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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Interim Analysis for Phase 3 Oral Mucositis Trial Imminent…

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 (08/22/19)	$1.09
Valuation	**$8.00**

OUTLOOK

On August 13, 2019, Soligenix, Inc. (SNGX) announced financial results for the second quarter of 2019 and provided a business update. The company has three important catalysts coming up over the next 10 months: We anticipate an interim efficacy analysis for the Phase 3 clinical trial of SGX942 (dusquetide) for the prevention of oral mucositis (OM) in September 2019. In addition, we anticipate topline data from the company's Phase 3 clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL) in the first quarter of 2020. Lastly, we anticipate topline data from the Phase 3 trial of SGX942 in the first half of 2020, pending the outcome of the interim analysis.

SUMMARY DATA

52-Week High	**$2.10**
52-Week Low	**$0.67**
One-Year Return (%)	**-22.14**
Beta	**1.16**
Average Daily Volume (sh)	**152,621**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$22**
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	**-2.3**
P/E using 2019 Estimate	**-2.7**

Risk Level	**High**
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	1.4 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	-$0.12 A	-$0.12 E	-$0.12 E	-$0.45 E
2019					-$0.48 E
2020					-$0.48 E

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WHAT'S NEW

Business Update

Multiple Important Near-Term Catalysts

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:

- Sep. 2019 – interim analysis of the Phase 3 clinical trial of SGX942 (dusquetide) in oral mucositis (OM);
- 1Q2020 – topline results from the Phase 3 clinical trial of SGX301;
- 1H2020 – topline results from the Phase 3 OM trial of SGX942, pending the outcome of the interim analysis

SGX942 in OM

In April 2019, Soligenix announced that the Phase 3 trial of SGX942 had reached the enrollment target to support the planned interim efficacy analysis by the independent Data Monitoring Committee (DMC). The Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) clinical trial is evaluating SGX942 for the treatment of severe 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.

The possible DMC recommendations stemming from the interim analysis include: a) stopping the study for overwhelming efficacy; b) stopping the study for serious safety concern; c) stopping the study for futility; d) continuing enrollment in the study at the pre-specified sample size of approximately 190 subjects; or e) re-estimating sample size up or down to maintain the study's statistical power. *We recently conducted a Q&A about the upcoming interim analysis with Soligenix's Chief Medical Officer, Dr. Richard Straube, which can be accessed here.* We anticipate results from the interim analysis in September 2019.

In the meantime, the company will continue enrolling patients into the trial, and pending the outcome of the interim analysis, we currently estimate patient enrollment will complete in the fourth quarter of 2019 and topline results being announced in the first half of 2020.

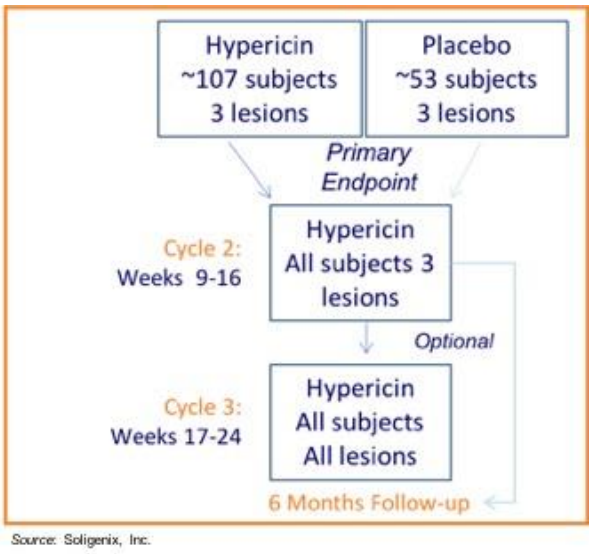
SGX301 in CTCL

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 the trial being completed by the end of 2019 and topline data being reported no later than 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.

Poster Presentations on Thermostable Ebola Vaccine Development

On July 31, 2019, Soligenix announced the presentation of two posters at the Colorado Protein Stability Conference. The posters discuss ongoing efforts at developing a trivalent, thermostabilized Ebola vaccine that is being funded through a five year NIH subaward, initially awarded in 2017, with the ultimate goal being the production of a thermostable trivalent filovirus vaccine for protection against Ebola and related viruses that would not require refrigeration.

Preservation of Quaternary Structure in Thermostable, Lyophilized Ebola Glycoprotein Vaccines – This poster described efforts to identify the optimal stability-indicating assay that would be sensitive enough to show protein degradation over time as well as predicting immunogenicity and long-term stability. Three formulations of an Ebola (EBOV) glycoprotein vaccine were produced: EBOV PBS (stored in pH 7.4 buffer); EBOV LIQ (stored in pH 7 buffer with 9.5% trehalose); EBOV LYO (lyophilized form of EBOV LIQ). All three formulations were stored at 25ºC and 40ºC for 12 weeks to accelerate protein degradation. The products were all tested by a series of different analytical methods and it was determined that the lyophilized vaccine retained its secondary, tertiary, and quaternary structure over the 12-week incubation period, even at elevated temperatures.

Preliminary Stability Assays for a Thermostable, Trivalent Filovirus Vaccine – This poster described efforts to formulate an Ebola vaccine with an adjuvant that maintains thermostability. Typically, adjuvants are added following reconstitution of a lyophilized vaccine and require cold-storage. In this study, various formulations of an Ebola vaccine were prepared with or without adjuvant and then lyophilized. Results showed that no protein or adjuvant degradation was detectable after lyophilization, with follow up studies to focus on stability studies at 25ºC and 40ºC for 12 weeks.

Grant to Explore SGX942 in Pediatric Indications

On August 15, 2019, Soligenix announced that the National Institute of Dental and Craniofacial Research (NIDCR), part of the NIH, has awarded the company a Phase 1 Small Business Innovation Research (SBIR) grant of approximately $150,000 to assess SGX942 in juvenile animals in support of future studies in pediatric populations including oral mucositis in pediatric patients undergoing stem cell transplants. Juvenile animal studies are necessary in order to conduct clinical trials in pediatric populations.

Financial Update

On August 13, 2019, Soligenix announced financial results for the second quarter of 2019. The company reported $1.5 million in revenue in the first quarter of 2019 compared to $1.7 million in the second 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 in the second quarter of 2019 were $1.9 million compared to $1.2 million in the second quarter of 2018. The increase was primarily due to higher clinical trial expenses. G&A expenses in the second quarter of 2019 were $0.8 million compared to $0.7 million in the second quarter of 2018. The increase was primarily due to higher professional fees. Net loss for the second quarter of 2019 was

$2.1 million, or $0.12 per share, compared to a net loss of $1.6 million, or $0.18 per share, for the second quarter of 2018.

As of June 30, 2019, Soligenix had cash and cash equivalents of approximately $7.0 as well as approximately $1.7 million in contracts and grants receivable. As of Aug. 8, 2019, the company had approximately 20.3 million common shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 27.7 million.

Conclusion

We look forward to the results of the interim analysis in September 2019 and believe the most likely outcome of that analysis is to continue the trial as planned or possibly the addition of more study participants to keep the trial powered at 90%. We are also looking forward to the results of the Phase 3 trial for SGX301 in the first 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 multiple near-term inflection points.

PROJECTED FINANCIALS

Soligenix, Inc.	2018 A	Q1 A	Q2 A	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	$1.5	$1.4	$1.5	$5.6	$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**	**$1.4**	**$1.5**	**$5.6**	**$5.8**	**$6.0**
Cost of Revenue	$4.6	$0.9	$1.1	$1.2	$1.3	$4.5	$4.9	$5.1
Gross Income	**$0.6**	**$0.2**	**$0.5**	**$0.2**	**$0.2**	**$1.1**	**$0.9**	**$1.0**
Gross Margin	*12.3%*	*18.9%*	*29.7%*	*13.1%*	*13.3%*	*19.0%*	*15.5%*	*15.8%*
Research & Development	$6.8	$1.6	$1.9	$1.9	$1.9	$7.3	$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)**	**($2.5)**	**($2.5)**	**($9.5)**	**($11.0)**	**($12.9)**
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.2	$0.0	$0.0	$0.1	$0.1	$0.2	$0.0	$0.0
Pre-Tax Income	**($8.9)**	**($2.3)**	**($2.1)**	**($2.5)**	**($2.5)**	**($9.3)**	**($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%*	*6.6%*	*0.0%*	*0.0%*
Reported Net Income	**($8.9)**	**($1.6)**	**($2.1)**	**($2.5)**	**($2.5)**	**($8.7)**	**($11.0)**	**($12.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.09)**	**($0.12)**	**($0.12)**	**($0.12)**	**($0.45)**	**($0.48)**	**($0.48)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	13.2	18.1	18.4	20.3	20.5	19.3	23.0	27.0

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

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