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Soligenix, Inc.

(SNGX-NASDAQ)

SNGX: CTCL Phase 3 Trial Fully Enrolled; Data in 1Q20…

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 (12/05/19)	$1.01
Valuation	**$8.00**

OUTLOOK

On December 3, 2019, Soligenix, Inc. (SNGX) announced the completion of enrollment for the Phase 3 clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL). We anticipate topline data being reported in the first quarter of 2020.

The company is also continuing enrollment in the Phase 3 clinical trial of SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer and we anticipate topline data in the second quarter of 2020.

SUMMARY DATA

52-Week High	**$1.31**
52-Week Low	**$0.67**
One-Year Return (%)	**0.75**
Beta	**1.32**
Average Daily Volume (sh)	**63,409**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$21**
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

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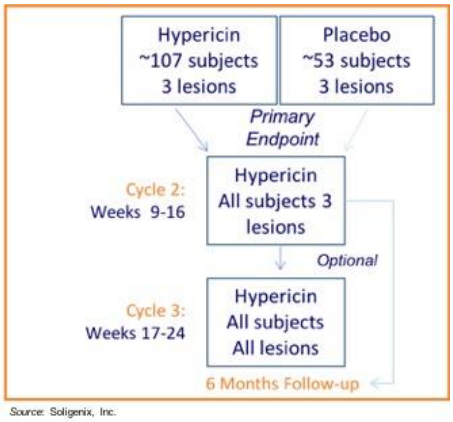
Business Update

Phase 3 Trial of SGX301 in CTCL Fully Enrolled; Data in 1Q20

On December 3, 2019, Soligenix, Inc. (SNGX) announced that enrollment has completed 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). In October 2018, the company announced a positive recommendation from the independent Data Monitoring Committee (DMC), which recommended that the company enroll an additional 40 subjects into the trial to maintain 90% statistical power for the primary endpoint. A total of 169 subjects were ultimately enrolled into the trial. *Please see our previous Q&A session with Soligenix's Chief Medical Officer that provides additional details about the interim analysis and the recommendations from the DMC.*

The trial consists of three treatment cycles, with each cycle lasting eight weeks. Each study subject will have three target lesions treated during the trial. In cycle one, patients will be randomized 2:1 to receive twice weekly treatment of either 0.25% SGX301 or placebo (an ointment with the same light exposure as for SGX301) for six weeks, with treatment response determined at the end of the eighth week. In cycle two, all subjects will receive 0.25% SGX301 on their target lesions, and for those that decide to continue in the trial there is a third treatment cycle where 0.25% SGX301 will be applied to all of the patient's lesions. Thus far, the majority of patients who have made it to the third cycle of the trial have elected to continue with it.

The primary endpoint of the trial is the percentage of patients treated with SGX301 achieving a partial or complete response of the treated lesions, which is defined as a ≥50% reduction in the total Composite Assessment of Index Lesion Disease Severity (CAILS) score at the end of cycle 1 (week 8), compared to patients receiving placebo. Secondary endpoints include duration of treatment response, degree of lesion improvement, and safety. An outline of the trial is shown below.



With enrollment now complete, we anticipate topline results in the first quarter of 2020.

Phase 2 Study Showed SGX301 to be Safe and Efficacious

A multicenter, open label, placebo controlled phase 2 study of SGX301 was previously conducted to test its safety and efficacy in patients with mycosis fungoides (MF) or plaque psoriasis (PS) (Rook *et al*., 2010). A total of 25 patients were enrolled (n=12 in MF arm; n=13 in PS arm) with 24 evaluable.

Hypericin was administered in concentrations of 0.05%, 0.1%, or 0.25% twice weekly followed 24 hours later by visible fluorescent light treatment. The following table shows the results for the MF patients, with 7/12 (58.3%) of all hypericin-treated patients being responders. In addition, 5/9 (55.6%) patients treated with 0.25% hypericin (the dosage used in the ongoing Phase 3 trial) were responders compared to only 1/12 (8.3%) treated with placebo.

Treatment group	Responders/total*	Percent responders*
All hypericin responders	7/12	58.3%†
Hypericin 0.25% dose	5/9‡	55.6%†
Hypericin 0.1% dose	5/12	41.7%†
Hypericin 0.05% dose	1/2	50.0%
Placebo responders	1/12	8.3%

Source: Rook et al., 2010

Importantly, there were no serious adverse events reported during the study. The most common adverse events reported were mild to moderate and included burning, itching, erythema, and pruritis.

Phase 3 Trial of SGX942 in OM Continuing to Enroll Patients

In addition to the Phase 3 FLASH trial, Soligenix is also currently conducting the Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) clinical trial to evaluate SGX942 (dusquetide) for the treatment of oral mucositis (OM) in patients with squamous cell carcinoma of the oral cavity and oropharynx undergoing chemoradiation therapy. The trial is being supported in part by a $1.5 million SBIR grant awarded by the National Institute of Dental and Craniofacial Research (NIDCR), a part of the NIH.

In Aug. 2019, the company announced a positive recommendation from the independent DMC to continue enrollment in the trial and 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 second quarter of 2020. *Please see our previous Q&A session with Soligenix's Chief Medical Officer that provides additional details about the interim analysis and the recommendations from the DMC.*

Conclusion

Soligenix is set to have a potentially transformative next few months with the release of topline data from the Phase 3 trials of both SGX301 and SGX942. 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*

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