

Soligenix, Inc. (NASDAQ/SNGX)

December 4, 2019

BUY: Data Is Coming, It Could Be Transformative

Soligenix, as promised, announced that patient enrollment has now been completed with final top-line results expected in 1Q20 for the Phase 3 study for the treatment of cutaneous T-cell lymphoma (CTCL). In addition, the Phase 3 trial for SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer (HNC) receiving chemoradiation therapy is expected to complete enrollment 1Q20 and provide topline results in 2Q20.

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Current Price **\$1.13**
 Price Target **\$3.00**

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 10,836	\$ 11,053	\$ 12,907
1Q March	\$ 2,517	\$ 2,763	\$ 3,227
2Q June	\$ 2,623	\$ 2,763	\$ 3,227
3Q September	\$ 3,056	\$ 2,763	\$ 3,227
4Q December	\$ 2,640	\$ 2,763	\$ 3,227
	F2019E	F2020E	F2021E
EPS (diluted)	\$ (0.45)	\$ (0.32)	\$ 0.09
1Q March	\$ (0.09)	\$ (0.07)	\$ 0.02
2Q June	\$ (0.12)	\$ (0.09)	\$ 0.02
3Q September	\$ (0.14)	\$ (0.08)	\$ 0.02
4Q December	\$ (0.11)	\$ (0.08)	\$ 0.02
EBITDA/Share	(\$0.41)	(\$0.42)	\$0.12
EV/EBITDA (x)	0.0	0.0	0.0
Stock Data			
52-Week Range	\$0.65	-	\$2.20
Shares Outstanding (mil.)	18.5		
Market Capitalization (mil.)	\$21		
Enterprise Value (mil.)	\$14		
Debt to Capital	0%		
Book Value/Share	\$0.72		
Price/Book	2.4		
Average Three Months Trading Volume (K)	12		
Insider Ownership	14.4%		
Institutional Ownership	16.2%		
Short interest (mil.)	1.6%		
Dividend / Yield	\$0.00/0.0%		

Investment Highlights

CTCL is now fully enrolled. This news follows the positive recommendation received from the independent DMC for the pivotal (double-blind, placebo-controlled), study for the treatment of cutaneous T-cell lymphoma (CTCL) with SGX301 (synthetic hypericin). With enrollment now complete, top line data (from the first cycle of therapy) is expected by late 2Q/early 3Q20.

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).

SGX-942 for Mucositis too. This trial is expected to complete enrollment in 1Q20. 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 results in the first half of 2020.

Mucositis May Meet its Match. Soligenix has also commenced their 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. The oral mucositis development program has received ongoing partial funding of approximately \$1.5 million over two years from an SBIR grant awarded by the National Institute of Dental and Craniofacial Research (NIDCR).



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 top-line 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 their 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 outyear (2030) and assumes additional capital raises (dilution). This methodology results in a price target of \$3.00.

Exhibit 3. FCFF Model

Price Target \$	2
Year	2019

DCF Valuation Using FCF (mln):

units ('000 - Cnd\$)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(10,332)	(10,539)	3,945	22,012	40,660	62,284	84,482	107,354	130,931	150,115	161,148	175,035
Tax Rate	15%	20%	25%	30%	34%	34%	34%	34%	34%	34%	34%	34%
EBIT(1-t)	(8,782)	(8,431)	2,959	15,409	26,836	41,107	55,758	70,853	86,414	99,076	106,358	115,523
CapEx	-	-	-	-	-	-	-	-	-	-	-	-
Depreciation	117	122	129	135	142	149	156	164	172	181	190	199
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(8,666)	(8,308)	3,087	15,544	26,978	41,256	55,914	71,017	86,587	99,257	106,548	115,723
PV of FCF	(8,666)	(6,391)	1,827	7,075	9,446	11,111	11,584	11,318	10,615	9,360	7,729	6,457
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	403,034											
Terminal Value YE2020	22,489											
NPV	93,953											
NPV-Debt	1,583											
Shares out (thousands)	37,471	2030E										
NPV Per Share	\$ 2											

Source: Dawson James

Exhibit 4. Discounted EPS Model

Current Year	2019
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 3.09
NPV	\$ 1.72

Source: Dawson James

		Discount Rate and Earnings Multiple Varies, Year is Constant						
		2030 EPS						
Earnings Multiple		1.7	5%	10%	15%	20%	25%	30%
0		\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$ -
5		\$4.77	\$2.86	\$1.75	\$1.10	\$0.70	\$0.46	\$ 0.46
10		\$9.54	\$5.72	\$3.51	\$2.20	\$1.40	\$0.91	\$ 0.91
15		\$14.31	\$8.58	\$5.26	\$3.29	\$2.10	\$1.37	\$ 1.37
20		\$19.08	\$11.44	\$7.02	\$4.39	\$2.80	\$1.82	\$ 1.82
25		\$23.85	\$14.30	\$8.77	\$5.49	\$3.50	\$2.28	\$ 2.28
30		\$28.62	\$17.16	\$10.52	\$6.59	\$4.21	\$2.73	\$ 2.73
35		\$33.39	\$20.02	\$12.28	\$7.69	\$4.91	\$3.19	\$ 3.19

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						\$2.83
SGX942 (Oral Mucositis)	1%	30%	3	55%	\$100	\$345
NPV						\$0.92
Pipeline	1%	30%	6	15%	\$400	\$1,379
NPV						\$0.46
Net Margin						40%
MM Shrs OS						37
Total						\$4

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																					
Revenue (\$000)	1Q18A	2Q18A	3Q18A	4Q18A	2018A	1Q19A	2Q19A	3Q19A	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
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	777	1,368	1,064	756	3,965	640	1,061	947													
Grant Revenue	342	358	317	259	1,276	505	484	308													
Cost of Grant Revenue	(979)	(1,494)	(1,237)	(888)	(4,598)	(928)	(1,087)	(965)													
% Sequential Growth																					
Total Revenues	141	232	144	127	644	217	458	289	-	-	-	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%
Research and development	1,803	1,170	1,395	2,382	6,751	1,643	1,854	2,267	1,725	7,489	7,638	7,791	7,947	8,106	8,268	8,433	8,602	8,774	8,949	9,128	9,311
R&D % Revs																					
G&A	732	651	668	902	2,952	874	769	789	915	3,348	3,415	3,483	3,552	3,623	3,696	3,770	3,845	3,922	4,001	4,081	4,162
G&A																					
Stock-based compensation - R&D																					
Stock-based compensation - G&A																					
Non-GAAP, Adj																					
Total expenses	2,535	1,821	2,063	3,284	9,703	2,517	2,623	3,056	2,640	10,836	11,053	12,907	15,163	17,490	20,152	22,883	25,694	28,589	31,001	32,514	34,349
Oper. Inc. (Loss)	(2,394)	(1,589)	(1,919)	(3,157)	(9,059)	(2,300)	(2,165)	(2,767)	(2,640)	(10,836)	(11,053)	3,421	21,477	40,114	61,726	83,913	106,774	130,339	149,512	160,533	174,407
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0	1	1	1	1	1	1	1	1	1
Interest Income	17	33	57	52	159	50	41	46													
Interest expense																					
Other Income (expense)																					
Change in fair value of warrant liability																					
Pre-tax income	(2,377)	(1,556)	(1,862)	(3,105)	(8,900)	(2,250)	(2,124)	(2,721)	(2,640)	(10,836)	(11,053)	3,421	21,477	40,115	61,727	83,914	106,775	130,340	149,513	160,534	174,408
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0	1	1	1	1	1	1	1	1	1
Income Tax (Benefit)	-	-	-	-	-	-	-	(396)	(396)	(2,211)	(2,211)	855	6,444	13,640	20,988	28,532	36,304	44,317	50,835	54,582	59,300
Tax Rate	0%	0%	0%	0%	0%	0%	15%	15%	15%	15%	20%	25%	30%	34%	34%	34%	34%	34%	34%	34%	34%
GAAP Net Income (loss)	(2,377)	(1,556)	(1,862)	(3,105)	(8,900)	(2,250)	(2,124)	(2,721)	(2,244)	(9,339)	(8,842)	2,566	15,035	26,477	40,741	55,385	70,473	86,026	98,680	105,954	115,111
GAAP-EPS	(0.27)	(0.18)	(0.11)	(0.24)	(0.79)	(0.12)	(0.12)	(0.14)	(0.11)	(0.49)	(0.32)	0.09	0.52	0.88	1.30	1.69	2.07	2.43	2.68	2.76	2.88
Non GAAP EPS (dil)	(0.27)	(0.18)	(0.11)	(0.24)	(0.30)	(0.09)	(0.12)	(0.14)	(0.11)	(0.45)	(0.32)	0.09	0.52	0.88	1.30	1.69	2.07	2.43	2.68	2.76	2.88
Wgtd Avg Shrs (Bas) - '000s	8,735	8,743	17,495	13,178	13,178	18,079	18,437	20,095	20,296	19,227	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	8,735	8,743	17,495	13,178	13,178	18,079	18,437	20,095	20,296	19,227	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

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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	88%	2	9%
Market Perform (Neutral)	3	12%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	26	100%	2	8%

Analyst Certification:

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst’s compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.