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Toll-Free: 561-391-5555 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

Brainstorm (NASDAQ/BCLI)

October 16, 2020

BUY - On Track in ALS For Data by Year's End, Rolling our Valuation Forward - Raising Price Target from \$14.00 to \$25.00

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

Brainstorm reported a net loss in the quarter of \$19.9M driven by clinical costs of the pivotal trial. The company has \$33M in cash on the balance sheet at the end of 3Q20. Notably, management announced that the Phase 3 trial remains on track for top-line data at year's end. As a reminder, 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. Based on less than expected dilution and rolling our estimates out to 2021, our price target rises from \$14.00 to \$25.00

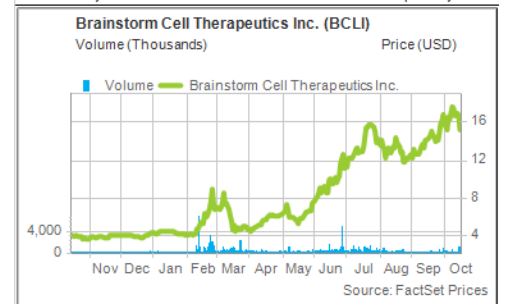
Investment Highlights

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 third-quarter 2020 results. The company spent \$20M on 3Q20. Management reported that as of October 14, 2020, the company has cash, cash equivalents, and short-term bank deposits of approximately \$33.1 million as well as remaining non-dilutive funding from CIRM, IIA, and other grants, that amounts to approximately \$36 million. Data for the ALS trial is expected 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 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.

Current Price	\$14.15		
Price Target	\$25.00		
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)	(2.45)
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)	(0.86)
EBITDA/Share			
EV/EBITDA (x)			
Stock Data			
52-Week Range	\$3.58	-	\$17.20
Shares Outstanding (mil.)			21
Market Capitalization (mil.)			\$293
Enterprise Value (mil.)			\$282
Debt to Capital			0.0%
Book Value/Share			\$0.31
Price/Book			
Average Three Months Trading Volume (M)			1.6
Insider Ownership			20.5%
Institutional Ownership			20.1%
Short interest (mil.)			18.8%
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. Brainstorm is 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 FCF, discounted EPS, and sum-of-the-parts models, rounded to the nearest whole number to arrive at a \$25.00 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.

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 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%	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 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%	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%	0%	0%	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	\$ 25.00
Price Target	\$ 19.00
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)	(68,894)	(41,472)	19,238	121,110	221,931	328,725	441,759	561,313	665,942
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)	(68,894)	(39,399)	17,314	102,944	177,545	246,544	309,231	364,854	419,544
CapEx (equipment)	(103)	(180)	(261)	(473)	(7)	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(5,085)	(5,132)	(10,487)	(23,726)	(68,901)	(39,399)	17,314	102,944	177,545	246,544	309,231	364,854	419,544
PV of FCF	(18,880)	(14,658)	(23,040)	(40,097)	(89,572)	(39,399)	13,319	60,914	80,813	86,322	83,285	75,589	66,861
Discount Rate	30%												
Long Term Growth Rate	1%												
Terminal Cash Flow	1,461,169												
Terminal Value YE2023	232,861												
NPV	570,992												
NPV-Debt	-												
Shares out ('000)	29,613												
NPV Per Share	\$ 19.28												

Source: Dawson James estimates, company reports

Exhibit 3. EPS Model

Current Year	2021
Year of EPS	2023
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 3.55
NPV	\$ 20.98

Discount Rate and Earnings Multiple Varies, Year is Constant							
2023 EPS							
Earnings Multiple	21.0	5%	10%	15%	20%	25%	30%
0	\$0.00	\$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	\$9.74
10	\$32.17	\$29.31	\$26.82	\$24.63	\$22.70	\$20.98	\$19.48
15	\$48.25	\$43.96	\$40.22	\$36.94	\$34.05	\$31.48	\$29.22
20	\$64.33	\$58.62	\$53.63	\$49.26	\$45.39	\$41.97	\$39.00
25	\$80.42	\$73.27	\$67.04	\$61.57	\$56.74	\$52.46	\$48.66
30	\$96.50	\$87.93	\$80.45	\$73.88	\$68.09	\$62.95	\$58.78
35	\$112.59	\$102.58	\$93.86	\$86.20	\$79.44	\$73.45	\$68.00

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%	1	70%	\$750	\$2,586
ALS						\$32.92
Nurown	1%	50%	5	50%	\$500	\$1,020
Pre-Clinical Pipeline						\$1.59
Net Margin						70%
MM Shrs OS						30
Total						\$34.51

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

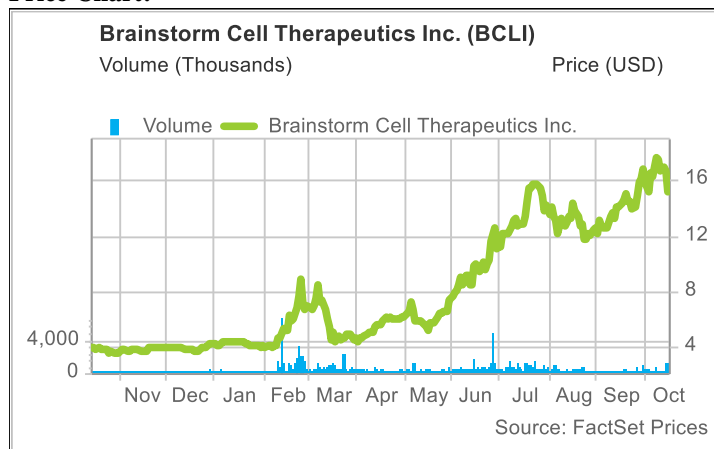
Brainstorm Cell Therapeutics, Inc.: Income Statement (\$000)																				
Brainstorm Cell Therapeutics: YE Dec. 31	2017A	2018A	1Q19E	2Q19E	3Q19E	4Q19E	2019A	1Q20A	2Q20A	3Q20A	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Nurown™ (U.S. sales)								-	-	-	-	-	-	77,318	199,133	307,721	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	1,500	1,500	1,500	1,500	-													
Total Product Sales		1,500	1,500	1,500	1,500	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	3,957	4,301	4,129	4,817	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	1,333	1,391	1,449	1,623	5,797	2,360	4,066	6,684	11,041	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	5,290	5,692	5,578	6,440	23,001	8,308	15,708	20,193	24,685	68,894	104,802	221,187	414,088	605,110	807,299	1,021,156	1,247,201	1,445,607
Oper. Inc. (Loss)	(4,999)	(10,226)	(3,790)	(4,192)	(4,078)	(4,940)	(23,001)	(8,308)	(15,708)	(20,193)	(24,685)	(68,894)	(41,472)	19,238	121,110	221,931	328,725	441,759	561,313	665,942
Financial income expenses, net	47						(252)	194	200	197										
Taxes on income																				
Other income																				
Pre-tax income	(4,952)	(10,226)	(3,790)	(4,192)	(4,078)	(4,940)	(23,253)	(8,114)	(15,508)	(19,996)	(24,685)	(68,894)	(41,472)	19,238	121,110	221,931	328,725	441,759	561,313	665,942
Income Tax Benefit (Provision)	-	-	-	-	-	-	-	-	-	-	-	-	(2,074)	1,924	18,167	44,386	82,181	132,528	196,460	246,399
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)	(10,165)	(3,790)	(4,192)	(4,078)	(4,940)	(23,253)	(8,114)	(15,508)	(19,996)	(24,685)	(68,303)	(39,999)	17,314	102,944	177,545	246,544	309,231	364,854	419,544
GAAP-EPS	(0.26)	(0.51)	(0.10)	(0.07)	(0.07)	(0.08)	(0.32)	(0.33)	(0.56)	(0.70)	(0.86)	(2.45)	(1.37)	0.60	3.55	6.09	8.43	10.53	12.37	14.17
Non GAAP EPS (dil)	(0.26)	(0.51)	(0.10)	(0.07)	(0.07)	(0.08)	(0.32)	(0.33)	(0.56)	(0.70)	(0.86)	(2.45)	(1.37)	0.60	3.55	6.09	8.43	10.53	12.37	14.17
Wtd Avg Shrs (Bas) - '000s	18,777	19,989	30,715	45,718	45,722	45,727	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
Wtd Avg Shrs (Dil) - '000s	18,777	20,036	37,920	59,958	60,018	60,078	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

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	# of Companies	% of Total	# of Companies	% of Totals
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