

Brainstorm (NASDAQ/BCLI)

May 7, 2020

BUY On Track in ALS For Data by Year's End

Brainstorm reported a net loss in the quarter of \$8M driven by clinical costs of the pivotal trial. The company has \$14.5M in cash on the balance sheet at the end of 1Q20. Importantly, management announced that the Phase 3 trial remains on track for top-line data at year's end. COVID19 has not delayed enrollment / trial progress in ALS, but has slowed the Phase 2 MS trial. As a reminded we remain positive on the results as the safety for NurOwn is not an issue so any significant efficacy in ALS (a dramatically unmet medical need) should translate into approval.

Jason H. Kolbert
 Head of Healthcare Research
 646-465-6891

Current Price	\$5.95		
Price Target	\$14.00		
Estimates	F2018A	F2019A	F2020E
Revenues (\$000s)	\$1,500	\$6,000	\$0
1Q March	\$0	\$1,500	\$0
2Q June	\$0	\$1,500	\$0
3Q September	\$0	\$1,500	\$0
4Q December	\$1,500	\$1,500	\$0
	F2018A	F2019A	F2019E
EPS (diluted)	(0.51)	(0.32)	(1.23)
1Q March	(0.12)	(0.10)	(0.33)
2Q June	(0.16)	(0.07)	(0.27)
3Q September	(0.15)	(0.07)	(0.27)
4Q December	(0.08)	(0.08)	(0.36)
EBITDA/Share			
EV/EBITDA (x)			
Stock Data			
52-Week Range	\$3.43	-	\$10.00
Shares Outstanding (mil.)	21		
Market Capitalization (mil.)	\$123		
Enterprise Value (mil.)	\$112		
Debt to Capital	0.0%		
Book Value/Share	\$0.31		
Price/Book	#N/A		
Average Three Months Trading Volume (M)	0.2		
Insider Ownership	22.7%		
Institutional Ownership	9.1%		
Short interest (mil.)	11.1%		
Dividend / Yield	\$0.00/0.0%		

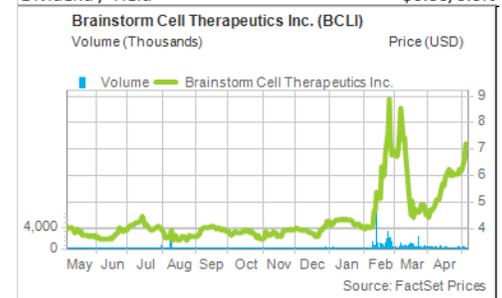
Investment Highlights

There is Hope in ALS. The FDA (Center for Biologics Evaluation and Research - CBER) indicated to the company that they would look at the "**totality of the evidence**" in the expected Phase 3 clinical trial. We believe that regulators now recognize that in the regenerative medicine – cell therapy space (not to be confused with CAR-T), there is a high safety margin. This, coupled with the unmet medical need, should set a lower bar for approval of these therapies if they can show even moderate efficacy.

Brainstorm reported the First Quarter 2020. The company spent \$8.3M in 1Q20. The company announced a \$2.2M grant from CIRM (for meeting prespecified milestones) and raised gross proceeds of \$10M from Abbhi Investments, LLC, and entered an ATM distribution agreement for up to \$50M.

Moving Towards Data. With enrollment in the Pivotal ALS trial complete as of last quarter, the company now is closing in on data by year-end.

What is NurOwn? It is an autologous (your own cells) cell therapy, which is modified to become a potent drug-like miniature factory to treat neural disorders. The company uses a proprietary growth media to induce these adult autologous mesenchymal stem cells (MSCs) to differentiate into specialized neuron-supporting cells that secrete neurotrophic, nerve-growth supporting factors, MSC-NTFS. The cells are then administered via intramuscular and, or intrathecal injection, which is painless and considered safe. The cells are believed to promote motor neuron growth, protect existing motor neurons, and help reestablish nerve-muscle interaction. The ALS opportunity represents an unmet medical need, and while it is designated as an orphan disease, it does have significant market potential. ALS affects 30,000 people in the U.S. and 450,000 worldwide. 5,000 new cases are diagnosed annually in the U.S. The average life expectancy is 2-5 years, and care is almost exclusively palliative. Advanced-stage patient care can reach \$200,000 per year, representing a \$6 billion cost to the healthcare system. Changes in regulations for the approval of cell therapy in the U.S., such as the 21st Century Act, and similar legislative changes in Europe and Japan should support the application for NurOwn, provided the pivotal trial demonstrates positive data. Brainstorm's initial focus will be on the U.S. and E.U. Markets but has had early discussions with potential partners in Japan.



Will the Phase 3 trial be successful? The enrollment criteria for the pivotal trial is designed to include only the fast-progressing patients who demonstrated superior outcomes in the prior Phase 2 trial. In this way, we view the trial as “enriched.” The trial itself is a 200 patient, randomized, placebo-controlled, double-blind, multi-dose trial conducted at six sites in the U.S. The primary outcome measure for the study will also use the ALSFR-S score responder analysis. We also note that these ALS patients in the current pivotal trial can now be treated with multiple doses. Once the patient's cells are initially harvested, they will be sent to the lab where they can be processed and then cryopreserved. Brainstorm has already successfully demonstrated the equivalence of cryopreserved cells to fresh cells. We view cryopreservation as an important part of the Brainstorm fundamental story as it allows a high cost of goods to be spread out across multiple doses, improving manufacturing margins. The idea of multiple doses is consistent with our knowledge of how cell therapy works, as cells have a half-life, and doses will need to be refreshed over the course of treatment.

Valuation. While the stock and its market capitalization have risen to just over \$139M, we still view the company as trading at a distressed valuation. Brainstorm today is now a pivotal company with a product that has an orphan designation, in a market where the need is both desperate and unmet. The Phase 2 trial demonstrated a high safety margin, so if efficacy is demonstrated in the pivotal trial, it creates a favorable risk-reward scenario. This, combined with changes in legislation around the approval of cell therapy in the U.S., Europe, and Japan, should create, in our opinion, a significant opportunity. In our model, we apply a 50% probability of success in our therapeutic models and a 30% discount rate in our valuation metrics. We assume dilution in our model too. Using these metrics, we model the market potential and discount back in our FCFE, discounted EPS, and sum-of-the-parts models, rounded to the nearest whole number to arrive at a \$14.00 price target.

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

Valuation Analysis. Given the fact that the company's market capitalization is approximately ~\$139 million, we still see the valuation as distressed. We see a company with a pivotal trial, orphan designation, in a market where the need is both desperate and unmet. The Phase 2 trial demonstrated an excellent safety profile, and the results helped to enrich the probability of a successful pivotal trial by identifying the importance of excluding slow-progressing patients. If the pivotal trial shows statistically significant p-values combined with changes in legislation around the approval of cell therapy in the U.S., Europe, and Japan, we could see a large global market opportunity. We also take note that the Phase 3 trial is being supported with non-dilutive capital from CIRM and the Israeli Innovative Authority.

Product Modeling Assumptions

1. We assume NurOwn's Phase 3 trial will demonstrate p-values on the primary and secondary endpoints and qualify for review and approval in the U.S. and Europe.
2. We assume pricing of \$151,000 per patient during the life of the patient, or duration of treatment in the U.S. and \$139,000 in Europe. Our price assumptions could prove to be too conservative as cell-based therapies typically charge multiples of our assumptions. We do this for conservatism.
3. We reduce the patient population pool by 25% to account for patients who may not have access to therapy or insurance.
4. We apply a 50% probability of success in our model, as NurOwn is not yet approved, and we acknowledge the novel nature of both cell therapy, the variability of this disease, and the complex nature of using Phase 2 data to predict a Phase 3 trial outcome.
5. We have not assumed revenues beyond the U.S. and Europe.

Exhibit 1. Market Model for the U.S. and Europe for Brainstorm's NurOwn in ALS Patients

Amyotrophic Lateral Sclerosis (ALS)																
ALS revenues model (US)																
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
ALS Prevalance	30,000	30,300	30,603	30,909	31,218	31,530	31,846	32,164	32,486	32,811	33,139	33,470	33,805	34,143	34,484	34,829
Market Size Growth	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Eligible patients with insurance (75%)	22,500	22,725	22,952	23,182	23,414	23,648	23,884	24,123	24,364	24,608	24,854	25,103	25,354	25,607	25,863	26,122
Market Penetration	0%	0%	0%	0%	0%	0%	0%	0%	0%	4%	10%	15%	20%	25%	30%	34%
Treatable Patients	0	0	0	0	0	0	0	0	0	984	2485	3765	5071	6402	7759	8881
Average Price of Therapy								\$151,000	\$154,020	\$157,100	\$160,242	\$163,447	\$166,716	\$170,051	\$173,452	\$176,921
Price Growth	0%	0%	0%	0%	0%	0%	0%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Total Sales (\$M)										\$ 154,637	\$ 398,266	\$ 615,441	\$ 845,370	\$ 1,088,625	\$ 1,345,802	\$ 1,571,305
Probability of Approval									50%	50%	50%	50%	50%	50%	50%	50%
Total Sales (US) (\$M)										\$ 77,318	\$ 199,133	\$ 307,721	\$ 422,685	\$ 544,313	\$ 672,901	\$ 785,652

Amyotrophic Lateral Sclerosis (ALS)																
ALS revenues model (Europe)																
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
ALS Prevalance	55,000	55,550	56,106	56,667	57,233	57,806	58,384	58,967	59,557	60,153	60,754	61,362	61,975	62,595	63,221	63,853
Market Size Growth	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Eligible patients with insurance (75%)	41,250	41,663	42,079	42,500	42,925	43,354	43,788	44,226	44,668	45,115	45,566	46,021	46,482	46,946	47,416	47,890
Market Penetration	0%	0%	0%	0%	0%	0%	0%	0%	2%	5%	10%	15%	20%	25%	30%	34%
Treatable Patients	0	0	0	0	0	0	0	0	893	2256	4557	6903	9296	11737	14225	16283
Average Cost of Therapy	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$139,000	\$141,780	\$144,616	\$147,508	\$150,458	\$153,467	\$156,537	\$159,667	\$162,861
Price Growth	0%	0%	0%	0%	0%	0%	0%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Total Sales (\$M)									\$ 126,660	\$ 326,213	\$ 672,130	\$ 1,038,642	\$ 1,426,678	\$ 1,837,205	\$ 2,271,226	\$ 2,651,793
Probability of Approval					0%	0%	0%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Sales (Europe) (\$M)									\$ 63,330	\$ 163,107	\$ 336,065	\$ 519,321	\$ 713,339	\$ 918,603	\$ 1,135,613	\$ 1,325,897

Source: Dawson James estimates.

Valuation. Our product models feed into our income statement and allow us to apply valuation metrics. For conservatism, we apply a 50% probability of approval in our product models as NurOwn is a new and novel therapy in a variable disease. Our product model reflects our assumptions for the product launch dates, product attributes, and pricing to determine the future revenue streams. Our valuation conclusion is an equally-weighted average of our FCF, EPS, and sum-of-the-parts analysis discounted at a rate of 30% to account for the risks of development-stage products. For companies that are well established with mature products and revenues, we typically will use a 10% risk rate. For companies in the early stages of product commercialization, we typically choose a higher risk rate of 15%. For Brainstorm, we use our maximum risk rate of 30% as the company does not yet have an approved therapeutic product. Our model does assume a capital raise, and our valuation is based on a fully-diluted out-year share forecast.

Exhibit 2. Discounted Free-Cash-Flow Model

Average	\$	14.00
Price Target	\$	11.00
Year		2020

DCF Valuation Using FCF (mln):

units ('000 - Cnd\$)	2016A	2017A	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
EBIT (Earnings before income tax)	(4,982)	(4,952)	(10,226)	(23,253)	(48,303)	(20,469)	40,662	142,963	244,221	351,460	464,949	584,967	690,069
Tax Rate	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	30%	35%	37%
EBIT(1-t) Earnings after income tax	(4,982)	(4,952)	(10,226)	(23,253)	(48,303)	(19,445)	36,596	121,518	195,377	263,595	325,464	380,228	434,743
CapEx (equipment)	(103)	(180)	(261)	(473)	(7)	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(5,085)	(5,132)	(10,487)	(23,726)	(48,310)	(19,445)	36,596	121,518	195,377	263,595	325,464	380,228	434,743
PV of FCF	(14,523)	(11,275)	(17,723)	(30,844)	(48,310)	(14,958)	21,654	55,311	68,407	70,994	67,428	60,596	53,295
Discount Rate	30%												
Long Term Growth Rate	1%												
Terminal Cash Flow	1,514,106												
Terminal Value YE2023	185,613												
NPV	520,031												
NPV-Debt	-												
Shares out ('000)	45,916												
NPV Per Share	\$ 11.33												

Source: Dawson James Securities

Exhibit 3. EPS Model

Current Year	2020
Year of EPS	2023
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 2.70
NPV	\$ 12.29

Discount Rate and Earnings Multiple Varies, Year is Constant							
2023 EPS							
Earnings Multiple	12.3	5%	10%	15%	20%	25%	30%
0		\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
5		\$11.66	\$10.14	\$8.88	\$7.81	\$6.91	\$ 6.14
10		\$23.32	\$20.29	\$17.75	\$15.62	\$13.82	\$ 12.29
15		\$34.99	\$30.43	\$26.63	\$23.44	\$20.74	\$ 18.43
20		\$46.65	\$40.57	\$35.51	\$31.25	\$27.65	\$ 24.58
25		\$58.31	\$50.71	\$44.38	\$39.06	\$34.56	\$ 30.72
30		\$69.97	\$60.86	\$53.26	\$46.87	\$41.47	\$ 36.87
35		\$81.63	\$71.00	\$62.13	\$54.69	\$48.38	\$ 43.01

Source: Dawson James estimates.

Exhibit 4. Sum-of-the-Parts Model

Brainstorm Cell Therapeutics, Inc (BCLI)	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	Term Val
Nurown	1%	30%	2	70%	\$750	\$2,586
ALS						\$16.33
Nurown	1%	50%	5	50%	\$500	\$1,020
Pre-Clinical Pipeline						\$1.02
Net Margin						70%
MM Shrs OS						46
Total						\$17.36

Source: Dawson James Securities

Exhibit 5. Income Statement

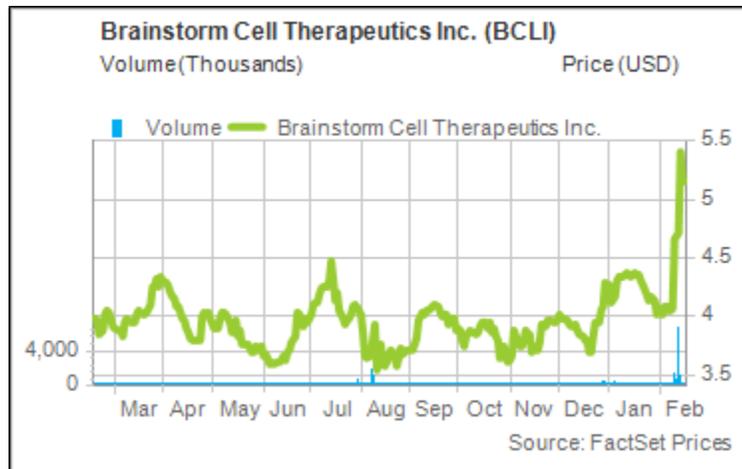
Brainstorm Cell Therapeutics, Inc.: Income Statement (\$000)																
Brainstorm Cell Therapeutics.: YE Dec. 31	2017A	2018E	2019A	1Q20A	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Nurown™ (U.S. sales)				-	-	-	-	-	-	77,318	199,133	307,721	422,685	544,313	672,901	785,652
Nurown™ (EU sales)					-	-	-		63,330	163,107	336,065	519,321	713,339	918,603	1,135,613	1,325,897
Supportive Development Grant Revenue		1,500	-													
Total Product Sales		1,500	6,000	-	-	-	-	-	63,330	240,425	535,198	827,041	1,136,024	1,462,915	1,808,514	2,111,549
Expenses																
Cost of goods sold				-	-	-	-	-	41,165	156,276	347,879	537,577	738,416	950,895	1,175,534	1,372,507
COGS % of Revenue				75%	75%	75%	75%	#DIV/0!	65%	65%	65%	65%	65%	65%	65%	65%
Research and development	977	5,933	17,204	5,948	6,007	6,068	6,128	24,151	24,634	25,127	25,630	26,142	26,665	27,198	27,742	28,297
R&D % of Revenue																
SG&A	4,022	5,793	5,797	2,360	5,796	6,038	9,957	24,151	18,000	18,360	18,727	19,102	19,484	19,873	20,271	20,676
SG&A % of Revenue																
Total expenses	4,999	11,726	23,001	8,308	11,804	12,105	16,085	48,303	83,799	199,763	392,235	582,821	784,564	997,967	1,223,547	1,421,480
Oper. Inc. (Loss)	(4,999)	(10,226)	(23,001)	(8,308)	(11,804)	(12,105)	(16,085)	(48,303)	(20,469)	40,662	142,963	244,221	351,460	464,949	584,967	690,069
Financial income expenses, net	47		(252)	194												
Taxes on income																
Other income																
Pre-tax income	(4,952)	(10,226)	(23,253)	(8,114)	(11,804)	(12,105)	(16,085)	(48,303)	(20,469)	40,662	142,963	244,221	351,460	464,949	584,967	690,069
Income Tax Benefit (Provision)	-	-	-	-	-	-	-	-	(1,023)	4,066	21,444	48,844	87,865	139,485	204,738	255,325
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	30%	35%	37%
GAAP Net Income (loss)	(4,952)	(10,165)	(23,253)	(8,114)	(11,804)	(12,105)	(16,085)	(48,109)	(19,445)	36,596	121,518	195,377	263,595	325,464	380,228	434,743
GAAP-EPS	(0.26)	(0.51)	(1.06)	(0.33)	(0.27)	(0.27)	(0.36)	(1.23)	(0.44)	0.82	2.70	4.32	5.81	7.15	8.31	9.47
Non GAAP EPS (dil)	(0.26)	(0.51)	(1.06)	(0.33)	(0.27)	(0.27)	(0.36)	(1.23)	(0.44)	0.82	2.70	4.32	5.81	7.15	8.31	9.47
Wgtd Avg Shrs (Bas) - '000s	18,777	19,989	21,906	24,424	34,426	34,430	34,433	31,928	34,442	34,466	34,469	34,483	34,497	34,511	34,525	34,538
Wgtd Avg Shrs (Dil) - '000s	18,777	20,036	21,906	24,424	44,448	44,493	44,537	39,476	44,649	44,828	45,007	45,187	45,368	45,550	45,733	45,916

Source: Dawson James estimates.

Companies mentioned in this report:

Important Disclosures:

Price Chart:



Price target and ratings changes over the past three years:

- Initiated – Buy – December 20, 2018 – Price Target \$12.00
- Update – Buy – May 23, 2019 – Price Target \$12.00
- Update – Buy – August 14, 2019 – Price Target \$12.00
- Update – Buy – October 15, 2019 – Price Target \$12.00
- Update – Buy – November 20, 2019 – Price Target \$12.00
- Update - Buy – February 12, 2020 – Price Target \$12.00
- Update - Buy – February 19, 2020 – Price Target \$14.00
- Update - Buy – May 7, 2020 – Price Target \$14.00

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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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	# of Companies	% of Total	# of Companies	% of Totals
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Market Perform (Neutral)	2	8%	1	50%
Market Underperform (Sell)	0	0%	0	0%
Total	24	100%	4	17%

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