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Toll-Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

Soligenix, Inc. (NASDAQ/SNGX)

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Neutral Rated: Cash on the Balance Sheet but few Events in 2022

Jason H. Kolbert
Senior Analyst
jkolbert@dawsonjames.com

Given the fall in the stock, we reviewed operating results to determine if valuation is now compelling. Soligenix has been raising capital with the use of an At the Market facility. The company closed 3Q with \$29M in cash and is burning between \$3 and \$4M in cash per quarter, so, the company has plenty of operating runway. With that said, SGX-301 has been delayed, according to the company; “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 targeting H2-22.

Investment Highlights

The company has cash, and that’s positive, but we see the next major event as a year plus away, sometime after the company files the NDA for SGX301 (2H-22). Recall that SGX301 is a therapy to treat CTCL lesions.

The Market is Small. 3,000 US cases annually. We understand that several partnership discussions have stalled (partners may have walked away) as the market is relatively small. In our opinion, the opportunity is not on par with an expensive orphan indication (\$8k annually).

What about Europe? In a letter to shareholders, management states: “We remain steadfast in our plans for partnership in the ex-U.S. markets and continue to pursue discussions with potential partners with similar reputation and expertise in this therapeutic area. We anticipate receiving marketing approval in the U.S. first, and with this approval in hand, we will aggressively pursue marketing authorizations in other key markets worldwide”.

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. Approximately 40 additional subjects are being randomized into the trial to maintain the assumption of 90% statistical power for the primary efficacy endpoint. We hold multiple concerns around this product as the technology is new and unproven, 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.

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 \$0.61
Price Target NA



Stock Data			
52-Week Range	\$0.58	-	\$2.48
Shares Outstanding (mil.)	42.9		
Market Capitalization (mil.)	\$26		
Enterprise Value (mil.)	\$19		
Debt to Capital	0%		
Book Value/Share	\$0.72		
Price/Book	10.5		
Average Three Months Trading Volume (K)	277		
Insider Ownership	0.3%		
Institutional Ownership	9.5%		
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.** With positive topline results from the SGX301 Phase 3 study we now expect the company to file the NDA 2H-22 and assume approval and commercialization in 2024.
- 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 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%			2%	5%	8%	11%	14%	18%	19%	20%
Treatable Patients	0	0	0	0	0	764	2024	3401	4910	6562	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)	\$ -	\$ 6	\$ 17	\$ 28	\$ 41	\$ 56	\$ 75	\$ 83	\$ 92				
Risk Adjusted	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Total Sales (US) (\$millions)	\$ -	\$ 1	\$ 2	\$ 3	\$ 4	\$ 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.

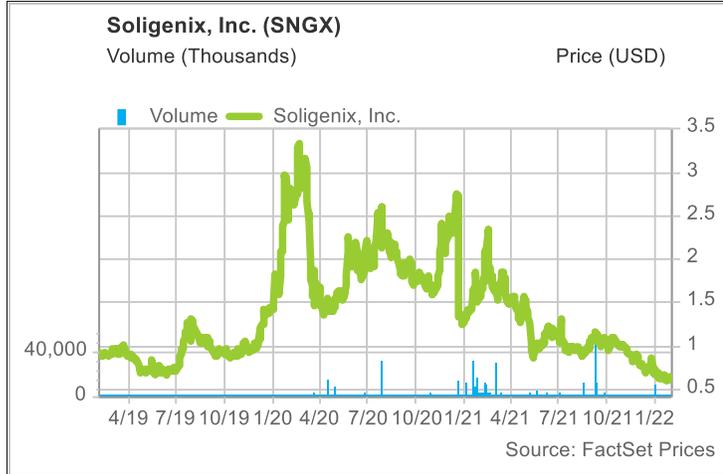
Exhibit 2. Income Statement

Soligenix Inc., Inc. Income Statement (\$000)																	
Soligenix Inc.: YE Dec. 31	2018A	2019A	2020A	1Q21A	2Q21A	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue (\$000)																	
SGX942 (Mucositis) (WW)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SGX-301	-	-	-	-	-	-	-	-	-	623	1,669	2,831	4,129	5,572	7,526	8,344	9,226
Total Product Sales	-	-	1,931	-	-	-	-	-	-	623	1,669	2,831	4,129	5,572	7,526	8,344	9,226
	% Chg																
License Revenue	3,965	3,216															
Grant Revenue	1,276	1,414		33	215	186		434									
Cost of Grant Revenue	(4,598)	(3,567)		112				112									
	% Sequential Growth																
Total Revenues	644	1,063	2,359	148	215	186	-	549	-	623	1,669	2,831	4,129	5,572	7,526	8,344	9,226
Expenses																	
Cost of Goods Sold & Acquired in Process R&D	-	-	1,821	122	204	166	-	493	-	62	167	283	413	557	753	834	923
COGS % Sales			10%	10%	10%	10%	10%	#DIV/0!	#DIV/0!	10%	10%	10%	10%	10%	10%	10%	10%
Research and development	6,751	8,123	15,146	1,367	2,105	2,481	2,481	8,435	8,604	8,776	8,951	9,130	9,313	9,499	9,689	9,883	10,080
R&D % Revs																	
G&A	2,952	3,481	3,979	891	915	914	914	3,635	3,707	3,782	3,857	3,934	4,013	4,093	4,175	4,259	4,344
G&A																	
Stock-based compensation - R&D																	
Stock-based compensation - G&A																	
Non-GAAP Adj																	
Total expenses	9,703	11,604	20,946	2,381	3,020	3,395	3,395	12,563	12,311	12,620	12,975	13,348	13,739	14,150	14,617	14,976	15,347
Oper. Inc. (Loss)	(9,059)	(10,541)	18,587	2,234	(3,010)	(3,375)	(3,395)	(12,014)	(12,311)	(11,996)	(11,307)	(10,516)	(9,610)	(8,577)	(7,091)	(6,632)	(6,121)
Oper Margin	NM	NM	8	15	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Interest Income	159	149	(23)	(214)	422	(67)		141									
Interest expense			(11)	57	17	(217)		(142)									
Other Income (expense)		426	95	27	(191)	72		(92)									
Change in fair value of warrant liability																	
Pre-tax income	(8,900)	(9,966)	(18,525)	(2,362)	(2,762)	(3,588)	(3,395)	(12,107)	(12,311)	(11,996)	(11,307)	(10,516)	(9,610)	(8,577)	(7,091)	(6,632)	(6,121)
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax (Benefit)		611	837	(591)	865	(897)	(849)	(1,472)	(3,693)	(4,079)	(3,844)	(3,576)	(3,267)	(2,916)	(2,411)	(2,255)	(2,081)
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)	(17,689)	(1,772)	(1,897)	(3,588)	(2,546)	(9,803)	(8,618)	(7,917)	(7,462)	(6,941)	(6,343)	(5,661)	(4,680)	(4,377)	(4,040)
GAAP-EPS	(0.79)	(0.49)	(0.64)	(0.06)	(0.05)	(0.09)	(0.06)	(0.26)	(0.20)	(0.18)	(0.16)	(0.15)	(0.13)	(0.11)	(0.09)	(0.08)	(0.07)
Non GAAP EPS (dil)	(0.30)	(0.49)	(0.64)	(0.06)	(0.05)	(0.09)	(0.06)	(0.26)	(0.20)	(0.18)	(0.16)	(0.15)	(0.13)	(0.11)	(0.09)	(0.08)	(0.07)
Wgtd Avg Shrs (Bas) - '000s	13,178	19,377	27,487	36,818	40,074	40,698	41,105	39,674	42,143	43,854	45,635	47,488	49,416	51,422	53,510	55,683	57,944
Wgtd Avg Shrs (Dil) - '000s	13,178	19,377	27,487	36,818	40,074	40,698	41,105	39,674	42,143	43,854	45,635	47,488	49,416	51,422	53,510	55,683	57,944

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
- Update – Neutral – February 2, 2022 – Price Target NA

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- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
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Current as of... 31-Jan-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	29	73%	6	21%
Market Perform (Neutral)	11	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	40	100%	6	15%

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