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UPDATE REPORT

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Soligenix, Inc. (NASDAQ/SNGX)

November 1, 2021

Neutral: SGX301 Delayed Until H2-2022 – Company Blames Covid (for Accrued Stability Data)?

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According to the company, SGX-301 is delayed as a result of "disruptions caused by COVID-19 resulting in delays by the commercial active pharmaceutical ingredient contract manufacturer which is now unable to provide the pre-requisite amount of accrued stability data required to file SGX301 (NDA). The timeline for anticipated NDA filing with the FDA is now delayed until H222".

Investment Highlights

In July 2021, we downgraded Soligenix and reviewed our concerns. One of the lead products, SGX942, failed. The company then raised capital (Dec. 2020) of $20M (debt) and now SGX301 is delayed. We see the future of the company as resting on the outcome of its SGX301 for CTCL lesions, which we see as its best chance of success but to a limited market. We continue to see no reason to become more constructive on the company at this time.

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 and unproven, and the market size is small.

The Market is Small. 3,000 US cases annually. Our understanding is that several partnership discussions have been stalled (partners may have walked away) as the market is quite small and the opportunity is not on par with an expensive orphan indication ($8k annually), in our opinion.

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.

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

Current Price	**$1.01**
Price Target	**NA**

Stock Data			
52-Week Range	$0.85	-	$2.80
Shares Outstanding (mil.)			40.1
Market Capitalization (mil.)			$41
Enterprise Value (mil.)			$33
Debt to Capital			0%
Book Value/Share			$0.72
Price/Book			10.5
Average Three Months Trading Volume (K)			108
Insider Ownership			2.0%
Institutional Ownership			10.4%
Short interest (mil.)			2.5%
Dividend / Yield			$0.00/0.0%

Source for the Exhibit at Top: Soligenix

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

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 to 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 could 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.

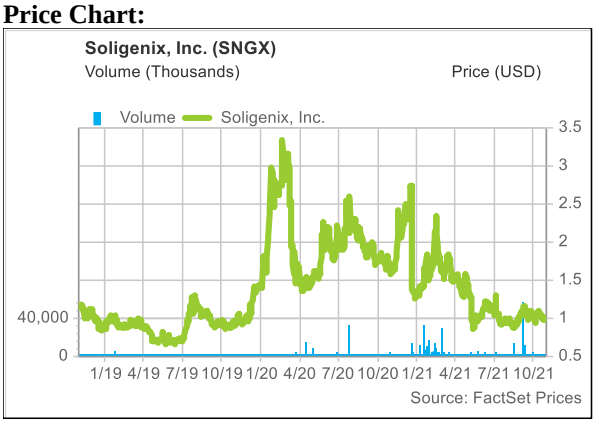
Exhibit 2. Income Statement

Soligenix Inc., Inc. Income Statement ($000)																	
Soligenix Inc..: YE Dec. 31	**2018A**	**2019A**	**2020E**	**1Q21E**	**2Q21E**	**3Q21E**	**4Q21E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**
Revenue ($000)																	
SGX942 (Mucositis) (WW)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SGX-301	-	-	-	272	272	272	272	1,088	1,747	2,494	3,337	4,247	5,255	6,369	7,526	8,344	9,226
Total Product Sales	**-**	**-**	**-**	**272**	**272**	**272**	**272**	**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	3,216															
Grant Revenue	1,276	1,414															
Cost of Grant Revenue	(4,598)	(3,567)															
% Sequential Growth																	
Total Revenues	**644**	**1,063**	**-**	**272**	**272**	**272**	**272**	**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	-	-	750	27	27	27	27	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	8,123	8,912	2,272	2,272	2,272	2,272	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	3,481	8,313	2,120	2,120	2,120	2,120	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**	**11,604**	**17,975**	**4,419**	**4,419**	**4,419**	**4,419**	**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)	(10,541)	(17,975)	(4,148)	(4,148)	(4,148)	(4,148)	(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
Interest Income	159	149															
Interest expense																	
Other Income (expense)		426															
Change in fair value of warrant liability																	
Pre-tax income	**(8,900)**	**(9,966)**	**(17,975)**	**(4,148)**	**(4,148)**	**(4,148)**	**(4,148)**	**(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
Income Tax (Benefit)		611	(810)	(1,037)	(1,037)	(1,037)	(1,037)	(4,148)	(4,904)	(5,452)	(5,318)	(5,166)	(4,987)	(4,778)	(4,559)	(4,446)	(4,316)
Tax Rate	0%	15%	20%	25%	25%	25%	25%	25%	30%	34%	34%	34%	34%	34%	34%	34%	34%
GAAP Net Income (loss)	**(8,900)**	**(9,356)**	**(14,168)**	**(3,111)**	**(3,111)**	**(3,111)**	**(3,111)**	**(12,443)**	**(11,444)**	**(10,583)**	**(10,323)**	**(10,029)**	**(9,681)**	**(9,276)**	**(8,849)**	**(8,630)**	**(8,378)**
GAAP-EPS	**(0.79)**	**(0.49)**	**(0.55)**	**(0.10)**	**(0.10)**	**(0.10)**	**(0.10)**	**(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)	(0.49)	(0.55)	(0.10)	(0.10)	(0.10)	(0.10)	(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	19,377	27,437	30,167	30,468	30,773	31,081	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	19,377	27,437	29,898	30,468	30,773	31,081	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
Update – Neutral – May 11, 2021 – Price Target NA
Update – Neutral – November 1, 2021 – Price Target NA

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Current as of… 15-Oct-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	69%	4	16%
Market Perform (Neutral)	11	31%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	4	11%

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