Zacks Small-Cap Research

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# Soligenix, Inc.

**(SNGX-NASDAQ)**

***SNGX: Interview with Dr. Straube Regarding the Upcoming Phase 3 CTCL Data Readout…***

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 (01/06/20) | $1.45 |
| **Valuation** | **$8.00** |

## OUTLOOK

Soligenix, Inc. (SNGX) is currently conducting a Phase 3 clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL). The company recently announced the final patient was enrolled and we anticipate topline data being reported in the first quarter of 2020.

We recently conducted an interview with Soligenix Chief Medical Officer Dr. Richard Straube to gain additional insight into CTCL, the upcoming data read out, and how SGX301 could potentially help patients with this debilitating disease.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$1.45** |
| **52-Week Low** | **$0.67** |
| **One-Year Return (%)** | **50.26** |
| **Beta** | **1.40** |
| **Average Daily Volume (sh)** | **173,914** |
| **Shares Outstanding (mil)** | **21** |
| **Market Capitalization ($mil)** | **$30** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **10** |
| **Insider Ownership (%)** | **16** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **-12.3** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2018 Estimate** | **-2.1** |
| **P/E using 2019 Estimate** | **-2.1** |

| | |
|---|---|
| **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 | 1.5 A | 1.3 A | 1.5 E | 5.4 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 | -$0.14 A | -$0.12 E | -$0.46 E |
| 2019 | | | | | -$0.48 E |
| 2020 | | | | | -$0.48 E |

## WHAT'S NEW

**Business Update**

*Interview with Dr. Richard Straube Regarding Upcoming Phase 3 Data for SGX301 in CTCL*

Soligenix, Inc. (SNGX) recently announced the completion of enrollment in the Phase 3 clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL). The FLASH (Fluorescent Light Activated Synthetic Hypericin) trial is a randomized, double blind, placebo controlled study that was originally expected to enroll approximately 120 subjects with either Stage IA, IB, or IIA mycosis fungoides (the most common type of CTCL) across 30 centers in the U.S (NCT02448381). We anticipate topline results in the first quarter of 2020.

To gain a better understanding of CTCL and what to expect from the upcoming data release, we conducted an interview with Soligenix Chief Medical Officer Dr. Richard Straube. We provide some highlights from the interview below that we think are the most important details for investors, with the full interview following.

- *"We expect the topline primary endpoint data to be available in the first quarter of 2020."*
- *"We conservatively estimate a total global market (in CTCL) of approximately $250M."*
- *"There is no cure for CTCL. Further, there is no approved front-line therapy for the disease, making it an area of unmet medical need."*
- *"SGX301 (synthetic hypericin) is a topical drug ointment that a patient applies to their lesions and then activates it with light therapy… it is NOT expected to be associated with an increased risk of malignancies nor of long-term skin damage."*
- *"Many of the participating investigators have stated that SGX301, if/when approved, will have a definite place in the CTCL armamentarium, where a safe, well tolerated, front-line therapy is currently needed."*

**DB**: Consistent with the company's guidance, Soligenix recently announced completion of enrollment in the Phase 3 trial of SGX301 in patients with CTCL. Just to confirm, when do you anticipate topline results?

**RS**: We expect the topline primary endpoint data to be available in the first quarter of 2020. Additional data reporting on the treatment outcomes at the end of the second and third open-label cycles of the study as well as safety outcomes at the end of the six-month follow-up period, will be available shortly thereafter in the following quarters.

**DB**: Can you provide a bit of background on CTCL and why it is an area of unmet medical need?

**RS**: CTCL is a rare type of Non-Hodgkin's Lymphoma (NHL) and is specifically caused by malignant T cells that are attracted to the skin. There is no cure for CTCL. Further, there is no approved front-line therapy for the disease, making it an area of unmet medical need. Disease management is the key goal for this chronic disease setting.

In the early stages of disease, the malignant T cells migrate to the surface of the skin, causing patches, plaques, and tumors that can come and go at the skin surface. In the later stages of disease, tumors can expand and the T cells can also circulate more systemically. Early stage disease has fairly good survival rates (~88% over 5 years), and is treated more like management of any chronic disease. For example, it may be similar to suffering from psoriasis, which is caused by the migration of non-malignant T cells to the skin surface. If the disease advances, which happens in a subset of patients that can't be readily predicted, then 5-year survival rates can be very low, around 24%.

For most patients and doctors, managing CTCL is about managing the discomfort of the lesions, which can be very painful, itchy, and are cosmetically unbecoming. The problem is that the treatments themselves are not benign. Cancer treatments are obviously meant to kill cancer cells, but there is often collateral damage, including damage to otherwise normal tissue. This is particularly true in CTCL where most of the current treatments are themselves mutagenic agents – that is, they kill the tumor cells by mutating DNA, and this can cause DNA mutations in the normal skin cells as well, significantly raising the risk for secondary cancers such as melanoma. Thus, patients and their caregivers are faced with trying to treat a less lethal, but difficult disease, with treatments that raise their risk of a more lethal cancer. Aside from the risk of cancer, there is also significant skin damage, which can cause premature aging, as well as allergic and local irritation associate with several of the treatments.

**DB**: How do you anticipate SGX301 being used in the treatment of CTCL?

**RS**: SGX301 (synthetic hypericin) is a topical drug ointment that a patient applies to their lesions and then activates it with light therapy. This is a type of Photodynamic Therapy, which is a very common and well known treatment among dermatologists. The first step involves the patient applying the ointment to their lesions at home the day before an expected doctor's visit. This allows hypericin to be preferentially absorbed by the malignant T cells. The next day, the patient visits the doctor's office and sits or stands in front of our proprietary, safe, fluorescent light device and the lesions are exposed to a specific wavelength of light for an average of 5-7 minutes.

This combination of ointment application and light exposure constitutes a single treatment. The treatment course in our Phase 3 trial is characterized by two of these treatments per week for a minimum of six weeks.

**DB**: What is the potential market size?

**RS**: While CTCL is relatively rare, the prevalence of the disease is estimated to be between 20,000 and 40,000 patients in the US alone. Each of these patients would be eligible for treatment with SGX301 sometime in the long-term management of their disease. Accounting for 20,000 patients in each of the US and Europe, we conservatively estimate a total global market of approximately $250M.

**DB**: Can you briefly review the type of therapy SGX301 is and its mechanism of action?

**RS**: SGX301 is a combination product – a topically applied ointment (synthetic hypericin) which is activated by safe, cost-effective fluorescent light, causing it to release free radicals (superoxide) which induce apoptosis (programmed cell death of the lesion cells). Importantly, cell death is NOT caused by DNA mutation, and therefore hypericin is not mutagenic. Moreover, the light source used (fluorescent light) is not carcinogenic. Damage to healthy tissue is minimized by applying the ointment only on the cancerous lesions themselves and selective uptake of the drug preferentially by malignant cells. Thus, compared to other CTCL therapies, SGX301 is uniquely positioned, as it is NOT expected to be associated with an increased risk of malignancies nor of long-term skin damage.

We expect SGX301 to have a significant impact, if approved, since it is expected to be a very safe therapy for a disease which currently has no available first-line therapy and all secondary therapies come with significant safety concerns. Additionally, because of its benign safety profile, we expect SGX301 to be used repeatedly, as needed. We also expect that it can be used in combination with most other therapies for the treatment of more severe, later-stage disease, again because of its benign safety profile and the lack of interference with other CTCL treatments.

**DB**: Can you briefly review the Phase 3 protocol design?

**RS**: The Phase 3 trial is actually designed as three distinct cycles of treatment.

The first cycle is defined as the treatment period for the primary endpoint in the trial. Cycle 1 is the randomized *double-blind* portion of the study with a 2:1 randomization of SGX301: placebo across approximately 160 subjects. The subjects treat their three index lesions twice a week for six weeks, with escalating light exposure until a study defined maximum light exposure is reached. After a 2-week rest period, the size and characteristics of the 3 index lesions are assessed and the improvement in lesion scores for all three lesions are compared to the cumulative score for those same lesions at baseline. An improvement of ≥ 50% is considered a successful response. It is worth noting that this Cycle 1 is placebo-controlled because there is no approved first-line therapy for management of early stage CTCL.

The second cycle of the study is an *unblinded* portion. All patients treat their three index lesions with SGX301, using the same procedure as in Cycle 1. The lesions are characterized at the beginning and the end (week 8) of the cycle.

The third cycle of the study is also *unblinded* and is *optional*. In this cycle, patients can treat all their lesions with SGX301, using the same procedure as in Cycle 1.

Following Cycle 3 (or Cycle 2 if the patients don't opt into Cycle 3), a six-month follow-up is undertaken.

This study design allows us to evaluate treatment response in the blinded portion of the trial, as well as the effect of extended treatment of some or all cancerous lesions in the subsequent unblinded cycles. This further allows us to assess if some patients (or some lesions with specific characteristics) benefit from longer treatment, as well as assessing safety of prolonged use.

It is important to recognize that while the clinical trial looks at treatment endpoints over specific treatment timelines, for comparison purposes, the realities of clinical use in the dermatological setting will likely dictate more customized treatment until the patient and/or clinician feels there is disease resolution and/or no further improvement. To better inform this clinical scenario, Cycles 2 and 3 were introduced into the study to assess SGX301's longer term use.

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

**RS**: The SGX301 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 smaller Phase 2 sample size. 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 recommendation to enroll additional subjects actually implies that they saw a meaningful difference with treatment.

**DB**: What does the competitive landscape look like in CTCL and how is SGX301 differentiated?

**RS**: As we talked about previously, there is no cure for CTCL and no approved first-line treatment. As CTCL is a chronic cancer, patients may rotate among many available treatments throughout their lifetime, attempting to manage this chronic disease and prevent progression to more fatal advanced disease. Because of this, there is no real "competition" in the market – every available treatment may eventually be used by most patients. However, there is an order of preference for treatment, and as noted, no approved first-line therapy for early stage CTCL. Therefore, SGX301 has the potential to fill this area of unmet medical need. Again, because of side effect profiles of all the currently available therapies, they are all meant to be used when other therapies fail – a bit of a chicken or egg situation that reflects the lack of any "front line" therapy for CTCL.

Our treatment is differentiated primarily on the basis of its expected safety. Using a compound which is not mutagenic, is preferentially absorbed by the malignant T cells and which is highly photosensitive, we are able to utilize a safe light source (fluorescent light vs. ultraviolet light) over a shorter period of time. This means that there should be no significant risk of skin damage or secondary cancers. This safety profile means that SGX301 has the potential to be a preferable long-term treatment approach for many patients at various disease stages, including patients that may be delaying all treatment because of the risk of secondary cancers.

**DB**: Have you received any initial thoughts or feedback from clinicians participating in the trial? Is there excitement for SGX301?

**RS**: The short answer is yes, there is excitement. I am hesitant to mention specific names of participating investigators at this time, as I have not received their clearance; however, what I can say is that many of the participating investigators have stated that SGX301, if/when approved, will have a definite place in the CTCL armamentarium, where a safe, well tolerated, front-line therapy is currently needed.

**DB**: Later in 2020 we expect data from the company's second Phase 3 program in oral mucositis, which has also received a positive recommendation from an independent DMC. Can you give us an update on the status of that trial?

**RS**: Our oral mucositis study is actively enrolling in a pivotal Phase 3 clinical trial in patients undergoing chemoradiation therapy for head and neck cancer. With a DMC recommendation to enroll a total of approximately 260 subjects, we expect to maintain our excellent enrollment rate across our US and European study sites, and to provide topline efficacy results on the heels of our Phase 3 CTCL study, in the second quarter of 2020.

We expect the first half of 2020 to be very productive and busy!

## Conclusion

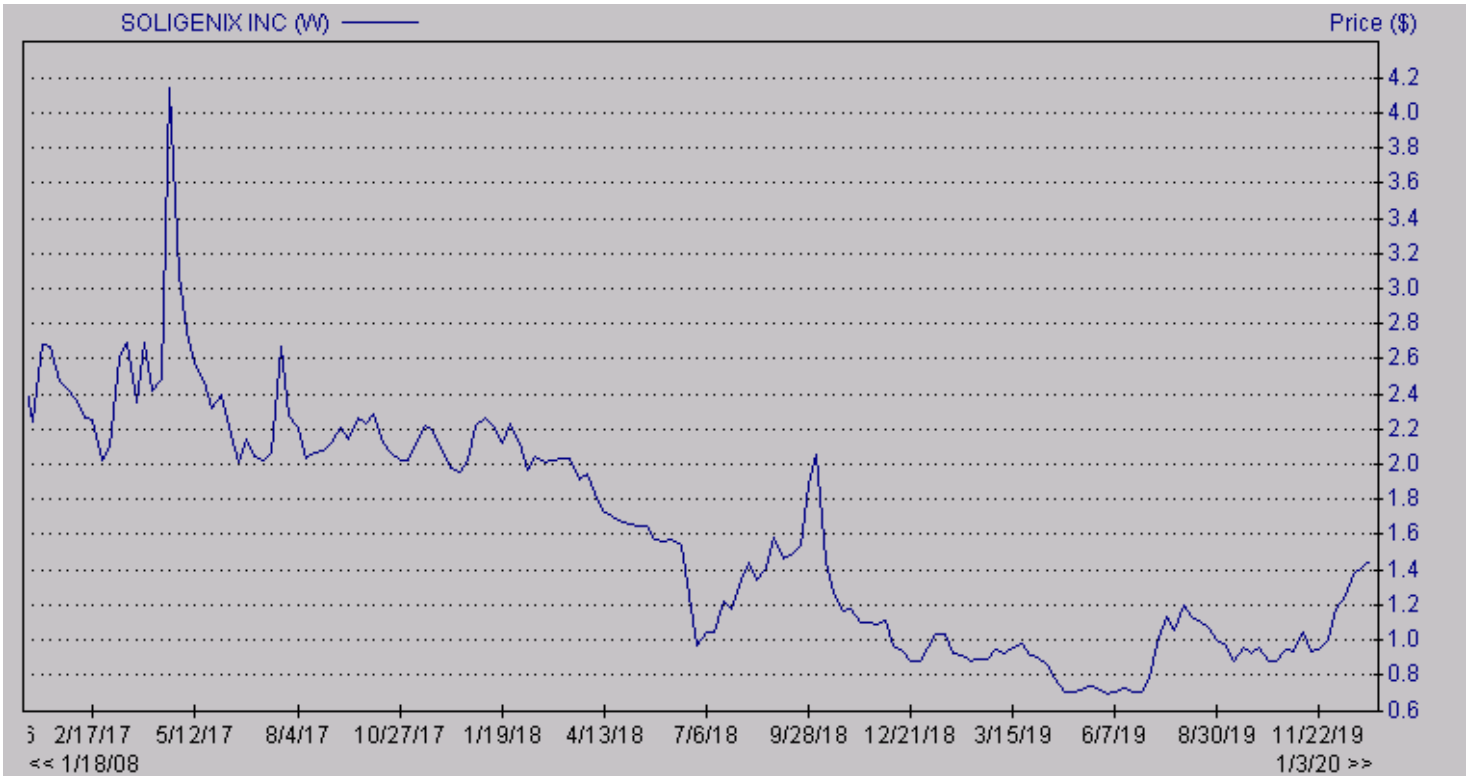
We thank Dr. Straube for providing an excellent overview of SGX301 and CTCL and we are looking forward to the results of the Phase 3 trial in the first quarter of 2020. The company will also be reporting data from the Phase 3 study of SGX942 in oral mucositis in the second quarter of 2020. With the stock trading at a significant discount to our current valuation of $8 per share, we believe investors should consider taking a closer look at Soligenix ahead of the very important near-term inflection points.

## PROJECTED FINANCIALS

| Soligenix, Inc. | 2018 A | Q1 A | Q2 A | Q3 A | 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 | $1.3 | $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** | **$1.5** | **$1.3** | **$1.5** | **$5.4** | **$5.8** | **$6.0** |
| Cost of Revenue | $4.6 | $0.9 | $1.1 | $1.0 | $1.3 | $4.3 | $4.9 | $5.1 |
| **Gross Income** | **$0.6** | **$0.2** | **$0.5** | **$0.3** | **$0.2** | **$1.2** | **$0.9** | **$1.0** |
| *Gross Margin* | *12.3%* | *18.9%* | *29.7%* | *23.1%* | *13.3%* | *21.4%* | *15.5%* | *15.8%* |
| Research & Development | $6.8 | $1.6 | $1.9 | $2.3 | $1.9 | $7.7 | $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)** | **($2.8)** | **($2.5)** | **($9.7)** | **($11.0)** | **($12.9)** |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Other Income (Net) | $0.2 | $0.0 | $0.0 | $0.0 | $0.1 | $0.2 | $0.0 | $0.0 |
| **Pre-Tax Income** | **($8.9)** | **($2.3)** | **($2.1)** | **($2.7)** | **($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)** | **($2.1)** | **($2.7)** | **($2.5)** | **($8.9)** | **($11.0)** | **($12.9)** |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($0.67)** | **($0.09)** | **($0.12)** | **($0.14)** | **($0.12)** | **($0.46)** | **($0.48)** | **($0.48)** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Basic Shares Outstanding | 13.2 | 18.1 | 18.4 | 20.1 | 20.5 | 19.3 | 23.0 | 27.0 |

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

## HISTORICAL STOCK PRICE




Source: Zacks Small Cap Research

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