

Brainstorm (NASDAQ/BCLI)

November 17, 2020

Neutral – A High Placebo Response in ALS Causes a Lack of Significance Between the Active Arm 35% vs. Placebo 28%. Is There a Path Forward?

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

Brainstorm's Phase 3 pivotal trial in a responder analysis evaluated the proportion of participants who experienced a 1.25 points per month improvement in the post-treatment Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) slope. The trial assumed a treatment response rate of 35% versus 15% on Placebo, which was actually 34.7%. A pre-specified sub-group of less severe patients (more motor neurons left to save) did perform as expected: 35% vs. 15%, P=0.288. The therapy is very safe with basically no side effects, so maybe there is a path forward? Maybe, but given the data, we step our rating down from Buy to Neutral.

Investment Highlights

Is There a Path Forward? Management believes there might be... 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 noted 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. As such, this efficacy combined with the very safe profile of NurOwn might create a pathway forward with regulators. Remember that ALS remains an unmet medical need.

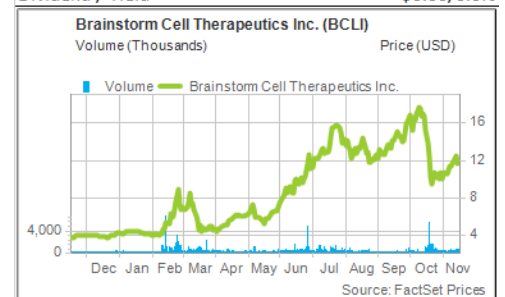
BioMarkers Data: Cerebrospinal fluid (CSF) biomarker data did show that treatment with NurOwn did translate into a statistically significant increase of neurotrophic factors and reduction in neurodegenerative and neuroinflammatory biomarkers that was not observed in the placebo treatment group. The key 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 in 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 to our valuation is our suggested fair value falls to \$4.00.

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

Current Price	\$11.94		
Suggest Fair Value	\$ 4.00		
Estimates	F2019A	F2020A	F2021E
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
	F2019A	F2020A	F2019E
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	\$3.63	-	\$17.95
Shares Outstanding (mil.)			21
Market Capitalization (mil.)			\$247
Enterprise Value (mil.)			\$236
Debt to Capital			0.0%
Book Value/Share			\$0.31
Price/Book			
Average Three Months Trading Volume (M)			0.4
Insider Ownership			19.9%
Institutional Ownership			22.0%
Short interest (mil.)			28.8%
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 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						0%	0%	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.

Valuation. Our product models feed into our income statement and allow us to apply valuation metrics. For conservatism, we had previously applied a 50% probability of approval, which now goes to just 30%, in our product models. 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	\$	4.00
Price Target or Suggested Fair value	\$	(2.00)	
	Year	2021	

DCF Valuation Using FCF (mln):													
units ('000 - Cnd\$)	2016A	2017A	2018A	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
EBIT (Earnings before income tax)	(4,982)	(4,952)	(10,226)	(23,253)	(64,853)	(63,638)	(56,951)	(32,205)	1,841	37,269	88,668	136,347	185,908
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)	(64,853)	(60,456)	(51,256)	(27,374)	1,473	27,952	62,067	88,626	117,122
CapEx (equipment)	(103)	(180)	(261)	(473)	(7)	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(5,085)	(5,132)	(10,487)	(23,726)	(64,860)	(60,456)	(51,256)	(27,374)	1,473	27,952	62,067	88,626	117,122
PV of FCF	(18,880)	(14,658)	(23,040)	(40,097)	(84,318)	(60,456)	(39,427)	(16,198)	670	9,787	16,717	18,361	18,665
Discount Rate	30%												
Long Term Growth Rate	1%												
Terminal Cash Flow	407,908												
Terminal Value YE2023	65,007												
NPV	(71,193)												
NPV-Debt	-												

Source: Dawson James estimates, company reports

Exhibit 3. EPS Model

Current Year	2021
Year of EPS	2028
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 3.96
NPV	\$ 6.30

Discount Rate and Earnings Multiple Varies, Year is Constant							
2028 EPS							
	6.3	5%	10%	15%	20%	25%	30%
Earnings Multiple	0	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
	5	\$16.08	\$14.65	\$13.41	\$12.31	\$11.35	\$10.49
	10	\$32.17	\$29.31	\$26.82	\$24.63	\$22.70	\$20.98
	15	\$48.25	\$43.96	\$40.22	\$36.94	\$34.05	\$31.48
	20	\$64.33	\$58.62	\$53.63	\$49.26	\$45.39	\$41.97
	25	\$80.42	\$73.27	\$67.04	\$61.57	\$56.74	\$52.46
	30	\$96.50	\$87.93	\$80.45	\$73.88	\$68.09	\$62.95
	35	\$112.59	\$102.58	\$93.86	\$86.20	\$79.44	\$73.45

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%	4	30%	\$750	\$2,586
ALS						\$6.42
Nurown	1%	50%	5	30%	\$500	\$1,020
Pre-Clinical Pipeline						\$0.95
Net Margin						70%
MM Shrs OS						30
Total						\$7.37

Source: Dawson James estimates.

Risk Factors

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

Exhibit 5. Income Statement

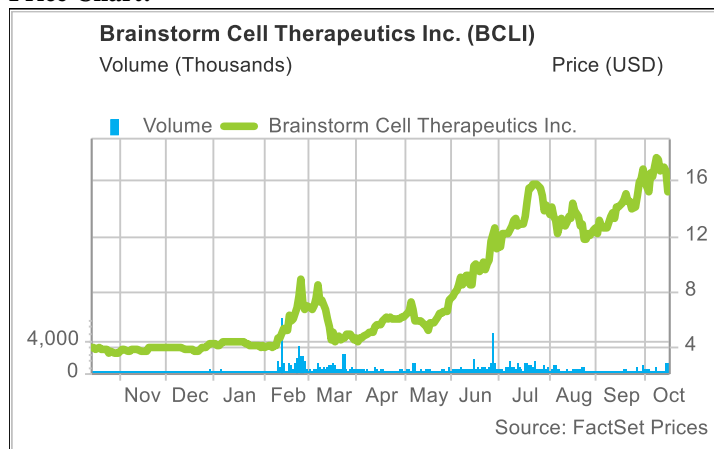
Brainstorm Cell Therapeutics, Inc.: Income Statement (\$'000)																
Brainstorm Cell Therapeutics.: YE Dec. 31	2017A	2018A	2019A	1Q20A	2Q20A	3Q20A	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Nurown™ (U.S. sales)				-	-	-	-	-	-	22,743	58,000	118,332	181,065	246,273	276,345	307,527
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

Dawson James Securities, Inc. (the “Firm”) is a member of the Financial Industry Regulatory Authority (“FINRA”) and the Securities Investor Protection Corporation (“SIPC”).

The Firm does not make a market in the securities of the subject company(s). The Firm has NOT engaged in investment banking relationships with BCLI in the prior twelve months, as a manager or co-manager of a public offering and has NOT received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has NOT received other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. As of October 31, 2020, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company(s) of this report. The Firm, its officers, directors, analysts or employees may affect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the company(s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm 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.

Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

Information about valuation methods and risks can be found in the "VALUATION" and "RISK FACTORS" sections of this report.

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

Ratings 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)	21	78%	4	19%
Market Perform (Neutral)	6	22%	1	17%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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.