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Soligenix, Inc. (NASDAQ/SNGX)

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Neutral: SGX942 in Mucositis Fails – We Kind of Thought So…

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Last July (7.28.20), we downgraded Soligenix to Neutral based on a combination of concerns that included capital raises in advance of Phase 3 results for SGX301 in Mucositis. At that time, we wrote: "The future of the company rests on the outcome of its two lead products, SGX301 for CTCL lesions, which we see as its best chance of success but to a limited market, and SGX942 in Mucositis, which we see as a very high-risk product." We had assumed (90% probability) that this compound would fail. We now remove SGX942 from our model, which projects a fair value close to zero.

Investment Highlights

SGX942. The company announced preliminary top-line results for its pivotal Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis - by modulating INNATE Immunity) trial evaluating SGX942 (dusquetide) in the treatment of severe oral mucositis (SOM) in patients with head and neck cancer (HNC) receiving chemoradiation. This was a Phase 3, n=268 randomized trial 1:1.

- **The primary endpoint of median duration of SOM did not achieve the pre-specified criterion for statistical significance (p≤0.05).**

Management highlighted that "biological activity" was observed with a 56% reduction in the median duration of SOM from 18 days in the placebo group to 8 days in the SGX942 treatment group. **Despite this clinically meaningful improvement, the variability in the distribution of the data yielded a p-value that was not statistically significant.**

SGX942 is Out. We previously assumed a 90% probability of failure**.** We have revised that to 100%. That leaves SGX301.

Gone in a "FLASH" (Fluorescent Light Activated Synthetic Hypericin). SGX301 (synthetic hypericin) is a topical ointment that 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. We maintain multiple concerns around this product as the technology is new, un-proven, and the market size is small.

Valuation: We assign a Neutral rating and have removed our price target. With that said, we do present our market models. We project the model out to 2030 and assume the company will continue to operate at a loss.

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

Current Price	**$1.29**
Price Target	**NA**

Estimates	F2019A	F2020E	F2021E
Expenses ($000s)	$ 11,604	$ 17,975	$ 17,678
1Q March	$ 2,517	$ 8,569	$ 4,419
2Q June	$ 2,623	$ 3,319	$ 4,419
3Q September	$ 3,056	$ 2,422	$ 4,419
4Q December	$ 3,407	$ 3,665	$ 4,419
	F2019A	F2020E	F2021E
EPS (diluted)	$ (0.49)	$ (0.55)	$ (0.41)
1Q March	$ (0.12)	$ (0.32)	$ (0.10)
2Q June	$ (0.12)	$ (0.08)	$ (0.10)
3Q September	$ (0.14)	$ (0.05)	$ (0.10)
4Q December	$ (0.11)	$ (0.10)	$ (0.10)
EBITDA/Share	($0.36)	($0.66)	($0.54)
EV/EBITDA (x)	0.0	0.0	0.0
Stock Data			
52-Week Range	$0.90	-	$3.54
Shares Outstanding (mil.)			29.8
Market Capitalization (mil.)			$39
Enterprise Value (mil.)			$31
Debt to Capital			0%
Book Value/Share			$0.72
Price/Book			21.6
Average Three Months Trading Volume (K)			873
Insider Ownership			2.6%
Institutional Ownership			13.4%
Short interest (mil.)			2.2%
Dividend / Yield			$0.00/0.0%

Modeling Assumptions: SGX301

1. **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.
2. **Clinical and regulatory outcome assumptions.** We assume final topline results for the SGX301 Phase 3 study will become available soon. If the trial is successful, we expect an NDA / approval in 2021. As such, we anticipate that Soligenix will begin to commercialize SGX301 in 2021.
3. **Product assumptions.** We assume that a yearly treatment cycle for SGX 301 costs $8,000. We also predict that the cost of the drug will increase by 1% per year, but this number may be too conservative since the current off-label treatments are priced at $10,000.
4. **Probability of Success.** We assign just a 10% risk adjustment to our therapeutic model of SGX301 based on the risks associated with the indications, which have a high failure rate, even in late stage trials.

Exhibit 1. SGX301 Model

SGX301 (CTCL) SGX301 Revenues Model	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
CTCL Prevalance	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
Elgible 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	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Total Sales (US) ($millions)	$ -	$ -	$ -	$ 1	$ 2	$ 2	$ 3	$ 4	$ 5	$ 6	$ 8	$ 8	$ 9

Source: Dawson James estimates, company reports

Modeling Assumptions: SGX942 (Dusquetide)

1. **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.
2. **Clinical and regulatory outcome assumptions.** We assume that the company can complete its Phase 3 study no later than 2020. We expect an NDA submission in 2020 with approval and marketing by 2021. For Europe, we assume approval a year later in 2022.
3. **Product assumptions.** We assume a mucositis product could charge $6,000 for a yearly treatment cycle is $6,000.

Exhibit 2. SGX942 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
Elgible 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	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total Sales (US) ($millions)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -

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
Elgible 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	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total Sales (EU) ($millions)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Total Sales (WW) ($millions)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -

Source: Dawson James estimates, company reports

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 its president and CEO, CFO, CSO, and CMO. Soligenix plans to bring its 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 it 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 parties' 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 its 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 3. Income Statement

Soligenix Inc., Inc. Income Statement ($000)																					
Soligenix Inc..: YE Dec. 31	**2018A**	**1Q19A**	**2Q19A**	**3Q19A**	**4Q19A**	**2019A**	**1Q20A**	**2Q20A**	**3Q20A**	**4Q20E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**
Revenue ($000)																					
SGX942 (Mucositis) (WW)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SGX-301	-	-	-	-	-	-	-	-	-	-	-	1,088	1,747	2,494	3,337	4,247	5,255	6,369	7,526	8,344	9,226
Total Product Sales	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1,088**	**1,747**	**2,494**	**3,337**	**4,247**	**5,255**	**6,369**	**7,526**	**8,344**	**9,226**
% Chg																					
License Revenue	3,965	640	1,061	947	568	3,216	845	292	507												
Grant Revenue	1,276	505	484	308	117	1,414	79	213	102												
Cost of Grant Revenue	(4,598)	(928)	(1,087)	(965)	(587)	(3,567)	(830)														
% Sequential Growth																					
Total Revenues	**644**	**217**	**458**	**289**	**98**	**1,063**	**95**	**505**	**609**	**-**	**-**	**1,088**	**1,747**	**2,494**	**3,337**	**4,247**	**5,255**	**6,369**	**7,526**	**8,344**	**9,226**
Expenses																					
Cost of Goods Sold & Acquired in Process R&D	-	-	-	-	-	-	-	363	387	-	750	109	175	249	334	425	525	637	753	834	923
COGS % Sales							10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Research and development	6,751	1,643	1,854	2,267	2,359	8,123	2,700	2,170	1,267	2,775	8,912	9,090	9,272	9,457	9,646	9,839	10,036	10,237	10,442	10,650	10,863
R&D % Rev's																					
G&A	2,952	874	769	789	1,048	3,481	5,869	786	768	890	8,313	8,479	8,649	8,822	8,998	9,178	9,362	9,549	9,740	9,935	10,133
G&A																					
Stock-based compensation - R&D																					
Stock-based compensation - G&A																					
Non-GAAP, Adj																					
Total expenses	**9,703**	**2,517**	**2,623**	**3,056**	**3,407**	**11,604**	**8,569**	**3,319**	**2,422**	**3,665**	**17,975**	**17,678**	**18,095**	**18,528**	**18,978**	**19,442**	**19,923**	**20,423**	**20,934**	**21,419**	**21,919**
Oper. Inc. (Loss)	(9,059)	(2,300)	(2,165)	(2,767)	(3,309)	(10,541)	(8,474)	(2,814)	(1,813)	(3,665)	(17,975)	(16,590)	(16,348)	(16,035)	(15,641)	(15,195)	(14,669)	(14,054)	(13,408)	(13,075)	(12,693)
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Interest Income	159	50	41	46	12	149	(23)	(4)	(8)												
Interest expense							22	2	0												
Other Income (expense)					426	426	57	37	30												
Change in fair value of warrant liability																					
Pre-tax income	**(8,900)**	**(2,250)**	**(2,124)**	**(2,721)**	**(2,872)**	**(9,966)**	**(8,418)**	**(2,779)**	**(1,790)**	**(3,665)**	**(17,975)**	**(16,590)**	**(16,348)**	**(16,035)**	**(15,641)**	**(15,195)**	**(14,669)**	**(14,054)**	**(13,408)**	**(13,075)**	**(12,693)**
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax (Benefit)		-			611	611	837	(556)	(358)	(733)	(810)	(4,148)	(4,904)	(5,452)	(5,318)	(5,166)	(4,987)	(4,778)	(4,559)	(4,446)	(4,316)
Tax Rate	0%	0%	15%	15%	15%	15%	20%	20%	20%	20%	20%	25%	30%	34%	34%	34%	34%	34%	34%	34%	34%
GAAP Net Income (loss)	**(8,900)**	**(2,250)**	**(2,124)**	**(2,721)**	**(2,261)**	**(9,356)**	**(7,581)**	**(2,223)**	**(1,432)**	**(2,932)**	**(14,168)**	**(12,443)**	**(11,444)**	**(10,583)**	**(10,323)**	**(10,029)**	**(9,681)**	**(9,276)**	**(8,849)**	**(8,630)**	**(8,378)**
GAAP-EPS	**(0.79)**	**(0.12)**	**(0.12)**	**(0.14)**	**(0.11)**	**(0.49)**	**(0.32)**	**(0.08)**	**(0.05)**	**(0.10)**	**(0.55)**	**(0.41)**	**(0.36)**	**(0.32)**	**(0.30)**	**(0.28)**	**(0.26)**	**(0.24)**	**(0.22)**	**(0.21)**	**(0.19)**
Non GAAP EPS (dil)	(0.30)	(0.12)	(0.12)	(0.14)	(0.11)	(0.49)	(0.32)	(0.08)	(0.05)	(0.10)	(0.55)	(0.41)	(0.36)	(0.32)	(0.30)	(0.28)	(0.26)	(0.24)	(0.22)	(0.21)	(0.19)
Wgtd Avg Shrs (Bas) - '000s	13,178	18,079	18,437	20,095	20,296	19,377	23,405	26,902	29,572	29,868	27,437	30,622	31,866	33,160	34,506	35,907	37,365	38,882	40,461	42,104	43,813
Wgtd Avg Shrs (Dil) - '000s	13,178	18,079	18,437	20,095	20,296	19,377	23,405	26,902	29,572	29,868	27,437	30,622	31,866	33,160	34,506	35,907	37,365	38,882	40,461	42,104	43,813

Source: Dawson James estimates 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
Rating Change – Neutral – July 28, 2020 – Price Target $2.00
Update – Neutral – September 2, 2020 – Price Target $2.00
Update – Neutral – October 22, 2020 – Price Target $2.00
Update – Neutral – November 12, 2020 – Price Target NA
Update – Neutral – December 22, 2020 – Price Target NA

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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.

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	81%	4	18%
Market Perform (Neutral)	5	19%	1	20%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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