oral mucositis is a high priority in cancer supportive care.

There is currently **NO approved drug** for the treatment of oral mucositis in patients that have solid tumors (e.g., head and neck cancer, breast cancer, colon cancer). The only drug ever approved was a tissue growth factor which came with the risk of increasing solid tumor growth and therefore was limited to hematological cancers only (e.g., leukemia). The best available care in mucositis includes ice chips, pain medication, and mouthwashes… so not very helpful.

DB: How is SGX942 expected to be used clinically?

RS*:* SGX942 is given as a short 4-minute IV infusion twice per week when the patient is already otherwise attending the clinic for radiation therapy. It can be given anytime during the day, irrespective of when radiation is planned. In head and neck cancer patients, SGX942 treatment is started when radiation treatment begins and continues until 2 weeks after radiation is completed.

The risk of the extreme mouth pain that many patients experience with head and neck cancer makes the decision to use a beneficial, convenient, occasional, and rapid IV infusion very easy for most patients. Other oral medications are problematic for patients since they generally prefer to put as little as possible in their mouths that are already extremely sore. The compliance rate with our treatment has been significantly better than in trials with oral products. The 4-minute infusion is also convenient in that it can be accomplished rapidly – not requiring an infusion suite nor an extended in-hospital visit - and is administered during a few of their scheduled RT visits.

DB: What is the potential oral mucositis market size?

RS: We are studying SGX942 as a treatment for oral mucositis in head and neck cancer patients. According to the NCI's SEER database, the prevalence of head and neck cancer in the U.S. is approximately 138,000, of which 80-90% will develop oral mucositis; thus, we conservatively estimate the U.S. patient population to be between 90,000 and 120,000. Similarly, we estimate there are approximately 90,000 patients in Europe (inclusive of the United Kingdom). We therefore estimate the worldwide market potential of oral mucositis in head and neck cancer to be greater than $500M*.* Because the pathophysiology of oral mucositis is similar across all the solid tumor cancers, we also see significant room for indication expansion. For instance, breast cancer patients that experience oral mucositis in cycle 1 of their chemotherapy are at increasing risk for severe oral mucositis in subsequent chemotherapy cycles.

DB: Can you please briefly review the type of therapy SGX942 is and its mechanism of action?

RS: SGX942 is a new class of drug, called an Innate Defense Regulator (IDR)*.* As I noted, the cause of oral mucositis is two-fold – a component due to the direct effects of chemoradiation and a component due to the response of the body to the damage. This response to damage is directed by the innate immune system and involves an initial inflammatory response, which is necessary but sometimes over-aggressive, followed by anti-infective and tissue healing action. This same innate immune response is also triggered in response to infection.

Our novel drug therapy specifically targets the innate immune response to the damage (or infection) signals. By modulating the signaling pathways at key nodal convergence points, SGX942 re-directs the response to control the over-aggressive inflammation while increasing the tissue healing and anti-infective pathways. SGX942 does NOT interfere with the tumor killing mechanisms directly and therefore does not interfere with tumor treatment.

Nonclinical studies have shown both a decrease in the duration of oral mucositis as well as control of infection in bacterial infection models. In addition, animal models have also suggested a potential direct decrease in tumor growth due to SGX942. Thus, nonclinical studies in many different animal species indicate that SGX942 would reduce the oral mucositis and the attendant infection (another serious side effect of chemoradiation therapy) and may help with tumor treatment.

In the Phase 2 study with SGX942 in 111 head and neck cancer subjects we demonstrated a 67% reduction in the median duration of oral mucositis in subjects receiving the recommended chemoradiation treatment protocol (minimum 55 Gy fractionated radiation plus 80-100 mg/m^2 cisplatin every third week, *P*=0.04). Safety monitoring also revealed a decreased infection rate and an increased tumor clearance rate in subjects receiving SGX942. There was also an associated increase in 12-month survival with SGX942 treatment compared to placebo. These results were all very consistent with the previous nonclinical findings.

DB: Can you please briefly review the Phase 3 protocol?

RS: The Phase 3 trial is very similar in design to the Phase 2 protocol. Specifically, patients planned to receive 55 Gy of radiation and 80-100 mg/m^2 cisplatin chemotherapy every third week were given study drug (1.5 mg/kg SGX942 or placebo, randomized 1:1) twice a week starting when radiation therapy started and continuing until 2 weeks after completion of radiation. This double-blind study included monitoring of oral mucositis twice weekly through to 6 weeks post-radiation to allow the assessment of the duration of severe oral mucositis (WHO score of 3 or 4 reflecting an inability to eat and/or drink, respectively).

The study enrolled 268 subjects, in accordance with the positive recommendation of the Data Monitoring Committee at the interim analysis in August 2019.

DB: Can you remind us of the outcome of your positive DMC recommendation for the study and why this feedback is important?

RS: The SGX942 pivotal Phase 3 trial was an adaptive trial design, meaning it included an interim analysis that was specifically designed to mitigate risk when extrapolating from the Phase 2 study to design our Phase 3 program, particularly given the historically reported variability in the oral mucositis population. The interim analysis allowed an independent Data Monitoring Committee (DMC) to review the unblinded data, calculate response rates in the actual trial population, and recommend adjustment in sample size to maintain the pre-defined rigorous 90% statistical power. The DMC could have made a number of recommendations, including stopping the study for futility. In order to recommend enrollment of additional subjects, which they did, they had to have seen a promising signal. Thus, the DMC recommendation to enroll additional subjects actually implies that they saw a meaningful difference with treatment and that there were no concerning safety signals.

DB: What does the competitive landscape look like in oral mucositis and how is SGX942 differentiated?

RS: As we talked about previously, there is no approved drug for oral mucositis in the setting of any solid tumor cancer, including head and neck cancer. Best available care involves ice chips, opioids for pain, and mouth washes for oral maintenance.

SGX942 is currently the most advanced candidate for the treatment of oral mucositis. Other products in development include a manganese complex directed toward “mopping up” free radicals formed by

radiation therapy and other oral therapies. Oral therapies are generally disfavored due to the need to introduce the product into the mouth (extremely painful in the context of head and neck cancer and oral mucositis), resulting in potential patient compliance issues. Previous oral therapies have been attempted in oral mucositis and have not fared well, up to and including the most recent Phase 2 failure announced in April 2020.

With respect to the manganese adduct in development, one of the most outstanding differences in the programs is in the clinical convenience. The manganese product is administered daily, Monday through Friday, for approximately 7 weeks. It requires a 1-hour infusion to be completed no more than one hour prior to radiation. This significantly extends the time the patient must spend in the clinic daily and markedly complicates clinical logistics. In addition, ancillary benefits provided by SGX942, including reduced infection rates and increased tumor clearance, have not been reported for the manganese adduct. I believe the manganese product has also experienced both manufacturing delays in 2019 and COVID-19 delays in 2020, resulting in a delayed completion date with topline data expected towards the end of 2021.

Assuming clinical success, we therefore expect SGX942 potentially to be first to market with a very clinically convenient product with significant ancillary benefits.

DB: What are clinicians' impressions of SGX942 and what do they consider a clinically meaningful response?

RS: Based on feedback from our clinical investigators, they see a need for approved, efficacious treatment options and they really like the ease of administration of SGX942 compared to other therapies currently being studied in the clinic.

During our Phase 2 study, clinicians had indicated that even a few days decrease in the duration of severe oral mucositis would be clinically meaningful, since the risk of hospitalization, treatment breaks, and impairment in quality of life increases markedly as the duration of severe oral mucositis increases. In fact, in the Phase 2 study, we saw substantially more improvement than a few days, decreasing the median duration of severe oral mucositis from 30 days to only 10 days (67% reduction, P=0.04) in the highest risk population.

DB: With two programs achieving Phase 3 trial readouts in 2020 – what do you expect 2021 to bring?

RS: I believe in 2021 and 2022 you will continue to see us build on our successes in 2020! With the positive results in our Phase 3 trial in CTCL, including a 40% response rate (P<0.0001) after just 12 weeks of treatment with SGX301, the next milestones for the CTCL program are the completion of the last optional cycle (Cycle 3), the long-term safety follow-up (expected by end of year), and marketing application for CTCL in the U.S. While we expect to partner SGX301 outside of the U.S., we are still evaluating whether we should commercialize CTCL within the U.S. ourselves or partner in this jurisdiction.

Assuming positive Phase 3 data from the oral mucositis study, 2021 will focus on completing the 12-month safety follow-up, preparing for marketing applications in both the U.S. and Europe, and securing a potential partnership.

Conclusion

We thank Dr. Straube for providing an in-depth overview of SGX942, OM, and the Phase 3 trial and we look forward to the topline results of the DOM-INNATE trial in the fourth quarter of 2020. Even with the aforementioned positive results from the Phase 3 trial of SGX301 announced earlier this year, the stock continues to trade at a substantial discount to our current valuation of $12 per share. However, with positive Phase 3 data in hand and another Phase 3 read-out later this year, we don't expect the stock to remain at these levels and investors should consider using the current weakness as a buying opportunity.

PROJECTED FINANCIALS

Soligenix, Inc.	2019 A	Q1 A	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	$0.9	$1.1	$1.1	$1.1	$4.2	$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**	**$1.1**	**$1.1**	**$1.1**	**$4.2**	**$4.5**	**$25.5**
Cost of Revenue	$3.6	$0.8	$0.9	$0.9	$0.9	$3.5	$3.7	$8.0
Gross Income	**$1.1**	**$0.1**	**$0.2**	**$0.2**	**$0.2**	**$0.7**	**$0.8**	**$17.5**
Gross Margin	*22.9%*	*10.3%*	*18.2%*	*18.2%*	*18.2%*	*16.5%*	*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	$0.9	$0.9	$1.0	$3.7	$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)	($2.9)	($3.1)	($3.3)	($17.8)	($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)**	**($8.4)**	**($2.9)**	**($3.1)**	**($3.3)**	**($17.6)**	**($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)**	**($2.9)**	**($3.1)**	**($3.3)**	**($16.7)**	**($19.0)**	**($12.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.48)**	**($0.32)**	**($0.11)**	**($0.11)**	**($0.12)**	**($0.64)**	**($0.63)**	**($0.37)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	19.4	23.4	26.6	26.8	27.0	26.0	30.0	33.0

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

HISTORICAL STOCK PRICE

Source: Zacks Small Cap Research

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