

Soligenix, Inc. (NASDAQ/SNGX)

June 24, 2020

BUY: Mucositis Trial Reaches Full Enrollment

Soligenix announced it has completed patient enrollment in its Phase 3 DOM-INNATE ("Dusquetide treatment in Oral Mucositis - by modulating INNATE Immunity") study for SGX942 (dusquetide) in the treatment of oral mucositis (OM) in head and neck cancer (HNC) patients. The study successfully enrolled 268 subjects, following positive interim analysis which included a prospectively defined, unblinded assessment of the study's primary efficacy endpoint by an independent Data Monitoring Committee (DMC). With enrollment completed, top-line results are expected in the fourth quarter of 2020.

Investment Highlights

SGX-942 completes enrollment. Recall that a recent positive DMC's recommendation indicated that a positive effect has been seen, but to account for variability and maintain 90% statistical power, an increase was recommended. No safety issues were observed, and the study remains on target to provide topline later this year.

Mucositis May Meet its Match. Soligenix has also commenced its Phase 3 clinical study in oral mucositis in head and neck cancer patients. Oral mucositis is a common complication of cancer chemotherapy and radiation that causes the mucosal lining of the mouth to break down, forming severe ulcers. This is an area of unmet medical need where there are currently no approved drug therapies. Consequently, Soligenix introduced Dusquetide, which is a small-molecule peptide that modulates the innate immune system and has shown favorable results in Phase 1 and 2 studies.

SGX301. The company announced positive synthetic hypericin (SGX301) data, a treatment response, out to 12 weeks. The response rate in patients receiving a total of 12 weeks treatment increased two and a half-fold. This data follows the previously announced six weeks results where SGX301 met its primary endpoint. The study enrolled 169 patients randomized 2:1 to receive either SGX301 or placebo, demonstrating statistically significant treatment response (p=0.04) in the Composite Assessment of Index Lesion Score (CAILS) primary endpoint assessment at eight weeks for Cycle 1.

Gone in a "FLASH" (Fluorescent Light Activated Synthetic Hypericin). SGX301 (synthetic hypericin) is a topical ointment which is applied to CTCL lesions and then activated by safe, visible fluorescent light. This photodynamic therapy has reached its pivotal stage (Phase 3), and approximately 40 additional subjects are being randomized into the trial to maintain the assumption of 90% statistical power for the primary efficacy endpoint. This program has also received ongoing partial funding of approximately \$1.5 million over two years from the Small Business Innovative Research (SBIR) grant awarded by the National Cancer Institute (NCI).

Risk to our thesis, include the following: (1) clinical trial; (2) commercial; (3) employee; (4) financial; (5) intellectual property; (6) partnership; and (7) regulatory.

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Current Price	\$1.80		
Price Target	\$3.00		
Estimates	F2019A	F2020E	F2021E
Expenses (\$000s)	\$ 11,604	\$ 11,836	\$ 13,705
1Q March	\$ 2,517	\$ 2,959	\$ 3,426
2Q June	\$ 2,623	\$ 2,959	\$ 3,426
3Q September	\$ 3,056	\$ 2,959	\$ 3,426
4Q December	\$ 3,407	\$ 2,959	\$ 3,426
	F2019A	F2020E	F2021E
EPS (diluted)	\$ (0.45)	\$ (0.34)	\$ 0.07
1Q March	\$ (0.09)	\$ (0.08)	\$ 0.02
2Q June	\$ (0.12)	\$ (0.09)	\$ 0.02
3Q September	\$ (0.14)	\$ (0.08)	\$ 0.02
4Q December	\$ (0.11)	\$ (0.09)	\$ 0.02
EBITDA/Share	(\$0.38)	(\$0.45)	\$0.09
EV/EBITDA (x)	0.0	0.0	0.0
Stock Data			
52-Week Range	\$0.70	-	\$3.54
Shares Outstanding (mil.)	26.6		
Market Capitalization (mil.)	\$48		
Enterprise Value (mil.)	\$41		
Debt to Capital	0%		
Book Value/Share	\$0.72		
Price/Book	21.6		
Average Three Months Trading Volume (K)	3,291		
Insider Ownership	2.9%		
Institutional Ownership	15.1%		
Short interest (mil.)	1.3%		
Dividend / Yield	\$0.00/0.0%		



Modeling Assumptions: SGX 301

- Prevalence.** There are an estimated 40,000 individuals who have been diagnosed with CTCL worldwide. In the United States, 3,000 new cases are diagnosed each year.
- Clinical and regulatory outcome assumptions.** We assume final topline results for the SGX301 Phase 3 study will become available Q1-20. If the trial is successful, we can expect an NDA / approval in 2021. As such, we anticipate that Soligenix will begin to commercialize SGX301 in 2021.
- Product assumptions.** We assume that a yearly treatment cycle for SGX 301 at \$8,000. We also predict that the cost of the drug will increase by 1% a year, but this number may be too conservative since the current off-label treatments are priced at \$10,000.
- Risk adjustment.** We assign a 33% risk adjustment to our therapeutic model of SGX 301 based on the Phase 3 approval rate of drugs in the oncology field, according to BioMedTracker and Amplion.

Exhibit 1. SGX 301 Model:

SGX301 (CTCL)													
SGX301 Revenues Model	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
CTCL Prevalence	40,000	42,800	45,796	49,002	51,942	55,058	58,362	61,280	64,344	67,561	70,264	73,074	75,997
Market Size Growth	7%	7%	7%	6%	6%	6%	5%	5%	5%	4%	4%	4%	3%
Treated with SGX 301	37,000	39,590	42,361	45,327	48,046	50,929	53,985	56,684	59,518	62,494	64,994	67,594	70,297
Eligible patients with insurance etc. (75%)	27,750	29,693	31,771	33,995	36,035	38,197	40,489	42,513	44,639	46,871	48,745	50,695	52,723
Market Penetration	0%	0%	0%	4%	6%	8%	10%	12%	14%	16%	18%	19%	20%
Treatable Patients	0	0	0	1360	2162	3056	4049	5102	6249	7499	8774	9632	10545
Average Cost of Therapy	\$8,000	\$8,000	\$8,000	\$8,000	\$8,080	\$8,161	\$8,242	\$8,325	\$8,408	\$8,492	\$8,577	\$8,663	\$8,749
Price Growth	0%	0%	0%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Total Sales (\$millions)	\$ -	\$ -	\$ -	\$ 11	\$ 17	\$ 25	\$ 33	\$ 42	\$ 53	\$ 64	\$ 75	\$ 83	\$ 92
Risk Adjusted	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%
Total Sales (US) (\$millions)	\$ -	\$ -	\$ -	\$ 4	\$ 6	\$ 8	\$ 11	\$ 14	\$ 17	\$ 21	\$ 25	\$ 28	\$ 30

Source: Dawson James

Modeling Assumptions: SGX 942 (Dusquetide)

- Prevalence.** Oral Mucositis affects over 180,000 head and neck cancer patients worldwide. We expect that the number of patients with this condition can continue to grow by 1% annually.
- Clinical and regulatory outcome assumptions.** We assume that the company can complete its Phase 3 study no later than 1H-20. We expect an NDA submission in 2020 with approval and marketing by 2021. For Europe, we assume approval a year later in 2022.
- Product assumptions.** We assume the cost of a yearly treatment cycle is \$6,000.
- Risk adjustment.** We assign a 33% risk adjustment to our therapeutic model of SGX942 based on the Phase 3 approval rate of drugs in the field of oncology, according to BioMedTracker and Amplion.

Exhibit 2. SGX 942 Model:

SGX942 (Mucositis)													
SGX942 Revenues Model U.S.	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Head and neck cancer	180,000	181,800	183,618	185,454	187,309	189,182	191,074	192,984	194,914	196,863	198,832	200,820	202,829
Market Size Growth	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Treated with Radiation	166,500	168,165	169,847	171,545	173,261	174,993	176,743	178,511	180,296	182,099	183,920	185,759	187,616
Eligible patients with insurance etc. (75%)	124,875	126,124	127,385	128,659	129,945	131,245	132,557	133,883	135,222	136,574	137,940	139,319	140,712
Market Penetration	0%	0%	0%	5%	7%	10%	15%	20%	25%	30%	33%	33%	34%
Treatable Patients	0	0	0	6433	9096	13124	19884	26777	33805	40972	45520	45975	47842
Average Cost of Therapy	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000
Price Growth	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total Sales (\$millions)	\$ -	\$ -	\$ -	\$ 39	\$ 55	\$ 79	\$ 119	\$ 161	\$ 203	\$ 246	\$ 273	\$ 276	\$ 287
Risk Adjusted	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%
Total Sales (US) (\$millions)	\$ -	\$ -	\$ -	\$ 13	\$ 18	\$ 26	\$ 39	\$ 53	\$ 67	\$ 81	\$ 90	\$ 91	\$ 95

SGX942 (Mucositis)													
SGX942 Revenues Model EU.	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Head and neck cancer	180,000	181,800	183,618	185,454	187,309	189,182	191,074	192,984	194,914	196,863	198,832	200,820	202,829
Market Size Growth	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Treated with Radiation	166,500	168,165	169,847	171,545	173,261	174,993	176,743	178,511	180,296	182,099	183,920	185,759	187,616
Eligible patients with insurance etc. (75%)	124,875	126,124	127,385	128,659	129,945	131,245	132,557	133,883	135,222	136,574	137,940	139,319	140,712
Market Penetration	0%	0%	0%	0%	5%	9%	12%	15%	18%	21%	24%	27%	30%
Treatable Patients	0	0	0	0	6497	11812	15907	20082	24340	28681	33106	37616	42214
Average Cost of Therapy	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000	\$6,000
Price Growth	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total Sales (\$millions)	\$ -	\$ -	\$ -	\$ -	\$ 39	\$ 71	\$ 95	\$ 120	\$ 146	\$ 172	\$ 199	\$ 226	\$ 253
Risk Adjusted	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%	33%
Total Sales (EU) (\$millions)	\$ -	\$ -	\$ -	\$ -	\$ 13	\$ 23	\$ 31	\$ 40	\$ 48	\$ 57	\$ 66	\$ 74	\$ 84
Total Sales (WW) (\$millions)	\$ -	\$ -	\$ -	\$ 13	\$ 31	\$ 49	\$ 71	\$ 93	\$ 115	\$ 138	\$ 156	\$ 166	\$ 178

Source: Dawson James

Valuation. Our valuation methodology begins with our projected revenues from our product models. We apply assumptions for the timing of approval, launch dates, and product attributes to estimate revenues. These estimates feed into our income statement through the year 2030. Our therapeutic models include a probability of success factor or risk rate of 33% based on the success of Phase 3 drugs in the oncology industry, as stated by BioMedTracker and Amplion. The result of these projections is then fed into our income statement projections. Our price target is derived from an equal-weighted average of free cash flow to the firm (FCFF), discounted EPS (EPS), and sum-of-the-parts (SOP) models. For companies that have a strong foundation with established products and revenues (visible earnings), we typically discount 10% while emerging growth companies like Soligenix, which are not yet profitable we use our maximum risk rate of 30%. The result is rounded to the nearest whole number. Our share count is based on the out-year (2030) and assumes additional capital raises (dilution). This methodology results in a price target of \$3.00.

Exhibit 3. FCFF Model

Average \$	3
Price Target \$	3
Year	2020

DCF Valuation Using FCF (mln):

units ('000 - Cnd\$)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(9,966)	(11,836)	2,622	20,663	39,284	60,880	83,050	105,893	129,441	148,596	159,598	173,454
Tax Rate	15%	20%	25%	30%	34%	34%	34%	34%	34%	34%	34%	34%
EBIT(1-t)	(8,471)	(9,468)	1,967	14,464	25,927	40,181	54,813	69,889	85,431	98,073	105,335	114,480
CapEx	-	-	-	-	-	-	-	-	-	-	-	-
Depreciation	54	57	60	63	66	69	73	77	80	84	89	93
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(8,417)	(9,411)	2,027	14,527	25,994	40,250	54,886	69,966	85,512	98,158	105,424	114,573
PV of FCF	(10,942)	(9,411)	1,559	8,596	11,831	14,093	14,782	14,495	13,628	12,033	9,941	8,311
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	399,029											
Terminal Value YE2020	28,945											
NPV	128,803											
NPV-Debt	1,583											
Shares out (thousands)	40,019											
NPV Per Share	\$ 3											

Source: Dawson James

Exhibit 4. Discounted EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 2.87
NPV	\$ 2.08

Source: Dawson James

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2030 EPS					
Earnings Multiple	2.1	5%	10%	15%	20%	25%	30%
0	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$ -
5	\$8.80	\$5.53	\$3.54	\$2.32	\$1.54	\$1.04	\$ 1.04
10	\$17.60	\$11.06	\$7.09	\$4.63	\$3.08	\$2.08	\$ 2.08
15	\$26.41	\$16.58	\$10.63	\$6.95	\$4.62	\$3.12	\$ 3.12
20	\$35.21	\$22.11	\$14.18	\$9.26	\$6.16	\$4.16	\$ 4.16
25	\$44.01	\$27.64	\$17.72	\$11.58	\$7.70	\$5.20	\$ 5.20
30	\$52.81	\$33.17	\$21.26	\$13.89	\$9.24	\$6.24	\$ 6.24
35	\$61.61	\$38.69	\$24.81	\$16.21	\$10.78	\$7.28	\$ 7.28

Source: Dawson James

Exhibit 5. Sum of the Parts Model

Soligenix Inc. Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	Term Val
SGX301 (CTCL)	1%	30%	2	65%	\$200	\$690
NPV						\$1.99
SGX942 (Oral Mucositis)	1%	30%	3	55%	\$100	\$345
NPV						\$0.65
Pipeline	1%	30%	6	15%	\$400	\$1,379
NPV						\$0.32
Net Margin						30%
MM Shrs OS						40
Total						\$3

Source: Dawson James

Risk Analysis

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to Soligenix are as follows:

Clinical Trial Risk. There can be no assurances that the outcome of the current trials is successful.

Commercial risk. Fluorescent Light Activated Synthetic Hypericin represents a new paradigm in the treatment of CTCL. Adoption may take longer than expected.

Employee risk. Soligenix Inc. has an experienced management team in their president and CEO, CFO, CSO, and CMO. Soligenix plans to bring their proposed products to market in the next two years. The success of the company may depend on the experience, abilities and continued services of its senior officers, sales staff, and key scientific personnel.

Financial risk. Soligenix is not a profitable company. While the company has a cash balance at this time, it's likely that they will need to raise additional capital continue to fund operations through NDA application and approval. There are no assurances that the company will be able to successfully raise capital and do so on favorable terms.

Intellectual property risk. The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed upon or will be held as valid if challenged, and the company may infringe on third party's patents.

Partnership risks. Soligenix depends on government funding for the public health solutions program. This funding can be canceled at any time.

Regulatory risk. Soligenix must be able to obtain NDA approval before commercial sales of their products can commence in the United States. The timing of these approvals is uncertain. Additionally, the government's biodefense priority might change affecting the commercial development of RiVax.

Exhibit 6. Income Statement

Soligenix Inc., Inc. Income Statement (\$000)																	
Soligenix Inc.: YE Dec. 31	2018A	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue (\$000)																	
SGX942 (Mucositis) (WW)	-	-	-	-	-	-	-	12,737	30,875	49,374	70,865	92,781	115,128	137,912	155,679	165,511	178,311
SGX-301	-	-	-	-	-	-	-	3,590	5,765	8,229	11,013	14,015	17,340	21,016	24,835	27,536	30,446
Total Product Sales	-	-	-	-	-	-	-	16,327	36,640	57,604	81,878	106,796	132,468	158,928	180,513	193,047	208,756
% Chg																	
License Revenue	3,965	3,216															
Grant Revenue	1,276	1,414															
Cost of Grant Revenue	(4,598)	(3,567)															
% Sequential Growth																	
Total Revenues	644	1,063	-	-	-	-	-	16,327	36,640	57,604	81,878	106,796	132,468	158,928	180,513	193,047	208,756
Expenses																	
Cost of Goods Sold & Acquired in Process R&D	-	-	-	-	-	-	-	1,633	3,664	5,760	8,188	10,680	13,247	15,893	18,051	19,305	20,876
COGS % Sales			10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Research and development	6,751	8,123	2,071	2,071	2,071	2,071	8,285	8,451	8,620	8,792	8,968	9,147	9,330	9,517	9,707	9,901	10,099
R&D % Revs																	
G&A	2,952	3,481	888	888	888	888	3,551	3,622	3,694	3,768	3,843	3,920	3,998	4,078	4,160	4,243	4,328
G&A																	
Stock-based compensation - R&D																	
Stock-based compensation - G&A																	
Non-GAAP Adj																	
Total expenses	9,703	11,604	2,959	2,959	2,959	2,959	11,836	13,705	15,978	18,320	20,999	23,747	26,576	29,488	31,919	33,449	35,303
Oper. Inc. (Loss)	(9,059)	(10,541)	(2,959)	(2,959)	(2,959)	(2,959)	(11,836)	2,622	20,662	39,283	60,879	83,049	105,892	129,440	148,595	159,597	173,453
Oper Margin	NM	NM	NM	NM	NM	NM	NM	0	1	1	1	1	1	1	1	1	1
Interest Income	159	149															
Interest expense																	
Other Income (expense)		426															
Change in fair value of warrant liability																	
Pre-tax income	(8,900)	(9,966)	(2,959)	(2,959)	(2,959)	(2,959)	(11,836)	2,622	20,663	39,284	60,880	83,050	105,893	129,441	148,596	159,598	173,454
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	0	1	1	1	1	1	1	1	1	1
Income Tax (Benefit)		611	(592)	(592)	(592)	(592)	(2,367)	656	6,199	13,357	20,700	28,238	36,004	44,011	50,523	54,264	58,975
Tax Rate	0%	15%	20%	20%	20%	20%	20%	25%	30%	34%	34%	34%	34%	34%	34%	34%	34%
GAAP Net Income (loss)	(8,900)	(9,356)	(2,367)	(2,367)	(2,367)	(2,367)	(9,468)	1,967	14,465	25,929	40,182	54,814	69,891	85,433	98,075	105,336	114,481
GAAP-EPS	(0.79)	(0.49)	(0.08)	(0.09)	(0.08)	(0.09)	(0.34)	0.07	0.50	0.86	1.28	1.68	2.05	2.41	2.66	2.75	2.87
Non GAAP EPS (dil)	(0.30)	(0.49)	(0.08)	(0.09)	(0.08)	(0.09)	(0.34)	0.07	0.50	0.86	1.28	1.68	2.05	2.41	2.66	2.75	2.87
Wgtd Avg Shrs (Bas) - '000s	13,178	19,377	25,499	25,754	27,011	27,281	26,386	27,970	29,106	30,288	31,518	32,797	34,129	35,515	36,957	38,458	40,019
Wgtd Avg Shrs (Dil) - '000s	13,178	19,377	30,296	25,754	28,011	27,281	26,386	27,970	29,106	30,288	31,518	32,797	34,129	35,515	36,957	38,458	40,019

Source: Dawson James and Company Reports

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – August 5, 2019 – Price Target \$3.00
- Update – Buy – August 14, 2019 – Price Target \$3.00
- Update – Buy – August 28, 2019 – Price Target \$3.00
- Update – Buy – November 20, 2019 – Price Target \$3.00
- Update – Buy – December 4, 2019 – Price Target \$3.00
- Update – Buy – February 12, 2020 – Price Target \$3.00
- Update – Buy – March 31, 2020 – Price Target \$3.00
- Update – Buy – May 1, 2020 – Price Target \$3.00
- Update – Buy – June 24, 2020 – Price Target \$3.00

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Rating Definitions:

- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	92%	3	13%
Market Perform (Neutral)	2	8%	1	50%
Market Underperform (Sell)	0	0%	0	0%
Total	25	100%	4	16%

Analyst Certification:

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