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## Soligenix, Inc. (NASDAQ/SNGX)

July 26, 2022

### Neutral Rated: The P3 is Complete, Is an NDA Next?

*Soligenix announced the completion of the P3 trial of HyBryte (cutaneous T-cell lymphoma CTCL). This is a topical treatment for early-stage CTCL. The company is now preparing to submit a New Drug Application to the FDA. We view the CTCL market as small and not as an unmet medical need suggesting pricing will be modest, we estimate \$8k annually.*

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#### Investment Highlights

The next major event is the filing of the NDA for SGX301 (2H-22). Recall that SGX301 is a therapy to treat CTCL lesions. The company has cash, but the balance is steadily decreasing, and we expect a capital raise next year.

**The Market is Small.** We estimate 3,000 U.S. cases annually and, according to the company, a 27k prevalence. We understand several partnership discussions have stalled (partners may have walked away) as the market is relatively small. See our market model next page.

**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 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 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 \$0.86  
Price Target NA



Stock Data			
52-Week Range	\$0.38	-	\$1.23
Shares Outstanding (mil.)	42.9		
Market Capitalization (mil.)	\$37		
Enterprise Value (mil.)	\$30		
Debt to Capital	0%		
Book Value/Share	\$0.72		
Price/Book	2.6		
Average Three Months Trading Volume (K)	355		
Insider Ownership	0.4%		
Institutional Ownership	7.6%		
Short interest (mil.)	1.4%		
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%	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%										
<b>Total Sales (\$millions) \$</b>	<b>-</b>	<b>\$</b>	<b>-</b>	<b>\$</b>	<b>11</b>	<b>\$</b>	<b>17</b>	<b>\$</b>	<b>25</b>	<b>\$</b>	<b>33</b>	<b>\$</b>	<b>42</b>	<b>\$</b>	<b>53</b>	<b>\$</b>	<b>64</b>	<b>\$</b>	<b>75</b>	<b>\$</b>	<b>83</b>	<b>\$</b>	<b>92</b>
Risk Adjusted	10%	10%	10%	0%	0%	0%	10%	10%	10%	10%	10%	10%	10%										
<b>Total Sales (US) (\$millions) \$</b>	<b>-</b>	<b>\$</b>	<b>-</b>	<b>\$</b>	<b>-</b>	<b>\$</b>	<b>-</b>	<b>\$</b>	<b>-</b>	<b>\$</b>	<b>3</b>	<b>\$</b>	<b>4</b>	<b>\$</b>	<b>5</b>	<b>\$</b>	<b>6</b>	<b>\$</b>	<b>8</b>	<b>\$</b>	<b>8</b>	<b>\$</b>	<b>9</b>

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	2021A	1Q22A	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Revenue (\$000)</b>																	
SGX942 (Mucositis) (WW)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SGX-301	-	-	-	-	-	-	-	-	-	-	3,337	4,247	5,255	6,369	7,526	8,344	9,226
<b>Total Product Sales</b>	-	-	-	-	-	-	-	-	-	-	3,337	4,247	5,255	6,369	7,526	8,344	9,226
<b>% Chg</b>																	
License Revenue	3,965	3,216			50												
Grant Revenue	1,276	1,414			138												
Cost of Grant Revenue	(4,598)	(3,567)															
<b>% Sequential Growth</b>																	
<b>Total Revenues</b>	<b>644</b>	<b>1,063</b>	<b>-</b>	<b>824</b>	<b>188</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>3,337</b>	<b>4,247</b>	<b>5,255</b>	<b>6,369</b>	<b>7,526</b>	<b>8,344</b>	<b>9,226</b>
<b>Expenses</b>																	
Cost of Goods Sold & Acquired in Process R&D	-	-	750	(729)	92	-	-	-	92	-	334	425	525	637	753	834	923
COGS % Sales			10%			10%	10%	10%	#DIV/0!	#DIV/0!	10%	10%	10%	10%	10%	10%	10%
Research and development	6,751	8,123	8,912	8,389	1,747	1,747	1,747	1,747	8,557	8,728	8,902	9,081	9,262	9,447	9,636	9,829	10,026
R&D % Revs																	
G&A	2,952	3,481	8,313	4,847	2,552	2,552	2,552	2,552	4,944	5,043	5,144	5,247	5,351	5,459	5,568	5,679	5,793
Stock-based compensation - R&D																	
Stock-based compensation - G&A																	
Non-GAAP, Adj																	
<b>Total expenses</b>	<b>9,703</b>	<b>11,604</b>	<b>17,975</b>	<b>13,263</b>	<b>4,391</b>	<b>4,298</b>	<b>4,298</b>	<b>4,298</b>	<b>13,593</b>	<b>13,771</b>	<b>14,380</b>	<b>14,752</b>	<b>15,139</b>	<b>15,543</b>	<b>15,957</b>	<b>16,342</b>	<b>16,741</b>
Oper. Inc. (Loss)	(9,059)	(10,541)	(17,975)	(13,140)	(4,203)	(4,298)	(4,298)	(4,298)	(13,593)	(13,771)	(11,043)	(10,505)	(9,885)	(9,174)	(8,431)	(7,998)	(7,515)
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Interest Income	159	149		421													
Interest expense				(39)	(108)												
Other Income (expense)		426		(862)	(201)												
Change in fair value of warrant liability				204	163												
<b>Pre-tax income</b>	<b>(8,900)</b>	<b>(9,966)</b>	<b>(17,975)</b>	<b>(13,416)</b>	<b>(4,349)</b>	<b>(4,298)</b>	<b>(4,298)</b>	<b>(4,298)</b>	<b>(13,593)</b>	<b>(13,771)</b>	<b>(11,043)</b>	<b>(10,505)</b>	<b>(9,885)</b>	<b>(9,174)</b>	<b>(8,431)</b>	<b>(7,998)</b>	<b>(7,515)</b>
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax (Benefit)		611	(810)	864	-	(1,290)	(1,290)	(1,290)	(3,869)	(4,682)	(3,754)	(3,572)	(3,361)	(3,119)	(2,867)	(2,719)	(2,555)
Tax Rate	0%	15%	20%			30%	30%	30%	30%	34%	34%	34%	34%	34%	34%	34%	34%
<b>GAAP Net Income (loss)</b>	<b>(8,900)</b>	<b>(9,356)</b>	<b>(14,168)</b>	<b>(12,550)</b>	<b>(4,349)</b>	<b>(3,009)</b>	<b>(3,009)</b>	<b>(3,009)</b>	<b>(13,375)</b>	<b>(9,089)</b>	<b>(7,288)</b>	<b>(6,933)</b>	<b>(6,524)</b>	<b>(6,055)</b>	<b>(5,564)</b>	<b>(5,279)</b>	<b>(4,960)</b>
GAAP-EPS	(0.79)	(0.49)	(0.55)	(0.31)	(0.10)	(0.07)	(0.07)	(0.07)	(0.31)	(0.20)	(0.15)	(0.14)	(0.13)	(0.11)	(0.10)	(0.09)	(0.08)
Non GAAP EPS (dil)	(0.30)	(0.49)	(0.55)	(0.31)	(0.10)	(0.07)	(0.07)	(0.07)	(0.31)	(0.20)	(0.15)	(0.14)	(0.13)	(0.11)	(0.10)	(0.09)	(0.08)
Wgtd Avg Shrs (Bas) - '000s	13,178	19,377	27,437	40,132	42,920	43,349	43,783	44,221	43,568	45,337	47,178	49,094	51,087	53,161	55,320	57,566	59,904
Wgtd Avg Shrs (Dil) - '000s	13,178	19,377	27,437	40,132	42,920	43,349	43,783	44,221	43,568	45,337	47,178	49,094	51,087	53,161	55,320	57,566	59,904

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
- Update – Neutral – June 17, 2022 – Price Target NA
- Update – Neutral – July 26, 2022 – Price Target NA

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Current as of 25-Jul-22

	<b>Company Coverage</b>		<b>Investment Banking</b>	
<b>Ratings Distribution</b>	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	30	68%	5	17%
Market Perform (Neutral)	13	30%	0	0%
Market Underperform (Sell)	1	2%	0	0%
<b>Total</b>	<b>44</b>	<b>100%</b>	<b>5</b>	<b>11%</b>

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