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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Interim Analysis for SGX942 Phase 3 Trial Expected in Sep. 2019…

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 (05/22/19)	$0.68
Valuation	**$8.00**

OUTLOOK

Soligenix, Inc. (SNGX) recently announced that patient enrollment in the Phase 3 clinical trial of SGX942 (dusquetide) is sufficient to allow for the planned interim efficacy analysis by the independent Data Monitoring Committee (DMC). The DMC can recommend either stopping the study for overwhelming efficacy, stopping the study for any serious safety concern, stopping the study for futility, continuing enrollment up to the pre-specified sample size of approximately 190, or re-estimating the sample size up or down to maintain the trial's statistical power. We anticipate the results of the interim analysis in September 2019. Currently, we estimate final enrollment of the trial should complete by the fourth quarter of 2019 with topline results likely in the first half of 2020, pending the outcome of the interim analysis.

SUMMARY DATA

52-Week High	**$2.10**
52-Week Low	**$0.68**
One-Year Return (%)	**-58.84**
Beta	**1.22**
Average Daily Volume (sh)	**47,567**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$11**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**15**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-4.8**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-1.4**
P/E using 2019 Estimate	**-1.4**

Risk Level	**Above Avg.**
Type of Stock	**Small-Blend**
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	1.4 E	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	-$0.13 E	-$0.14 E	-$0.14 E	-$0.49 E
2019					-$0.48 E
2020					-$0.48 E

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WHAT'S NEW

Business Update

Enrollment Target Reached for Interim Analysis of SGX942 Phase 3 Trial

On April 18, 2019, Soligenix, Inc. (SNGX) announced that it has reached the enrollment target for the Phase 3 clinical trial of SGX942 (dusquetide) 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 sever 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.

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 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.

Pediatric Investigation Plan for SGX942 Accepted by EMA

On April 9, 2019, Soligenix announced that the European Medicines Agency (EMA) has agreed to the company's Pediatric Investigation Plan (PIP) for SGX942. In addition, the EMA agreed that the company may defer conducting the PIP until successful completion of the ongoing Phase 3 DOM-INNATE clinical trial. All pharmaceuticals approved in Europe must have an approved PIP. In Soligenix's case, the company will be allowed to file a Marketing Authorization Application (MAA) for the adult indication prior to completion of the PIP due to the Pediatric Committee of the EMA permitting its deferral until the risk/benefit of SGX942 has been established in an adult population.

Non-Dilutive Funding from NJ Tax Program

On April 15, 2019, Soligenix announced the receipt of approximately $611,000 via the state of New Jersey's Technology Business Tax Certificate Transfer Program. The program allows for various technology companies to sell their Net Operating Loss (NOL) Carryovers and unused R&D Tax Credits to unaffiliated, corporate taxpayers in New Jersey. This is the ninth year that the company has received NOL funding and all told has received approximately $5 million over that span.

Expansion of IP Protection for IDR's

On April 4, 2019, Soligenix announced the US Patent and Trademark Office will issue U.S. Patent No. 10,253,068 titled "Novel Peptides for Treating and Preventing Immune-Related Disorders, Including Treating and Preventing Infection by Modulating Innate Immunity". The patent provides composition of matter protection for a number of innate defense regulator (IDR) analogs and includes therapeutic use claims in oral mucositis, colitis, and infectious disease, with and without the use of antibiotics.

Financial Update

On May 14, 2019, Soligenix announced financial results for the first quarter of 2019. The company reported $1.1 million in revenue in both the first quarter of 2019 and 2018. Revenues were comprised of

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 first quarter of 2019 were $1.6 million compared to $1.8 million in the first quarter of 2018. The decrease was primarily due to higher clinical trial site fees incurred in the first quarter of 2018. G&A expenses in the first quarter of 2018 were $0.9 million compared to $0.7 million in the first quarter of 2018. The increase was primarily due to higher professional fees. Net loss for the first quarter of 2019 was $1.6 million, or $0.09 per share, compared to a net loss of $2.4 million, or $0.27 per share, for the first quarter of 2018.

As of March 31, 2019, Soligenix had approximately $7.2 million in cash and cash equivalents as well as approximately $1.1 million in contract and grant receivables. As of May 9, 2019, the company had approximately 18.5 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 25.8 million.

Conclusion

We value Soligenix using a probability adjusted discounted cash flow analysis based on potential future revenues of SGX301 in CTCL and SGX942 in OM. For SGX301, we model for approval in 2021 and peak revenues of approximately $200 million worldwide. Using a 70% probability of approval and a 13% discount rate leads to a net present value of $73 million. For SGX942, we model for approval in 2021 and peak revenues of approximately $350 million worldwide. Using a 60% probability of approval and a 13% discount rate leads to a net present value of $104 million. Combining the net present value for those two products with the company's current cash position, the potential cash from exercising warrants, and using a fully diluted share count of 25.8 million shares leads to a valuation of approximately $8.00 per share. Soligenix is currently trading at a significant discount to our valuation, and with two Phase 3 readouts due by the first half of 2020 we believe investors would be well served to take a closer look at the company in the leadup to those readouts.

PROJECTED FINANCIALS

Soligenix, Inc.	2018 A	Q1 A	Q2 E	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	$1.4	$1.4	$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**	**$1.4**	**$1.4**	**$1.5**	**$5.4**	**$5.8**	**$6.0**
Cost of Revenue	$4.6	$0.9	$1.2	$1.2	$1.3	$4.6	$4.9	$5.1
Gross Income	**$0.6**	**$0.2**	**$0.2**	**$0.2**	**$0.2**	**$0.8**	**$0.9**	**$1.0**
Gross Margin	*12.3%*	*18.9%*	*14.3%*	*13.1%*	*13.3%*	*14.7%*	*15.5%*	*15.8%*
Research & Development	$6.8	$1.6	$1.8	$1.9	$1.9	$7.2	$8.2	$9.8
General & Administrative	$3.0	$0.9	$0.8	$0.8	$0.8	$3.3	$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)**	**($2.4)**	**($2.5)**	**($2.5)**	**($9.7)**	**($11.0)**	**($12.9)**
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.2	$0.0	$0.1	$0.1	$0.1	$0.2	$0.0	$0.0
Pre-Tax Income	**($8.9)**	**($2.3)**	**($2.4)**	**($2.5)**	**($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)**	**($2.4)**	**($2.5)**	**($2.5)**	**($8.9)**	**($11.0)**	**($12.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.09)**	**($0.13)**	**($0.14)**	**($0.14)**	**($0.49)**	**($0.48)**	**($0.48)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	13.2	18.1	17.9	18.0	18.1	18.0	23.0	27.0

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

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