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Soligenix, Inc. (NASDAQ/SNGX)

August 14, 2019

BUY: Data Read-Outs Approaching in Two Pivotal Trials

Soligenix reported 2Q19, spending \$2.1M and closing the period with \$7.0M in cash. Management highlighted multiple accomplishments and is now focused on the two pivotal programs in CTCL (SGX301) and Mucositis (Dusquetide) while moving the public health solutions platform forward.

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Investment Highlights

Soligenix is now approaching data read-out in two Phase 3 clinical programs. The enrollment for the Mucositis trial (SGX942), N=90 to support the interim efficacy analysis is approaching in September. The completion of full enrollment in the study is expected in 2H19, with final top-line results anticipated in the 1H20. 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). Soligenix is continuing to enroll patients and anticipate completing study enrollment in the 2H19, with final top-line results in 1Q20.

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).

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).

Public Health Solutions (biodefense). This division of Soligenix has mainly been working to advance RiVax, a ricin toxin vaccine. The drug has reached Phase 1/2 vaccine immunogenicity and safety study in healthy volunteers utilizing RiVax in the 2H19. Simultaneously, additional efficacy studies in nonhuman primates are planned in the coming months which enables a larger database of biomarkers for correlation with human clinical results. In addition, RiVax is being developed in combination with ThermoVax which eliminates the need for cold-chain management of alum-formulated vaccines. RiVax is being developed under the FDA animal rule and is supported by up to \$24.7 million over six years awarded by the National Institute of Health (NIH).

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

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 10,332	\$ 10,539	\$ 12,382
1Q March	\$ 2,517	\$ 2,635	\$ 3,096
2Q June	\$ 2,555	\$ 2,635	\$ 3,096
3Q September	\$ 2,620	\$ 2,635	\$ 3,096
4Q December	\$ 2,640	\$ 2,635	\$ 3,096
	F2019E	F2020E	F2021E
EPS (diluted)	\$ (0.45)	\$ (0.32)	\$ 0.11
1Q March	\$ (0.09)	\$ (0.07)	\$ 0.03
2Q June	\$ (0.12)	\$ (0.09)	\$ 0.03
3Q September	\$ (0.12)	\$ (0.08)	\$ 0.03
4Q December	\$ (0.12)	\$ (0.08)	\$ 0.03
EBITDA/Share	(\$0.42)	(\$0.43)	\$0.15
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%		



Update - August 14, 2019 - Buy - Price Target \$3.00

Valuation. We have modeled CTCL and oral mucositis both with 33% risk rates. We do not include any value for the biodefense programs. To the overall result, we apply a discount rate of 30%. We assume dilution and triangulate FCF, discounted EPS, and sum-of-the-parts models—averaged and equally weighted to derive an NPV of \$3.00.

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

Earnings Multiple	Discount Rate and Earnings Multiple Varies, Year is Constant						
	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.: YE Dec. 31	1Q18A	2Q18A	3Q18A	4Q18A	2018A	1Q19A	2Q19E	3Q19E	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	
Revenue (\$000)																						
SGX942 (Mucositis) (WW)	-	-	-	-	-	-	-	-	-	-	-	13,123	31,811	50,871	73,013	95,592	118,617	142,092	160,396	170,527	183,714	
SGX-301	-	-	-	-	-	-	-	-	-	-	-	3,699	5,940	8,479	11,347	14,440	17,865	21,653	25,587	28,370	31,368	
Total Product Sales												16,822	37,750	59,349	84,359	110,032	136,482	163,744	185,984	198,897	215,082	
% Chg																						
License Revenue	777	1,368	1,064	756	3,965	640																
Grant Revenue	342	358	317	259	1,276	505																
Cost of Grant Revenue	(979)	(1,494)	(1,237)	(888)	(4,598)	(928)																
% Sequential Growth																						
Total Revenues	141	232	144	127	644	217	-	-	-	-	-	16,822	37,750	59,349	84,359	110,032	136,482	163,744	185,984	198,897	215,082	
Expenses																						
Cost of Goods Sold & Acquired in Process R&D	-	-	-	-	-	-	-	-	-	-	-	1,682	3,775	5,935	8,436	11,003	13,648	16,374	18,598	19,890	21,508	
COGS % Sales											10%	10%	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	1,655	1,700	1,725	6,723	6,857	6,994	7,134	7,277	7,423	7,571	7,722	7,877	8,034	8,195	8,359	
R&D % Revs																						
G&A	732	651	668	902	2,952	874	900	920	915	3,609	3,681	3,755	3,830	3,907	3,985	4,065	4,146	4,229	4,313	4,400	4,488	
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	2,555	2,620	2,640	10,332	10,539	12,432	14,739	17,119	19,843	22,639	25,516	28,480	30,946	32,484	34,355	
Oper. Inc. (Loss)	(2,394)	(1,589)	(1,919)	(3,157)	(9,059)	(2,300)	(2,555)	(2,620)	(2,640)	(10,332)	(10,539)	4,390	23,011	42,231	64,516	87,393	110,966	135,264	155,038	166,412	180,727	
Oper Margin	NM	NM	0	1	1	1	1	1	1	1	1	1	1									
Interest Income	17	33	57	52	159	50																
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)	(2,555)	(2,620)	(2,640)	(10,332)	(10,539)	4,391	23,011	42,231	64,517	87,394	110,966	135,265	155,038	166,413	180,728	
Pretax Margin	NM	NM	0	1	1	1	1	1	1	1	1	1	1									
Income Tax (Benefit)	-	-	-	-	-	-	(383)	(393)	(396)	(1,172)	(2,108)	1,098	6,904	14,359	21,936	29,715	37,729	45,991	52,714	56,581	61,448	
Tax Rate	0%	0%	0%	0%	0%	0%	15%	15%	15%	15%	20%	25%	30%	34%	34%	34%	34%	34%	34%	34%	34%	34%
GAAP Net Income (loss)	(2,377)	(1,556)	(1,862)	(3,105)	(8,900)	(2,250)	(2,172)	(2,227)	(2,244)	(8,893)	(8,431)	3,293	16,109	27,874	42,583	57,682	73,239	89,277	102,327	109,834	119,282	
GAAP-EPS	(0.27)	(0.18)	(0.11)	(0.24)	(0.79)	(0.12)	(0.12)	(0.12)	(0.12)	(0.48)	(0.32)	0.13	0.59	0.99	1.45	1.88	2.30	2.69	2.96	3.06	3.19	
Non GAAP EPS (dil)	(0.27)	(0.18)	(0.11)	(0.24)	(0.30)	(0.09)	(0.12)	(0.12)	(0.12)	(0.45)	(0.32)	0.13	0.59	0.99	1.45	1.88	2.30	2.69	2.96	3.06	3.19	
Wgtd Avg Shrs (Bas) - '000s	8,735	8,743	17,495	13,178	13,178	18,079	18,260	18,442	18,627	18,352	24,675	26,190	27,253	28,360	29,511	30,709	31,956	33,254	34,604	36,009	37,471	
Wgtd Avg Shrs (Dil) - '000s	8,735	8,743	17,495	13,178	13,178	18,079	18,260	18,442	18,627	18,352	24,675	26,190	27,253	28,360	29,511	30,709	31,956	33,254	34,604	36,009	37,471	

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

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Information about valuation methods and risks can be found in the “STOCK VALUATION” and “RISK ANALYSIS” sections of this report.

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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)	42	84%	13	31%
Market Perform (Neutral)	8	16%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	50	100%	13	26%

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.