Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

August 1, 2019
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Soligenix, Inc. (SNGX-NASDAQ)

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

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 (08/01/19)	$1.29
Valuation	**$8.00**

OUTLOOK

Soligenix, Inc. (SNGX) is a late-stage clinical biopharmaceutical company developing treatments in oncology, GI disorders, and biodefense. The company has three important catalysts coming up over the next 6 to 12 months: an interim efficacy analysis from the Phase 3 trial of SGX942 in oral mucositis (OM) in Sep. 2019; topline results from the Phase 3 trial of SGX301 in CTCL in the first quarter of 2020; and topline results from the Phase 3 OM trial in the first half of 2020. We recently spoke with Dr. Richard Straube, Soligenix's Chief Medical Officer, to get a better understanding of what to expect from the upcoming interim analysis.

SUMMARY DATA

52-Week High	**$2.10**
52-Week Low	**$0.67**
One-Year Return (%)	**6.61**
Beta	**1.14**
Average Daily Volume (sh)	**328,251**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$25**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**15**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-4.8**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-1.4**
P/E using 2019 Estimate	**-1.4**

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)
2018	1.1 A	1.7 A	1.4 A	1.0 A	5.2 A
2019	1.1 A	1.4 E	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	-$0.13 E	-$0.14 E	-$0.14 E	-$0.49 E
2019					-$0.48 E
2020					-$0.48 E

© Copyright 2019, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

Soligenix, Inc. (SNGX) is a biopharmaceutical company currently conducting two pivotal Phase 3 clinical trials with its lead development compounds.

- SGX301 is in a Phase 3 trial for the treatment of cutaneous T cell lymphoma (CTCL). Following a recommendation from an independent Data Monitoring Committee (DMC) to enroll an additional 40 patients in the trial to maintain 90% statistical power, we anticipate topline results in the first quarter of 2020.

- SGX942 is in a Phase 3 clinical trial for the treatment of oral mucositis in patients with squamous cell carcinoma of the oral cavity and oropharynx undergoing chemoradiation therapy. In April 2019, the company announced the trial had reached the enrollment target to support the planned interim efficacy analysis by the independent DMC targeted to take place no later than September 2019.

In preparation for the results of the interim analysis for the SGX942 trial, we interviewed Dr. Richard Straube, Soligenix's Chief Medical Officer, and asked him a few questions regarding what to expect from the upcoming interim analysis.

DB: Could you give us a brief overview of the mechanism of action of SGX942?

RS: Dusquetide (the active ingredient in SGX942) is an Innate Defense Regulator. The innate immune system is the pre-programmed, immediate-action component of the immune system which protects a person from a majority of threats and helps contain threats until the adaptive immune system (B-cells, T-cells, and antibodies) can be launched. The innate immune system acts rapidly through a plethora of pre-programmed receptors and response molecules. Dusquetide is unique in its mechanism because instead of trying to interact with one of the many pre-programmed receptors or a specific response molecule such as TNFα, it instead targets an intracellular convergence point in the innate immune system, changing the response of the innate immune system to increase its ability to fight infection and heal tissue while controlling the inflammatory response. Many times, the response of the innate immune system is problematic because of "runaway" inflammation – dusquetide controls the amount of inflammation preventing the secondary damage inflicted by the "runaway" inflammation.

DB: How does SGX942 compare with other treatments that are in development for OM?

RS: Other compounds in development for OM either try to "mop up" the free radicals generated by radiation therapy or some of the signaling molecules from the dying cells (damage associated molecular patterns or DAMPs) – both of which are involved in triggering the inflammatory response of the innate immune response. Other compounds target tissue repair mechanisms. Each of these mechanisms addresses a single aspect of the pathophysiology of oral mucositis. In contrast, dusquetide modulates the innate immune response to *any* trigger (free radicals, DAMPs, etc) and increases both tissue healing and infection fighting *without* potentially increasing tumor growth or interfering with tumor treatment.

DB: Are there any treatments available for OM?

RS: There is currently no approved drug for the treatment of oral mucositis in the context of any solid tissue cancer (including head and neck cancer, breast cancer, etc.). Symptomatic treatments include ice chips (to help control inflammation in the mouth), mouth rinses and gels to prevent abrasion of the mucosal surface in the mouth, and topical and systemic pain medications (e.g., topical lidocaine, topical & systemic opioids).

There has been an approved drug for the prevention of oral mucositis in patients with blood cancers undergoing stem cell transplantation. This product, a tissue growth factor, is contra-indicated in any solid tumor setting due to its potential to trigger tumor growth.

DB: Can you briefly remind us what you had seen in your Phase 2 Study?

RS: In our Phase 2 study we saw a reduction in the duration of severe oral mucositis of at least 50% and up to 67% in patients with the highest risk of oral mucositis. It is this high risk population we are also studying in our Phase 3 study. The real risk of oral mucositis (the inability to eat and/or drink) is the length of time it occurs for. A single day of not eating and/or drinking has minimal risk; however, a couple of weeks of impaired eating and/or drinking is associated with increased dehydration, malnutrition, and ultimately with hospitalization and severe infection. Thus, decreasing the duration of severe oral mucositis is critical to mitigating its consequences. In the Phase 2 study, the highest risk patient group receiving placebo had a median duration of 30 days (1 month) of severe oral mucositis (with some patients experiencing in excess of 70 days) while the SGX942 treatment group had a median duration of only 10 days of severe oral mucositis. Other secondary endpoints such as the incidence of severe oral mucositis, the duration of ulcerative oral mucositis (lower grade of oral mucositis), the number of days with severe oral mucositis, etc., showed improvements with SGX942 treatment as well. Of particular importance, there were also 2 ancillary benefits associated with SGX942 treatment: 1) an increase in the rate of tumor resolution in patients treated with SGX942 and 2) a decrease in the rate of infection in patients treated with SGX942. We also saw an increase in survival in the SGX942 treated group over the 1-year follow-up period. In principle it is not known if these positive benefits were a direct action of SGX942 or due to the reduction in the duration of oral mucositis, but in either case there was a clear potential benefit to the patient.

DB: What is the primary endpoint of the Phase 3 trial?

RS: The primary endpoint of the Phase 3 trial in oral mucositis is a reduction in the duration of severe oral mucositis. Severe oral mucositis results in patients being unable to eat and/or drink. A few days of this is unpleasant, but bearable. Weeks of severe oral mucositis can result in dehydration, malnutrition, hospital admission and increased risk of serious infection. Thus, reducing the duration of severe oral mucositis addresses the core clinical issue, allowing patients to better tolerate their cancer treatment and perhaps increasing the likelihood that they will complete the planned treatment regimen, enhancing their likelihood of survival.

DB: What is the purpose of the interim analysis? What are the potential outcomes?

RS: In any clinical study, the number of subjects to be enrolled is determined on the basis of a number of assumptions. These include the rate of disease in the placebo population (e.g., what proportion of the head and neck patients will experience severe oral mucositis), the extent of disease in the placebo population (e.g., what will the duration of severe oral mucositis be in the placebo population), and what the response to drug is (e.g., how much improvement is expected in the treated population). Soligenix standardly makes conservative estimates, coupled with a 90% statistical power requirement, to estimate sample size. However, particularly in areas of unmet medical need or orphan disease, the estimates of disease rate in the placebo population are based on a limited number of studies and may be inaccurate. This could result in a study which just barely misses statistical significance due to inappropriate sample sizes. The interim analysis allows an independent DMC to look at the unblinded data partway through the study and recommend one of the following options:

1. To stop for futility
2. To stop for overwhelming efficacy (this is unlikely as the statistical threshold or hurdle required for significance in the trial is very high)
3. To continue the enrollment as planned (approximately 190 subjects for the trial)
4. To modify the total number of subjects planned to be enrolled.

Importantly, the company, the clinical investigators and the subjects in the trial remain completely blinded. The only information provided by the DMC to the company is one of these recommendations with no further justifications or explanations.

DB: If positive, will this study support an application for approval?

RS: Yes. Topline results for the study will be available in the first half of 2020, pending the recommendation of the DMC.

DB: How large is the market opportunity in OM?

RS: There are about 90,000 head and neck cancer patients in the US every year, most of which are at significant risk of experiencing severe oral mucositis. Similar patient populations occur in Europe. Just considering the US and Europe alone, we expect this to be a $500M+ market. Of course, there are a lot of head and neck cancer patients in other parts of the world.

Another consideration is that the pathophysiology of oral mucositis is the same regardless of whether it is triggered by radiation or chemotherapy. There are many other patients at risk of severe oral mucositis, including, for example, those with breast cancer receiving cycle chemotherapy. In the longer term, expansion of SGX942 to other indications would be expected to further increase the potential market.

DB: What is the company's IP position for SGX942?

RS: Soligenix has the composition of matter and therapeutic use patents for dusquetide, which is a novel chemical identity. In addition, Soligenix has protection for a number of associated analogs and moreover has additional proprietary analogs for use in other indications.

Conclusion and Valuation

We value Soligenix using a probability adjusted discounted cash flow analysis based on potential future revenues of SGX301 in CTCL and SGX942 in OM. For SGX301, we model for approval in 2021 and peak revenues of approximately $200 million worldwide. Using a 70% probability of approval and a 13% discount rate leads to a net present value of $73 million. For SGX942, we model for approval in 2021 and peak revenues of approximately $350 million worldwide. Using a 60% probability of approval and a 13% discount rate leads to a net present value of $104 million. Combining the net present value for those two products with the company's current cash position, the potential cash from exercising warrants, and using a fully diluted share count of 25.8 million shares leads to a valuation of approximately $8.00 per share.

Soligenix is currently trading at a significant discount to our valuation, and with an impending interim analysis report from one Phase 3 trial and a data readout in early 2020 from a second Phase 3 trial, we believe investors would be well served to take a closer look at the company in the leadup to those readouts.

PROJECTED FINANCIALS

Soligenix, Inc.	2018 A	Q1 A	Q2 E	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	$1.4	$1.4	$1.5	$5.4	$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**	**$1.4**	**$1.4**	**$1.5**	**$5.4**	**$5.8**	**$6.0**
Cost of Revenue	$4.6	$0.9	$1.2	$1.2	$1.3	$4.6	$4.9	$5.1
Gross Income	**$0.6**	**$0.2**	**$0.2**	**$0.2**	**$0.2**	**$0.8**	**$0.9**	**$1.0**
Gross Margin	*12.3%*	*18.9%*	*14.3%*	*13.1%*	*13.3%*	*14.7%*	*15.5%*	*15.8%*
Research & Development	$6.8	$1.6	$1.8	$1.9	$1.9	$7.2	$8.2	$9.8
General & Administrative	$3.0	$0.9	$0.8	$0.8	$0.8	$3.3	$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)**	**($2.4)**	**($2.5)**	**($2.5)**	**($9.7)**	**($11.0)**	**($12.9)**
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.2	$0.0	$0.1	$0.1	$0.1	$0.2	$0.0	$0.0
Pre-Tax Income	**($8.9)**	**($2.3)**	**($2.4)**	**($2.5)**	**($2.5)**	**($9.5)**	**($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%*	*6.4%*	*0.0%*	*0.0%*
Reported Net Income	**($8.9)**	**($1.6)**	**($2.4)**	**($2.5)**	**($2.5)**	**($8.9)**	**($11.0)**	**($12.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.09)**	**($0.13)**	**($0.14)**	**($0.14)**	**($0.49)**	**($0.48)**	**($0.48)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	13.2	18.1	17.9	18.0	18.1	18.0	23.0	27.0

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

© Copyright 2019, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2019, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.