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August 28, 2019
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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Q&A on SGX942 Phase 3 Trial Interim Analysis…

Based on our probability adjusted DCF model that takes into account potential future revenues from SGX301 and SGX942, SNGX is valued at $8.00 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 (08/28/19)	$1.08
Valuation	**$8.00**

OUTLOOK

On August 28, 2019, Soligenix, Inc. (SNGX) announced a positive recommendation from the independent Data Monitoring Committee (DMC) to continue enrollment in the ongoing Phase 3 clinical trial of SGX942 in the treatment of oral mucositis in patients with head and neck cancer. The DMC recommended that approximately 70 additional subjects be randomized into the trial to maintain the 90% statistical power for the primary outcome. To get a better understanding of the DMC's recommendation, we spoke with Dr. Richard Straube, Soligenix's Chief Medical Officer, and asked him a few questions regarding the outcome of the interim analysis.

SUMMARY DATA

52-Week High	**$2.10**
52-Week Low	**$0.67**
One-Year Return (%)	**-27.27**
Beta	**1.16**
Average Daily Volume (sh)	**111,591**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$22**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-9.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-2.3**
P/E using 2019 Estimate	**-2.7**

Risk Level	**High**
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)
2018	1.1 A	1.7 A	1.4 A	1.0 A	5.2 A
2019	1.1 A	1.5 A	1.4 E	1.5 E	5.6 E
2020					5.8 E
2021					6.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.27 A	-$0.18 A	-$0.11 A	-$0.17 A	-$0.67 A
2018	-$0.09 A	-$0.12 A	-$0.12 E	-$0.12 E	-$0.45 E
2019					-$0.48 E
2020					-$0.48 E

WHAT'S NEW

Business Update

Positive Interim Analysis of SGX942 Phase 3 Clinical Trial

On August 28, 2019, Soligenix, Inc. (SNGX) announced a positive recommendation from the independent Data Monitoring Committee (DMC) to continue enrollment in the ongoing Phase 3 clinical trial of SGX942 in the treatment of oral mucositis in patients with head and neck cancer. The DMC recommended that approximately 70 additional subjects be randomized into the trial to maintain the 90% statistical power for the primary outcome, which will increase the study sample size from 190 to 260 subjects.

The DMC's recommendation is indicative of a promising signal in the primary endpoint. The increase in study sample size was required to account for any potential variability observed in the Phase 3 trial that differs from the trials original design assumptions. In addition, no safety concerns were reported by the DMC based on the interim analysis. Most importantly, the study remains on target to complete enrollment and provide topline results in the first half of 2020.

To get a better understanding of the DMC's recommendation, we spoke with Dr. Richard Straube, Soligenix's Chief Medical Officer, and asked him a few questions regarding the outcome of the interim analysis.

Investors should be aware that Soligenix remains 100% blinded to the data and the below answers are based on knowledge of the underlying assumptions used to design the clinical trial and general statistical principles and not on any actual analyses of the SGX942 Phase 3 clinical data for the treatment of oral mucositis in head and neck cancer patients.

DB: Some investors may be surprised by the required addition of 70 patients to the study. Why were you off from your original number? Does this mean something is wrong with the study?

RS: Nothing is wrong with the study. Given the uncertainties involved with predicting outcomes for any clinical trial, the recommended increase in sample size is not dramatic. Reviewing the medical histories of the patients currently enrolled in the trial, there is nothing to lead us to believe that there is anything other than increased inter-patient variability that always changes between clinical trials. This could easily arise with expansion of the trial to a larger number of clinical sites and expansion into Europe that was required to complete the larger trial in a reasonable timeframe, and to support use of the study for a marketing authorization application with the European Health Authorities.

DB: How was the original sample size decided? Why was a change needed?

RS: I will try to explain without being too technical. Please bear with me. The initial sample size of 190 was a "best estimation" based on both statistical requirements and expected relative outcomes in the treated and control arms of the Phase 2 clinical trial. Statistically, you must decide the degree of risk that you will accept that the trial will be "negative" despite the drug actually working (false negative result) referred to as the power of the trial (statistical jargon "1-β"; in our case set to 90%) and the risk that the trial is "positive" despite the drug actually working (false positive result), referred to as the statistical threshold (in our case set at $p<0.05$ level as required for pivotal studies). The expected success rates in the treated and control groups were estimated based on the Phase 2 data with the drug. The adjusted sample size of 260 is based on the ***actual*** responses in the current Phase 3 study and confirms that there is a beneficial effect being observed AND increases confidence that the study would achieve 90% power.

But again, differences between the Phase 2 and Phase 3 study are anticipated given the broader number of clinical centers in more countries included in the Phase 3 study, which was critical to ultimately allow us to pursue marketing approval in Europe and the US, and other jurisdictions, as well as enabling us to complete the trial in a reasonable timeframe.

DB: What do you think may be occurring in the Phase 3 trial that you didn't see in the Phase 2 trial?

RS: The blinded nature of the analysis does not allow us to dissect and interpret with precision the recommendation of the DMC. Our original estimates were based on the most recent rates of response for both drug and placebo from our Phase 2 study, which informed the size of the current Phase 3 trial. Of course, these rates may vary a bit and may affect sample size. Any variance observed would further be amplified by the high statistical power we are employing to maximize our likelihood of success.

Among the potential possibilities, a contributing factor of the resizing recommendation could be that the placebo population is responding a little differently than they did in our Phase 2 study, which is not unexpected. In almost every clinical study done in recent years in oral mucositis, the placebo populations have varied in their response from trial to trial. Remember, one of the main reasons we wanted to do the interim analysis in the first place and designed the trial this way is to take variability into account and be able to adjust for it, if needed.

The proactive inclusion of the interim analysis gives us a great opportunity to double-check our assumptions on sizing by getting a read of what is going on in "real time" and adjusting what we are doing, instead of solely running the trial based off of response rates from historical results and hoping they don't change.

DB: Why are you focused on 90% Power? Couldn't you do something less and enroll less patients? Why not 85 or 85% instead? Any idea how much smaller would the increase have been with an 80% Power?

RS: I know for those not living clinical development, this concept of power can be difficult to understand. Power basically measures the risk that an efficacious drug does NOT achieve statistical significance. A power of 80% vs. 90% doubles the risk that the drug works but does not achieve statistical significance (that is, would not meet the $p<0.05$ threshold that is mandated for Phase 3 studies).

We believe SGX942 has the potential to dramatically affect these critically ill patients. This belief is anchored in the very consistent results ranging from preclinical to clinical studies. Therefore, we have determined that the additional sample size to give SGX942 the best opportunity for success is well worthwhile. Since Soligenix remains completely blinded, it is impossible for us to estimate what the sample sizes would be at other powers, but it's safe to say it would be less.

DB: If you were to enroll 190 evaluable patients, what do you think the power would be? Could you still show significance?

RS: We have no idea what the power of the trial would be if the same rates of success in the two treatment groups continued through the remainder of enrollment to 190 patients, other than it is less than 90%. In fact, we may still have achieved statistical significance at 190 patients; however, you must keep in mind that for the efficacy analysis, the DMC was tasked with providing guidance so that our high power calculation of 90% was maintained, assuming there was a promising and meaningful signal in the primary endpoint, which there obviously appears to have been.

DB: What were your original assumptions and what caused the original assumptions made to be so far off?

RS: To estimate the trial size, we assumed that the results would be similar to that seen in the Phase 2 trial and assumed that the results would be slightly less positive. Unfortunately, the statistics required are 'non-parametric' (*note: see below for more detailed discussion of this point for the more technically interested*). Basically, this means we can't compare averages, for which statistics are very powerful, but must instead compare all the patients and their relative responses. As a result, when doing power calculations with non-parametric statistics, you essentially have to assume the variability in the placebo and treated arms of the study will remain the same. As we noted above in question 1, we knew this could likely not be the case, which is why we built in the interim analysis. While the need for about 70 additional patients may sound large, it may represent a fairly small shift in changes in either the placebo or treatment arm and, again, does indicate that there is a beneficial effect observed by the DMC.

Given the brisk enrollment rate that we have seen to date, the time to complete enrollment of the additional patients into the trial should be relatively small allowing us to disclose topline results by the end of the first half of 2020 as previously disclosed.

DB: What confidence do you have that the study will be successful with the need for 70 additional patients?

RS: With no other information, the chance of a positive trial at 260 evaluable patients is 90%. Risk is further reduced in this calculation because it is based on the actual patient population being enrolled in the Phase 3 trial across our current sites in both the US and Europe. Moreover, enrollment of the additional patients is also expected to further increase the chances that many of our secondary endpoints may also show statistical benefit, including infection rate and tumor resolution, which we believe could be important differentiating characteristics for SGX942.

DB: Why did you wait until the 90 patient mark for the interim analysis and not do something with a smaller number of patients?

RS: The primary objective of inclusion of the DMC interim analysis was to optimize the study's likelihood for success. The most critical information coming from the interim analysis was whether the assumptions concerning the relative success rates between and variability within the two treatment arms were 100% accurate. Assuming that they were not (which is what happened), the more precise measurement of the ***actual*** rates allowed for a more precise calculation on the total number of patients needed to conclusively prove that SGX942 was working. A lower number of patients at the interim would provide a less accurate (i.e., higher risk) recommendation. The more data points you have when evaluating an endpoint, the more confident you are in the accuracy of that evaluation. We felt comfortable that at 90 patients, the DMC would be able to assess the responses and provide an accurate recommendation, giving the study and SGX942 the best opportunity for success.

DB: Did you stop enrollment while you were doing the analysis or did you continue to enroll?

RS: As prospectively defined, the trial continued to enroll patients while the initial approximately 90 patients finished their treatment and data for the interim analysis was being cleaned, locked and analyzed. As we had indicated in our press release, we are currently at over 160 subjects enrolled.

DB: What is the impact to study timelines? How long will it take to get topline results?

RS: Again, there is NO change to the study timeline for topline final results.

The primary endpoint is determined about 3.5 - 4 months after enrollment and the necessary monitoring, review and audit of the data required to lock the database is complete. Thus, we expect that topline results will be available in this timeframe after the last patient is enrolled. Given the increased sample size of approximately 70 patients or a total of 260, our current enrollment rate would suggest that enrollment would be completed no later than Q1 2020 with topline results in the first half of 2020 as originally indicated.

DB: Do you have the money to complete the trial or will you need to raise additional capital?

RS: Given our currently available cash resources, we believe we have the capital to complete the trial.

DB: Do you expect to have trouble enrolling further patients because of the news that more patients are needed?

RS: No. We expect that most investigators participating in the trial will view the DMC feedback as positive since it strongly suggests that the drug is beneficial and requires only about 70 more patients to conclusively prove that SGX942 potentially works. Moreover, the clinical convenience of our program is something many investigators have noted. At the rate we are enrolling, the change in enrollment is within our currently anticipated timelines. We do not expect any problems with continuing our enrollment rate through to the end of the trial.

DB: For our more technically minded readers, what are non-parametric statistics and why are they important in this study?

RS: The most commonly used statistics (average, standard deviation, t-test, ANOVA) are all made possible by the intrinsic assumption that the underlying data forms a bell-shaped curve – with most of the data around the mean and fewer outliers making them more "predictable". However, some data is not distributed this way, like in complex patient populations with oral mucositis – it may be skewed to one end or the other (e.g., more high responders, or more low responders, or both). When this occurs, the statistical comparisons have to be done on the actual distributions of the data (that is, by accounting for every patient and their relative response to all other patients) rather than comparing summary statistics (mean and standard deviation). This means that non-parametric statistics have less "power" – sometimes a larger sample size is needed to see the same difference we would see with fewer samples in a bell-shaped curve. This does not mean you are seeing less of a clinical impact, just that it requires more subjects to elucidate benefit with the same statistical certainty.

The oral mucositis response is generally not parametric in nature. This was not only true of our Phase 2 data, but also of the oral mucositis data generated in previous trials (which Soligenix has proprietary access to). This is why we knew that an interim analysis for this study would be important. Again, the recommendation by the DMC indicated a beneficial effect is being observed and that additional subjects should allow for elucidating that benefit at 90% power.

Conclusion

We view the recommendation by the DMC to continue enrolling patients as a clear positive and that it is likely indicative of a treatment effect. The addition of 70 subjects into the trial is not a concern as the company has sufficient funds in place to finance the expanded trial and most importantly, it does not increase the time-frame to topline data, which is still expected in the first half of 2020. We are maintaining our $8.00 valuation.

PROJECTED FINANCIALS

Soligenix, Inc.	2018 A	Q1 A	Q2 A	Q3 E	Q4 E	2019 E	2020 E	2021 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$5.2	$1.1	$1.5	$1.4	$1.5	$5.6	$5.8	$6.0
SGX301	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
SGX942	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$5.2**	**$1.1**	**$1.5**	**$1.4**	**$1.5**	**$5.6**	**$5.8**	**$6.0**
Cost of Revenue	$4.6	$0.9	$1.1	$1.2	$1.3	$4.5	$4.9	$5.1
Gross Income	**$0.6**	**$0.2**	**$0.5**	**$0.2**	**$0.2**	**$1.1**	**$0.9**	**$1.0**
Gross Margin	*12.3%*	*18.9%*	*29.7%*	*13.1%*	*13.3%*	*19.0%*	*15.5%*	*15.8%*
Research & Development	$6.8	$1.6	$1.9	$1.9	$1.9	$7.3	$8.2	$9.8
General & Administrative	$3.0	$0.9	$0.8	$0.8	$0.8	$3.2	$3.7	$4.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	**($9.1)**	**($2.3)**	**($2.2)**	**($2.5)**	**($2.5)**	**($9.5)**	**($11.0)**	**($12.9)**
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.2	$0.0	$0.0	$0.1	$0.1	$0.2	$0.0	$0.0
Pre-Tax Income	**($8.9)**	**($2.3)**	**($2.1)**	**($2.5)**	**($2.5)**	**($9.3)**	**($11.0)**	**($12.9)**
Net Taxes (benefit)	$0.0	($0.6)	$0.0	$0.0	$0.0	$0.6	$0.0	$0.0
Tax Rate	*0.4%*	*27.1%*	*0.0%*	*0.0%*	*0.0%*	*6.6%*	*0.0%*	*0.0%*
Reported Net Income	**($8.9)**	**($1.6)**	**($2.1)**	**($2.5)**	**($2.5)**	**($8.7)**	**($11.0)**	**($12.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.09)**	**($0.12)**	**($0.12)**	**($0.12)**	**($0.45)**	**($0.48)**	**($0.48)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	13.2	18.1	18.4	20.3	20.5	19.3	23.0	27.0

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

HISTORICAL STOCK PRICE

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