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February 18, 2020
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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: KOL Interview with Dr. Brian Poligone, an Investigator in P3 FLASH Study in CTCL…

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 (02/18/20)	$2.79
Valuation	**$8.00**

OUTLOOK

On February 11, 2020, Soligenix, Inc. (SNGX) announced that Brian Poligone, MD, PhD, who is the Director of the Rochester Skin Lymphoma Medical Group in Fairport, NY and an Investigator in the ongoing Phase 3 FLASH clinical trial of SGX301 in patients suffering from cutaneous T cell lymphoma (CTCL), recently presented a patient case study at the 4th World Congress of Cutaneous Lymphoma. The presentation described a CTCL patient that achieved complete clearance of disease as a participant in the FLASH trial. The patient had previously failed at least five therapies.

We were also fortunate to get Dr. Poligone to answer some questions about CTCL, how he currently treats CTCL patients, and where SGX301 could fit into the treatment paradigm for the disease.

SUMMARY DATA

52-Week High	**$2.98**
52-Week Low	**$0.67**
One-Year Return (%)	**211.00**
Beta	**1.38**
Average Daily Volume (sh)	**537,614**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$58**
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	**-7.0**
P/E using 2019 Estimate	**-15.1**

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

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WHAT'S NEW

Business Update

Interview with Dr. Brian Poligone Regarding SGX301 and the Phase 3 FLASH Trial

Soligenix, Inc. (SNGX) is currently conducting a 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.

Following his presentation of a case study regarding a CTCL patient who participated in the FLASH Trial (discussed below), we were fortunate to get Dr. Brian Poligone, the Director of the Rochester Skin Lymphoma Medical Group in Fairport, NY and an Investigator in the FLASH trial, to answer some questions about CTCL, how he currently treats CTCL patients, and where SGX301 could fit into the CTCL treatment paradigm. Some highlights from the interview with Dr. Poligone are listed below, with the full interview following.

- *"The safety of SGX301, coupled with the long-term treatment effect was extremely impressive."*
- *"Our main goal is to get the disease to respond to therapy without introducing new risks or side effects to the patient."*
- *"We need full body skin-directed therapies that are safer and have less long-term side effects."*
- *"It (SGX301) would be a first-line option for early stage patients."*
- *"Through its different mechanism of action, SGX301 is practical for all early stage patients."*
- *"SGX301 could be an appropriate option to consider for a majority of my early stage patients."*

DB: How long have you been treating cutaneous T cell lymphoma (CTCL)?

BP: I have directed a large clinic for 11 years and treated CTCL for 15 years.

DB: Briefly, can you tell me why the SGX301 patient case study you recently presented was important to share at the World Congress?

BP: There are many types of CTCL – and FMF (folliculotropic mycosis fungoides) is particularly difficult to treat because it is "deep" within the skin layer. This often requires earlier adoption of systemic therapies, which are associated with more severe side effects. The success in this case is particularly meaningfully because of the prior failures with standard therapies, including topical treatments, oral medications, and phototherapy, before being treated with SGX301. The safety of SGX301, coupled with the long-term treatment effect was extremely impressive.

DB: What are the main characteristics of early stage CTCL?

BP: Patients present with a skin eruption that mimics multiple other entities in dermatology, but most commonly dermatitis. Usually, up to 80% of the surface of the skin is affected and lesions appear as plaques or patches. The most common areas of the skin involved are the sun-protected areas of the body that don't normally get exposed to much sunlight during the course of a day. The areas of visible disease may have scales and show wrinkling, and patients often have itching and sometimes pain.

DB: What are the primary concerns of patients who have CTCL?

BP: Initially, patients are concerned with the prognosis and mortality of this cancer because there is currently no definitive cure for this disease. Then, the concerns shift to the burden of skin disease; that includes skin exposure to treatments, itching that can get quite severe, scaling, and the impact on one's personal life. Patients with skin-restricted disease generally have a good quality of life and most will die with the disease, not because of it. We work to treat symptoms when present, induce clearance of the skin lesions, and help avoid the adverse effects of treatment.

DB: What are the primary concerns of physicians treating patients with CTCL?

BP: The primary concern for a physician is achieving a complete response, but more realistically there are concerns around controlling symptoms to improve patient quality of life, disfiguring lesions that are cosmetically distressing, and preventing progression to advanced disease. There is also the consideration of long-term cumulative side effects and toxicities from certain treatments and choosing treatments that are affordable and sustainable. Our main goal is to get the disease to respond to therapy without introducing new risks or side effects to the patient. Since they may live with this chronic condition for a long time, the side effect profile of every potential treatment is a critical consideration. In particular, any accumulating risk for other malignancies (e.g., melanoma) is also a strong treatment driver.

DB: For early stage CTCL patients, can you discuss the level of importance and priority you give to alleviation of symptoms versus complete clearance of disease in your treatment goals?

BP: With complete clearance you obtain alleviation of symptoms (e.g., itching, burning, scaling, and flaking of skin). Therefore, I strive for complete clearance with the knowledge that I often won't get there. On the journey, we demand an alleviation of symptoms, while we do not demand complete clearance. Symptom management is a key factor and influences the decisions in my treatment paradigm. For example, I will not necessarily stop a treatment just because we have not completely cleared it after 6-12 months on therapy. However, I will change if there is not an alleviation of these difficult and disruptive symptoms.

DB: Why is there such an unmet medical need in first-line treatment of CTCL?

BP: CTCL can be an isolating disease – it's rare, takes a while to get diagnosed, and most laypersons and physicians have never heard of it or have seen only one case. Even once a diagnosis is achieved, there is no curative treatment.

We only have three main therapies for early stage CTCL: topical mustard, topical steroids, and phototherapy. Many of these are not FDA approved specifically for treatment of CTCL, and all have their limitations. Additional treatment options which have minimal side effects are needed. Topical steroids reduce redness/inflammation and may reduce the lesion size, but even if they completely clear the lesion, the lesions eventually relapse over several months and long-term use is not an option due to the side effect profile. Other topicals, such as retinoids and imiquimod, are associated with irritation, which can reduce compliance. Narrow-band phototherapy can be helpful for treating larger surface involvement, but phototherapy also carries the potential for relapse and has an increased skin cancer risk. We need full body skin-directed therapies that are safer and have less long-term side effects.

DB: What are your thoughts on SGX301 and its place in the treatment paradigm? Assuming FDA approval, would you anticipate using (SGX301) first-line? How does SGX301 compare to other therapies for early stage CTCL?

BP: By all current indications, SGX301 appears to be safe, well tolerated, and effective. It is a photodynamic therapy with a non-UV light which provides an advantage in that it does not carry the same concern of increased risk of secondary skin cancers that are associated with UV treatments. This would be a very important treatment option for patients. It would be a first-line option for early stage patients. Compared to other treatments, the main differentiating factor is the superior long-term side effect profile since the mechanism of action does not cause genetic mutation, unlike traditional phototherapy, and

there is no known increase in long-term risk of skin cancers/melanoma. The treatment procedure is similar to phototherapy. It requires the patient to apply SGX301 sensitizer 18-24 hours prior to light exposure, so coordination is required. However, it is convenient to have a treatment used only a few times a week instead of daily. It has also been well tolerated and photosensitivity is less of a problem than what is typically seen with traditional phototherapy.

DB: Why is safety such an important consideration in treating early disease?

BP: CTCL is a low-grade lymphoma without a cure. Initial trials to treat CTCL like systemic lymphoma were unsuccessful and proved no better than topical treatments. Systemic cytotoxic chemotherapy leads to severe side effects with short-term response followed by recurrence. Instead, patients are treated for years and chronic damage to the skin is common with topical steroids and phototherapy. Through its different mechanism of action, SGX301 is practical for all early stage patients. The reality is, we are likely to be treating each patient for many years, and I need options to treat the patients that do not put them at risk for other conditions. SGX301 could potentially do just that.

DB: Based on your experience with SGX301 in the clinical trial – how do you anticipate using the product clinically if/when approved? What patients do you think would be best treated with SGX301?

BP: The clinical trial was, of course, designed to present a concrete endpoint for statistical measurement to the FDA. However, in practice with skin-directed therapies, we typically treat continuously until we observe a response, which is generally months depending on the patient's severity of disease. Therefore, I would envision using the approved drug labeling as a starting point for treatment, and adjust treatment based on lesion response. Generally speaking, with currently available skin-directed therapies for CTCL, a reasonable response rate is in the range of 20-50% after months of treatment. We will know the Phase 3 SGX301 results soon enough, but I can't stress enough the importance of having new and safe modalities for first-line treatment of CTCL.

As for patient eligibility, I would discuss skin-directed options such as SGX301 for all patients that have greater than a few percent body surface area involvement. The treatment may also be preferable for those who are candidates for phototherapy, but already have significant sun damage. SGX301 could be an appropriate option to consider for a majority of my early stage patients. Overall, 30-50% of my patients may end up receiving this therapy.

Patient Case Study Presented at World Congress of Cutaneous Lymphomas

On February 11, 2020, Soligenix announced the presentation of a patient case study at the 4th World Congress of Cutaneous Lymphoma by Dr. Poligone. The presentation focused on a single patient suffering from FMF, a very difficult to treat type of CTCL. This patient participated in the Phase 3 FLASH trial, including the open-label cycles and six-month follow up, and had previously failed at least five therapies, including topical treatments, oral medications, and phototherapy. As a participant in the FLASH trial the patient received at least 12 weeks of SGX301 and eventually had complete clearance of disease that they had previously been suffering from for at least four years.

Conclusion

We thank Dr. Poligone for providing an excellent overview of CTCL and how SGX301 could be used in the treatment of CTCL patients. 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. While the stock is up >100% over the past couple of months it continues to trade at a significant discount to our current valuation of $8 per share, thus 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*

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HISTORICAL STOCK PRICE



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