

Brainstorm (NASDAQ/BCLI)

February 22, 2021

Neutral–FDA Says You Haven't Met the Threshold

Brainstorm announced that the FDA concluded from its initial review that: "the current level of clinical data does not provide the threshold of substantial evidence that FDA is seeking to support a Biologics License Application (BLA)." An odd statement in the press release suggests that the recommendation (you haven't met the clinical threshold) does not preclude Brainstorm from submitting the BLA. Not sure what that means, but at this point, we think approval is unlikely without another trial.

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Investment Highlights

Recall that Brainstorm's Phase 3 pivotal trial failed to show significant efficacy.

The data did show "numerical improvements" and consistent biomarkers. Management noted that treated patients who were more severe in terms of the state of their disease (ALS) had a diminished result, accounting for the statistical miss. Management notes that a pre-specified subgroup saw a 34.6% responders' rate (patients who met the primary endpoint) versus 15.6% on Placebo (p=0.288), which is in line with the original trial design assumptions. The average change from baseline to week 28 in ALSFRS-R total score was -1.77 on NurOwn and -3.78 on Placebo (p=0.198), an improvement of 2.01 ALSFRS-R points favoring NurOwn patients. Management has been hoping that the efficacy shown combined with the safe profile of Nurown might create a pathway forward with regulators as ALS is such a great unmet medical need. Our read is that the FDA wants to see another trial.

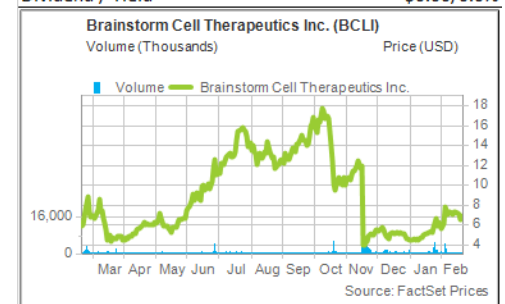
BioMarkers Data: Cerebrospinal fluid (CSF) biomarker data did show that treatment with NurOwn did translate into a statistically significant increase of neurotrophic factors and reduction in neurodegenerative and neuroinflammatory biomarkers that were not observed in the placebo treatment group. The key question that follows is, is there a correlation that will translate into function and disease progression rates?

So, NurOwn didn't have a big effect on worse patients; why? One explanation may be that patients who are at the late stages of the disease may have experienced so much motor neuron damage that the effect is de minimis.

Model Changes and Valuation: We reduce the probability of success from 50% to just 30% and cut our market share assumptions based on the likelihood that NurOwn does not appear to show benefit in advanced patients. The impact of this on our valuation is our suggested fair value falls to \$4.00.

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

Current Price	\$6.90		
Price Target	NA		
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	F2020E
EPS (diluted)	(0.51)	(0.32)	(2.31)
1Q March	(0.12)	(0.10)	(0.33)
2Q June	(0.16)	(0.07)	(0.56)
3Q September	(0.15)	(0.07)	(0.70)
4Q December	(0.08)	(0.08)	(0.72)
EBITDA/Share			
EV/EBITDA (x)			
Stock Data			
52-Week Range	\$3.80	-	\$17.95
Shares Outstanding (mil.)			21
Market Capitalization (mil.)			\$143
Enterprise Value (mil.)			\$132
Debt to Capital			0.0%
Book Value/Share			\$0.31
Price/Book			
Average Three Months Trading Volume (M)			3.7
Insider Ownership			20.0%
Institutional Ownership			26.7%
Short interest (mil.)			22.5%
Dividend / Yield			\$0.00/0.0%



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 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.

Product Modeling Assumptions

1. NurOwn's Phase 3 trial suggests the effect may be limited to early and or mid stage patients but not late stage. We have adjusted both our market share assumptions and our probability of success from 50% to 30%.
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 30% probability (previously 50%) 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 treating these patients.
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 Prevalence	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%	2%	5%	10%	15%	16%	17%	18%	
Treatable Patients	0	0	0	0	0	0	0	0	0	492	1243	2510	3803	4097	4397	4702	
Average Price of Therapy								\$151,000	\$152,510	\$154,035	\$155,575	\$157,131	\$158,703	\$160,290	\$161,892	\$163,511	
Price Growth	0%	0%	0%	0%	0%	0%	0%	1%	1%	1%	1%	1%	1%	1%	1%	1%	
Total Sales (\$M)										\$ 75,810	\$ 193,334	\$ 394,439	\$ 603,551	\$ 656,728	\$ 711,799	\$ 768,818	
Probability of Approval									30%	30%	30%	30%	30%	30%	30%	30%	
Total Sales (US) (\$M)										\$ 22,743	\$ 58,000	\$ 118,332	\$ 181,065	\$ 197,018	\$ 213,540	\$ 230,645	
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 Prevalence	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%	0%	0%	2%	4%	6%	10%	12%	14%	
Treatable Patients	0	0	0	0	0	0	0	0	0	0	911	1841	2789	4695	5690	6705	
Average Cost of Therapy	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$139,000	\$140,390	\$141,794	\$143,212	\$144,644	\$146,090	\$147,551	\$149,027	\$150,517	
Price Growth	0%	0%	0%	0%	0%	0%	0%	1%	1%	1%	1%	1%	1%	1%	1%	1%	
Total Sales (\$M)											\$ 130,511	\$ 266,268	\$ 407,430	\$ 692,699	\$ 847,947	\$ 1,009,156	
Probability of Approval								30%	30%	30%	30%	30%	30%	30%	30%	30%	
Total Sales (Europe) (\$M)											\$ 39,153	\$ 79,880	\$ 122,229	\$ 207,810	\$ 254,384	\$ 302,747	
Total sales (US and Europe) (\$M)											\$ 22,743	\$ 97,153	\$ 198,212	\$ 303,294	\$ 404,828	\$ 467,924	\$ 533,392

Source: Dawson James estimates.

Exhibit 2. Income Statement

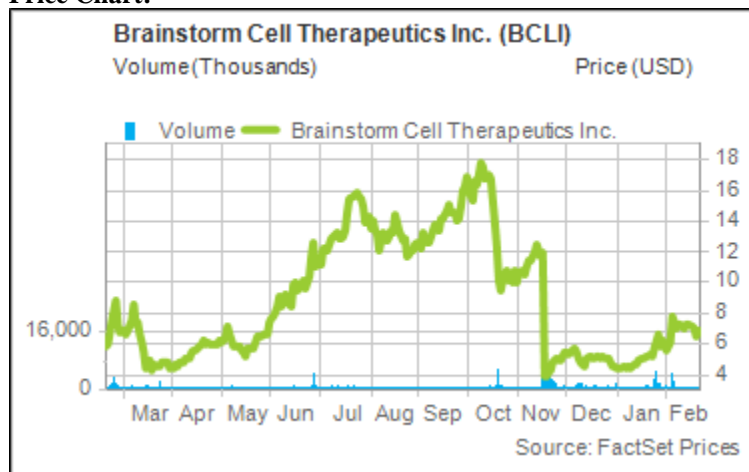
Brainstorm Cell Therapeutics, Inc.: Income Statement (\$'000)																
Brainstorm Cell Therapeutics.: YE Dec. 31	2017A	2018A	2019A	1Q20A	2Q20A	3Q20A	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Nurown™ (U.S. sales)				-	-	-	-	-	-	22,743	58,000	118,332	181,065	246,273	276,345	307,527
Nurown™ (EU sales)					-	-	-	-	-	-	39,153	79,880	122,229	207,810	317,980	432,496
Supportive Development Grant Revenue		1,500	-													
Total Product Sales		1,500	6,000	-	-	-	-	-	-	22,743	97,153	198,212	303,294	454,083	594,326	740,023
Expenses																
Cost of goods sold				-	-	-	-	-	-	14,783	63,150	128,838	197,141	295,154	386,312	481,015
COGS % of Revenue				75%	75%	75%	75%	#DIV/0!	#DIV/0!	65%	65%	65%	65%	65%	65%	65%
Research and development	977	5,933	17,204	5,948	11,642	13,509	13,644	44,743	45,638	46,551	47,482	48,431	49,400	50,388	51,396	52,424
R&D % of Revenue																
SG&A	4,022	5,793	5,797	2,360	4,066	6,684	7,000	20,110	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	15,708	20,193	20,644	64,853	63,638	79,694	129,359	196,371	266,025	365,415	457,978	554,115
Oper. Inc. (Loss)	(4,999)	(10,226)	(23,001)	(8,308)	(15,708)	(20,193)	(20,644)	(64,853)	(63,638)	(56,951)	(32,205)	1,841	37,269	88,668	136,347	185,908
Financial income expenses, net	47		(252)	194	200	197										
Taxes on income																
Other income																
Pre-tax income	(4,952)	(10,226)	(23,253)	(8,114)	(15,508)	(19,996)	(20,644)	(64,853)	(63,638)	(56,951)	(32,205)	1,841	37,269	88,668	136,347	185,908
Income Tax Benefit (Provision)	-	-	-	-	-	-	-	-	(3,182)	(5,695)	(4,831)	368	9,317	26,600	47,722	68,786
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)	(15,508)	(19,996)	(20,644)	(64,262)	(60,456)	(51,256)	(27,374)	1,473	27,952	62,067	88,626	117,122
GAAP-EPS	(0.26)	(0.51)	(0.32)	(0.33)	(0.56)	(0.70)	(0.72)	(2.31)	(2.10)	(1.77)	(0.94)	0.05	0.96	2.11	3.00	3.96
Non GAAP EPS (dil)	(0.26)	(0.51)	(0.32)	(0.33)	(0.56)	(0.70)	(0.72)	(2.31)	(2.10)	(1.77)	(0.94)	0.05	0.96	2.11	3.00	3.96
Wgtd Avg Shrs (Bas) - '000s	18,777	19,989	21,906	24,424	27,453	28,696	28,698	27,318	28,706	28,717	28,729	28,740	28,752	28,763	28,775	28,786
Wgtd Avg Shrs (Dil) - '000s	18,777	20,036	21,906	24,424	27,453	28,696	28,724	27,324	28,796	28,911	29,027	29,144	29,260	29,378	29,495	29,613

Source: Dawson James estimates, company reports

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
 Price Target Change - Buy – October 16, 2020 – Price Target \$25.00
 Update - Buy – October 22, 2020 – Price Target \$14.00
 Rating Change – Neutral – November 17, 2020 – Price Target NA
 Update – Neutral – February 22, 2021 – Price Target NA

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	72%	6	29%
Market Perform (Neutral)	8	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	6	21%

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