

Brainstorm (NASDAQ/BCLI)

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BUY NurOwn Published in the Journal of Neurology

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Brainstorm announced publication of "NurOwn Phase 2 Randomized Clinical Trial in ALS: Safety, Clinical and BioMarker Results," in the international, peer-reviewed journal Neurology: Volume 93, Number 24.

Current Price	\$3.78
Price Target	\$14.00

Investment Highlights

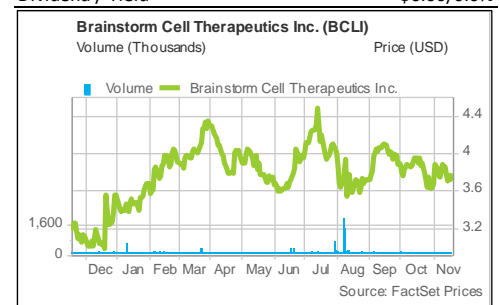
The article reviews some of the key efficacy findings from the Phase 2 trial.

- The rate of ALS disease progression (ALSFRS-R slope) was stabilized for up to 12-16 weeks in a pre-specified group of participants with rapid progression ($p < 0.05$) following a single transplantation
- A higher proportion of MSC-NTF treated study participants experienced ≥ 1.5 point/month improvement in ALSFRS-R slope at all post-treatment time points, and this was statistically significant at 4 and 12 weeks post-transplantation ($p = 0.004$ and 0.046 , respectively)
- CSF neurotrophic factors increased and inflammatory biomarkers decreased 2 weeks post-transplantation ($p < 0.05$)
- CSF MCP-1 levels (a marker of microglial activation and neuroinflammation) significantly decreased post-transplantation and correlated with ALSFRS-R slope improvement at all time points ($p < 0.05$)

Clinical progress towards a result. Management highlighted the enrollment progress of the pivotal ALS trial, which is now complete. We see this as a great accomplishment for the company and the patients who desperately need a viable therapy that can impact disease progression.

What is NurOwn? It is an autologous (your own cells) cell therapy which are modified to become potent drug like miniature factories 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 re-establish 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.

Estimates	F2017A	F2018A	F2019E
Revenues (\$000s)	\$0	\$0	\$1,500
1Q March	\$0	\$0	\$0
2Q June	\$0	\$0	\$0
3Q September	\$0	\$0	\$0
4Q December	\$0	\$0	\$1,500
	F2017A	F2018A	F2019E
EPS (diluted)	(0.26)	(0.69)	(0.86)
1Q March	(0.10)	(0.12)	(0.24)
2Q June	(0.06)	(0.16)	(0.23)
3Q September	(0.13)	(0.15)	(0.26)
4Q December	0.01	(0.26)	(0.13)
EBITDA/Share			
EV/EBITDA (x)			
Stock Data			
52-Week Range	\$2.92	-	\$4.50
Shares Outstanding (mil.)	21		
Market Capitalization (mil.)	\$78		
Enterprise Value (mil.)	\$67		
Debt to Capital	0.0%		
Book Value/Share	\$0.31		
Price/Book	14.7		
Average Three Months Trading Volume (M)	0.1		
Insider Ownership	11.8%		
Institutional Ownership	9.6%		
Short interest (mil.)	3.4%		
Dividend / Yield	\$0.00/0.0%		



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. With a market capitalization of just \$76M, we see the company as trading at a distressed valuation. Brainstorm today is now a pivotal company with a product that has 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. Using these metrics, we model the market potential and discount back in our FCFF, discounted EPS, and sum-of-the-parts models, rounded to the nearest whole number to arrive at a \$12.00 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 ~\$78 million we 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 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%	4%	10%	15%	20%	25%	30%	34%	40%
Treatable Patients	0	0	0	0	0	0	0	0	975	2461	3728	5021	6338	7682	8793	10449
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)									\$ 150,103	\$ 386,591	\$ 597,400	\$ 820,588	\$ 1,056,712	\$ 1,306,350	\$ 1,525,242	\$ 1,848,594
Probability of Approval									50%	50%	50%	50%	50%	50%	50%	50%
Total Sales (US) (\$M)									\$ 75,052	\$ 193,296	\$ 298,700	\$ 410,294	\$ 528,356	\$ 653,175	\$ 762,621	\$ 924,297

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%	2%	5%	10%	15%	20%	25%	30%	34%	40%
Treatable Patients	0	0	0	0	0	0	0	885	2233	4511	6835	9204	11620	14084	16121	19156
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)								\$ 122,947	\$ 316,650	\$ 652,426	\$ 1,008,194	\$ 1,384,856	\$ 1,783,348	\$ 2,204,646	\$ 2,574,057	\$ 3,119,757
Probability of Approval					0%	0%	0%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Sales (Europe) (\$M)								\$ 61,474	\$ 158,325	\$ 326,213	\$ 504,097	\$ 692,428	\$ 891,674	\$ 1,102,323	\$ 1,287,028	\$ 1,559,878

Total sales (US and Europe) (\$M)																		
										\$ 61,474	\$ 233,377	\$ 519,509	\$ 802,797	\$ 1,102,722	\$ 1,420,030	\$ 1,755,498	\$ 2,049,649	\$ 2,484,175

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 FCFE, 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. Regarding the company's financials, we estimate that today Brainstorm has approximately \$6M in cash on the balance sheet. However, we note the company is receiving support from CIRM and the Israel Innovative Authority which brings the effective cash balance closer to \$10M. Our model does assume a capital raise, and our valuation is based on a fully-diluted out-year share forecast.

Exhibit 1. Discounted Free-Cash-Flow Model

Average	\$	12.00
Price Target	\$	13.00
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)	(13,948)	(14,910)	(7,392)	50,667	150,192	248,711	353,039	463,439	580,181	682,449	833,834
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)	(13,948)	(14,910)	(7,392)	48,133	135,173	211,404	282,431	347,579	406,127	443,592	525,316
CapEx (equipment)	(103)	(180)	(369)	(25)	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(5,085)	(5,132)	(14,317)	(14,935)	(7,392)	48,133	135,173	211,404	282,431	347,579	406,127	443,592	525,316
PV of FCF	(14,523)	(11,275)	(24,196)	(19,416)	(7,392)	37,026	79,984	96,224	98,887	93,613	84,140	70,694	64,398
Discount Rate	30%												
Long Term Growth Rate	1%												
Terminal Cash Flow	1,829,548												
Terminal Value YE2023	224,283												
NPV	822,441												
NPV-Debt	-												
Shares out ('000)	63,892												
NPV Per Share	\$	12.87											

Source: Dawson James estimates.

Exhibit 2. EPS Model

Current Year	2020
Year of EPS	2028
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 8.22
NPV	\$ 10.08

		Discount Rate and Earnings Multiple Varies, Year is Constant						
		2028 EPS						
		10.1	5%	10%	15%	20%	25%	30%
Earnings Multiple	0		\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
	5		\$27.82	\$19.18	\$13.44	\$9.56	\$6.90	\$ 5.04
	10		\$55.65	\$38.36	\$26.88	\$19.12	\$13.79	\$ 10.08
	15		\$83.47	\$57.53	\$40.32	\$28.68	\$20.69	\$ 15.12
	20		\$111.30	\$76.71	\$53.76	\$38.24	\$27.59	\$ 20.16
	25		\$139.12	\$95.89	\$67.19	\$47.80	\$34.49	\$ 25.20
	30		\$166.95	\$115.07	\$80.63	\$57.36	\$41.38	\$ 30.24
	35		\$194.77	\$134.25	\$94.07	\$66.93	\$48.28	\$ 35.28

Source: Dawson James estimates.

Exhibit 3. 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						\$11.74
Nurown	1%	50%	5	50%	\$500	\$1,020
Pre-Clinical Pipeline						\$0.74
Net Margin						70%
MM Shrs OS						64
Total						\$12.47

Source: Dawson James estimates.

Exhibit 4. Income Statement

Brainstorm Cell Therapeutics, Inc.: Income Statement (\$000)																				
Brainstorm Cell Therapeutics: YE Dec. 31	2017A	2018A	1Q19A	2Q19A	3Q19A	4Q19E	2019E	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Nurown™ (U.S. sales)								-	-	-	-	-	75,052	193,296	298,700	410,294	528,356	653,175	762,621	924,297
Nurown™ (EU sales)								15,368	15,368	15,368	15,368	61,474	158,325	326,213	504,097	692,428	891,674	1,102,323	1,287,028	1,559,878
Supportive Development Grant Revenue		-				1,500	1,500													
Total Product Sales		-	-	-	-	1,500	1,500	15,368	15,368	15,368	15,368	61,474	233,377	519,509	802,797	1,102,722	1,420,030	1,755,498	2,049,649	2,484,175
Expenses																				
Cost of goods sold								11,526	11,526	11,526	11,526	46,105	151,695	337,681	521,818	716,769	923,020	1,141,074	1,332,272	1,614,714
COGS % of Revenue								75%	75%	75%	75%	75%	65%	65%	65%	65%	65%	65%	65%	65%
Research and development	977	8,293	3,456	3,554	4,008	3,000	14,018	3,289	3,575	3,432	4,004	14,298	14,584	14,876	15,174	15,477	15,787	16,102	16,424	16,753
R&D % of Revenue																				
SG&A	4,022	5,770	1,472	1,303	1,543	1,325	5,643	2,300	2,400	2,500	2,800	10,000	18,000	18,360	18,727	19,102	19,484	19,873	20,271	20,676
SG&A % of Revenue																				
Total expenses	4,999	14,063	4,928	4,857	5,551	4,325	19,661	17,115	17,501	17,458	18,330	70,404	184,279	370,917	555,719	751,348	958,290	1,177,050	1,368,967	1,652,143
Oper. Inc. (Loss)	(4,999)	(14,063)	(4,928)	(4,857)	(5,551)	(2,825)	(18,161)	(1,747)	(2,132)	(2,090)	(2,961)	(8,930)	49,098	148,592	247,078	351,374	461,740	578,449	680,682	832,032
Financial income expenses, net	47	115	(99)	(43)	(83)															
Taxes on income																				
Other income																				
Pre-tax income	(4,952)	(13,948)	(5,027)	(4,900)	(5,634)	(2,825)	(18,161)	(1,747)	(2,132)	(2,090)	(2,961)	(8,930)	49,098	148,592	247,078	351,374	461,740	578,449	680,682	832,032
Income Tax Benefit (Provision)													2,455	14,859	37,062	70,275	115,435	173,535	238,239	307,852
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	30%	35%	37%
GAAP Net Income (loss)	(4,952)	(13,948)	(5,027)	(4,900)	(5,634)	(2,825)	(18,386)	(1,747)	(2,132)	(2,090)	(2,961)	(8,930)	46,643	133,733	210,016	281,099	346,305	404,914	442,443	524,180
GAAP-EPS	(0.26)	(0.70)	(0.24)	(0.23)	(0.26)	(0.13)	(0.86)	(0.03)	(0.04)	(0.04)	(0.06)	(0.17)	0.90	2.56	4.01	5.35	6.56	7.64	8.31	9.81
Non GAAP EPS (dil)	(0.26)	(0.70)	(0.24)	(0.23)	(0.26)	(0.13)	(0.86)	(0.03)	(0.04)	(0.04)	(0.06)	(0.17)	0.90	2.56	4.01	5.35	6.56	7.64	8.31	9.81
Wtd Avg Shrs (Bas) - '000s	18,777	19,977	20,917	21,703	21,630	21,632	21,471	36,634	36,638	36,642	36,645	36,640	36,654	36,669	36,684	36,698	36,713	36,728	36,743	36,757
Wtd Avg Shrs (Dil) - '000s	18,777	19,977	20,917	21,703	21,630	21,652	21,471	51,673	51,725	51,777	51,828	51,751	51,958	52,166	52,375	52,585	52,796	53,007	53,220	53,433

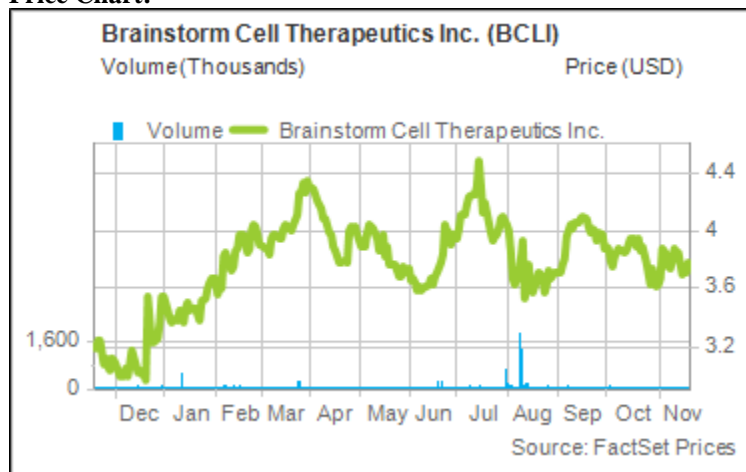
Source: Dawson James Securities

Source: Dawson James estimates.

Companies mentioned in this report:

Important Disclosures:

Price Chart:



Price target and ratings changes over the past 3 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

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Market Underperform (Sell)	0	0%	0	0%
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