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November 14, 2019
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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Two Phase 3 Data Readouts Over the Next Two Quarters…

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 (11/14/19)	$0.99
Valuation	**$8.00**

OUTLOOK

Soligenix, Inc. (SNGX) has two Phase 3 data readouts coming up over the next two quarters. For the Phase 3 clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL), we anticipate patient enrollment completing in the fourth quarter of 2019 and topline data to be reported in the first quarter of 2020. Following the recent positive recommendation from the independent DMC, the Phase 3 trial of SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer is continuing enrollment and we anticipate topline data in the second quarter of 2020.

SUMMARY DATA

52-Week High	**$1.31**
52-Week Low	**$0.67**
One-Year Return (%)	**-1.98**
Beta	**1.22**
Average Daily Volume (sh)	**51,736**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$20**
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	**-2.1**
P/E using 2019 Estimate	**-2.5**

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

Two Phase 3 Data Readouts in 2020

Soligenix, Inc. (SNGX) is a late-stage clinical biopharmaceutical company developing treatments in oncology, GI disorders, and biodefense. The company has a number of important near-term catalysts that we believe should be on investor's radars, including:

- 1Q2020 – topline results from the Phase 3 clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL)
- 2Q2020 – topline results from the Phase 3 trial of SGX942 (dusquetide) for treating oral mucositis (OM) in patients with head and neck cancer

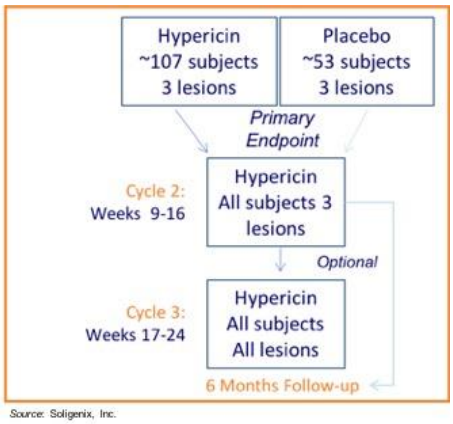
SGX301 in CTCL

Soligenix is currently conducting the Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial, which is testing SGX301 in patients with cutaneous T cell lymphoma (CTCL). 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. *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.*

SGX301, the active ingredient of which is synthetic hypericin, is a photodynamic therapy that is activated by visible light. Hypericin is topically applied to lesions on the skin, where it is taken up by malignant cells at a much higher rate than normal, healthy cells. Approximately 16-24 hours later the treated area is exposed to visible fluorescent light. Exposure of hypericin to light results in the production of singlet oxygen (Thomas *et al*., 1992), which is a highly reactive species that ultimately leads to the initiation of apoptosis in the cell.

The FLASH 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). Following the recommendation by the DMC, total enrollment is now anticipated to be approximately 160 subjects. 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.



Source: Soligenix, Inc.

The interim analysis was performed using data from approximately 100 subjects, and we anticipate enrollment being completed by the end of 2019 and topline data being reported 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.

New Patent Improved Production of Synthetic Hypericin Composition

On Oct. 24, 2019, Soligenix announced a notice of allowance from the USPTO for the divisional patent titled “Systems and Methods for Producing Synthetic Hypericin” that expands on the previous issued claims in the parent U.S. Patent No. 10,053,413 and is set to expire in 2036.

SGX942 in OM

Soligenix is 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 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.

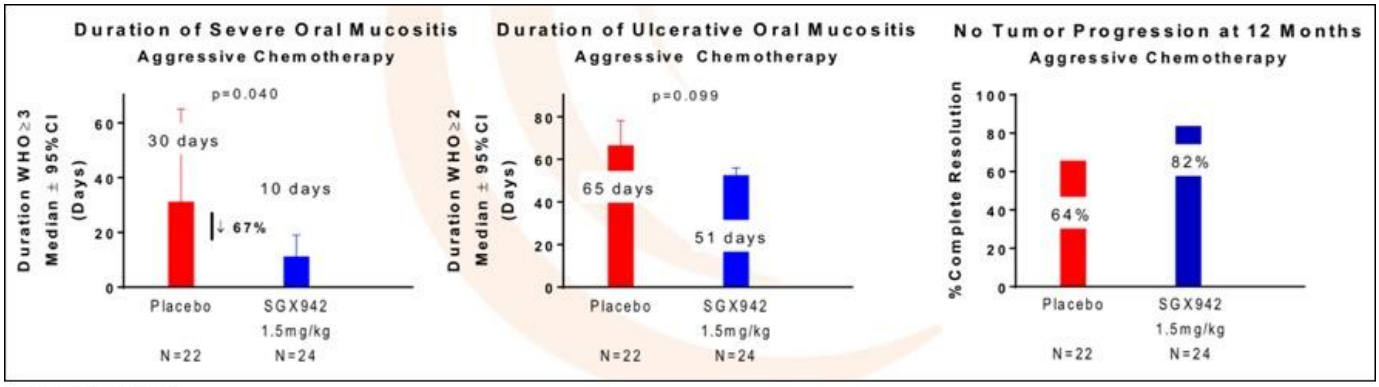
In Aug. 2019, the company announced a positive recommendation from the independent DMC to continue enrollment in the trial and that approximately 70 additional subjects be randomized into the trial

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.*

Phase 2 Study of SGX942 Showed Promising Results

A proof-of-concept Phase 2 study of SGX942 in 111 head and neck cancer patients in 2015 (Kudrimoti *et al*., 2016) showed that administration of 1.5 mg/kg SGX942 reduced the median duration of severe OM by 67% (30 days vs.10 days for the placebo and SGX942 groups, respectively) in those patients receiving the most aggressive form of chemoradiation therapy (below left). In addition, there was a decrease in the median duration of ulcerative OM, which met the pre-specified threshold for significance of *P*<0.1 (below middle). Lastly, treatment with SGX942 appeared to increase the efficacy of treatment, as a greater percentage of those treated with SGX942 saw complete resolution at the 12-month mark than those treated with placebo (below right).



Source: Soligenix, Inc.

Additions to Management Team

In Sep. 2019, Soligenix announced the hiring's of Mr. Daniel P. Ring as Vice President of Business Development and Strategic Planning and Mr. Jonathan Guarino as Senior Vice President and Chief Financial Officer.

Mr. Ring has over 22 years of business development experience in the biopharmaceutical industry. He was previously Vice President of Business Development at Exela Pharma Sciences, LLC, where he was responsible for creating the company's US commercial operations. Prior to that, Mr. Ring was an executive with Merck for 17 years in various sales, marketing, and finance positions. He has been involved in more than 40 executed transactions with a combined value greater than $7 billion.

Mr. Guarino has over 20 years of experience in the financial and strategic management of emerging growth and commercial companies. He was most recently Corporate Controller for Hepion Pharmaceuticals, Inc. where he was responsible for helping establish the financial infrastructure and assist with capital raises and debt financings. Prior to that, Mr. Guarino was Controller and senior manager of technical accounting for Suite K Value Added Services LLC and Covance, Inc.

Financial Update

On November 12, 2019, Soligenix announced financial results for the third quarter of 2019. The company reported $1.3 million in revenue for the third quarter of 2019 compared to $1.4 million for the third quarter of 2018. The revenues are derived from non-dilutive government grants and contracts in support of RiVax®, SGX301, and SGX942 as well as a subaward from the Ebola collaboration with the University of Hawaii. R&D expenses for the third quarter of 2019 were $2.3 million compared to $1.4 million for the third quarter of 2018. The increase was primarily due to higher clinical trial expenditures incurred for the ongoing Phase 3 clinical trials. G&A expenses were $0.8 million for the third quarter of 2019 compared to $0.7 million for the third quarter of 2018. The increase was primarily due to higher professional fees. Net loss for the third quarter of 2019 was $2.7 million, or $0.14 per share, compared to a net loss of $1.9 million, or $0.11 per share, for the third quarter of 2018.

As of September 30, 2019, Soligenix had cash and cash equivalents of approximately $6.6 million as well as approximately $0.9 million in contracts and grants receivable. As of Nov. 7, 2019, the company had approximately 20.7 million common shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 28.3 million.

Conclusion

Soligenix has a very exciting next couple of quarters coming up and we are looking forward to the topline data releases for the Phase 3 trials for 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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