

Brainstorm (NASDAQ/BCLI)

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BUY Marching To Results & Maybe Approval - ALS

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Brainstorm held an update call (2.18.20) and confirmed the timeline, recent meeting with the FDA (encouraging), and the company's judicious use of its ATM (At The Market) facility to fund operations and minimize shareholder dilution. We continue to view the stock as trading at a "distressed" valuation given the fact that NurOwn is in a pivotal trial in an unmet medical need, ALS.

Current Price	\$6.33
Price Target	\$14.00

Estimates	F2018A	F2019A	F2020E
Revenues (\$000s)	\$0	\$0	\$0
1Q March	\$0	\$0	\$0
2Q June	\$0	\$0	\$0
3Q September	\$0	\$0	\$0
4Q December	\$0	\$0	\$0

	F2018A	F2019E	
EPS (diluted)	(0.69)	(1.06)	(0.73)
1Q March	(0.12)	(0.24)	(0.23)
2Q June	(0.16)	(0.23)	(0.25)
3Q September	(0.15)	(0.26)	(0.12)
4Q December	(0.26)	(0.33)	(0.13)

EBITDA/Share

EV/EBITDA (x)

Stock Data

52-Week Range	\$3.43	-	\$6.67
Shares Outstanding (mil.)	21		
Market Capitalization (mil.)	\$131		
Enterprise Value (mil.)	\$134		
Debt to Capital	0.0%		
Book Value/Share	\$0.31		
Price/Book			
Average Three Months Trading Volume (M)	0.1		
Insider Ownership	17.6%		
Institutional Ownership	9.3%		
Short interest (mil.)	3.5%		
Dividend / Yield	\$0.00/0.0%		

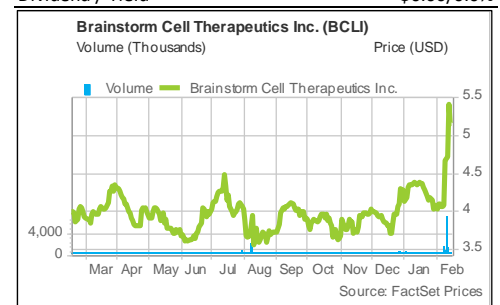
Investment Highlights

There is Hope in ALS. The FDA (Center for Biologics Evaluation and Research - CBER) indicated to the company (press release 2.11.2020) that they would look at the "totality of the evidence" in the expected Phase 3 clinical trial. We believe that regulators are now recognizing 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 Quarter. The company spent \$7.6M in 4Q19. To support operations, Brainstorm has judiciously used the At The Market (ATM) facility it put in place last year. Brainstorm raised in aggregate \$18.6M at \$4.75 per share, minimizing shareholder dilution.

Enrollment in the Pivotal ALS trial 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 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. The stock and its market capitalization have risen to just over \$100M versus our prior note at \$76M earlier this month; 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. 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 ~\$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 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%	5%	15%	20%	25%	30%	34%	40%
Treatable Patients	0	0	0	0	0	0	0	0	0	1230	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)										\$ 193,296	\$ 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)										\$ 96,648	\$ 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%	0%	0%	5%	15%	20%	25%	30%	34%	40%
Treatable Patients	0	0	0	0	0	0	0	0	0	2256	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)										\$ 326,213	\$ 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)										\$ 163,107	\$ 504,097	\$ 692,428	\$ 891,674	\$ 1,102,323	\$ 1,287,028	\$ 1,559,878

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 2. Discounted Free-Cash-Flow Model

Average	\$ 14.00
Price Target	\$ 12.00
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)	(23,253)	(27,548)	(35,899)	54,297	243,630	347,856	458,152	574,789	676,949	828,225
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)	(23,253)	(27,548)	(34,104)	48,867	207,085	278,285	343,614	402,352	440,017	521,781
CapEx (equipment)	(103)	(180)	(369)	(473)	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(5,085)	(5,132)	(14,317)	(23,726)	(27,548)	(34,104)	48,867	207,085	278,285	343,614	402,352	440,017	521,781
PV of FCF	(14,523)	(11,275)	(24,196)	(30,844)	(27,548)	(26,234)	28,916	94,258	97,435	92,545	83,358	70,124	63,965
Discount Rate	30%												
Long Term Growth Rate	1%												
Terminal Cash Flow	1,817,239												
Terminal Value YE2023	222,774												
NPV	699,593												
NPV-Debt	-												
Shares out ('000)	59,199	2028E											
NPV Per Share	\$ 11.82												

Source: Dawson James estimates.

Exhibit 3. EPS Model

Current Year	2020
Year of EPS	2023
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 3.57
NPV	\$ 16.24

		Discount Rate and Earnings Multiple Varies, Year is Constant						
		2023 EPS						
		16.2	5%	10%	15%	20%	25%	30%
Earnings Multiple	0	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
	5	\$15.41	\$13.41	\$11.73	\$10.33	\$9.14	\$ 8.12	
	10	\$30.83	\$26.81	\$23.47	\$20.65	\$18.27	\$ 16.24	
	15	\$46.24	\$40.22	\$35.20	\$30.98	\$27.41	\$ 24.37	
	20	\$61.66	\$53.63	\$46.93	\$41.31	\$36.54	\$ 32.49	
	25	\$77.07	\$67.03	\$58.66	\$51.63	\$45.68	\$ 40.61	
	30	\$92.48	\$80.44	\$70.40	\$61.96	\$54.82	\$ 48.73	
	35	\$107.90	\$93.84	\$82.13	\$72.28	\$63.95	\$ 56.85	

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 MM's	Term Val
Nurown	1%	30%	2	70%	\$750	\$2,586
ALS						\$12.67
Nurown	1%	50%	5	50%	\$500	\$1,020
Pre-Clinical Pipeline						\$0.79
Net Margin						70%
MM Shrs OS						59
Total						\$13.46

Source: Dawson James estimates.

Exhibit 5. Income Statement

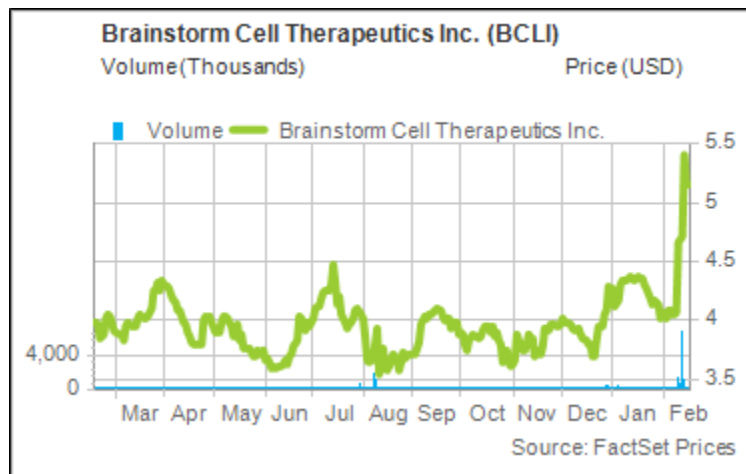
Brainstorm Cell Therapeutics, Inc.: Income Statement (\$'000)																
Brainstorm Cell Therapeutics.: YE Dec. 31	2017A	2018A	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Nurown™ (U.S. sales)				-	-	-	-	-	-	96,648	298,700	410,294	528,356	653,175	762,621	924,297
Nurown™ (EU sales)				-	-	-	-	-	-	163,107	504,097	692,428	891,674	1,102,323	1,287,028	1,559,878
Supportive Development Grant Revenue		-	-													
Total Product Sales		-	-	-	-	-	-	-	-	259,754	802,797	1,102,722	1,420,030	1,755,498	2,049,649	2,484,175
Expenses																
Cost of goods sold				-	-	-	-	-	-	168,840	521,818	716,769	923,020	1,141,074	1,332,272	1,614,714
COGS % of Revenue				75%	75%	75%	75%	#DIV/0!		65%	65%	65%	65%	65%	65%	65%
Research and development	977	8,293	17,204	4,036	4,387	4,212	4,913	17,548	17,899	18,257	18,622	18,995	19,374	19,762	20,157	20,560
R&D % of Revenue																
SG&A	4,022	5,770	5,797	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	23,001	6,336	6,787	6,712	7,713	27,548	35,899	205,457	559,167	754,866	961,878	1,180,709	1,372,700	1,655,951
Oper. Inc. (Loss)	(4,999)	(14,063)	(23,001)	(6,336)	(6,787)	(6,712)	(7,713)	(27,548)	(35,899)	54,297	243,630	347,856	458,152	574,789	676,949	828,225
Financial income expenses, net	47	115	(252)													
Taxes on income																
Other income																
Pre-tax income	(4,952)	(13,948)	(23,253)	(6,336)	(6,787)	(6,712)	(7,713)	(27,548)	(35,899)	54,297	243,630	347,856	458,152	574,789	676,949	828,225
Income Tax Benefit (Provision)	-	-	-	-	-	-	-	-	(1,795)	5,430	36,544	69,571	114,538	172,437	236,932	306,443
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	30%	35%	37%
GAAP Net Income (loss)	(4,952)	(13,948)	(23,253)	(6,336)	(6,787)	(6,712)	(7,713)	(27,548)	(34,104)	48,867	207,085	278,285	343,614	402,352	440,017	521,781
GAAP-EPS	(0.26)	(0.70)	(1.06)	(0.23)	(0.25)	(0.12)	(0.13)	(0.73)	(0.59)	0.85	3.57	4.78	5.87	6.85	7.46	8.81
Non GAAP EPS (dil)	(0.26)	(0.70)	(1.06)	(0.23)	(0.25)	(0.12)	(0.13)	(0.73)	(0.59)	0.85	3.57	4.78	5.87	6.85	7.46	8.81
Wgtd Avg Shrs (Bas) - '000s	18,777	19,977	21,906	27,288	27,291	42,294	42,298	34,793	42,309	42,326	42,342	42,359	42,376	42,393	42,410	42,427
Wgtd Avg Shrs (Dil) - '000s	18,777	19,977	21,906	27,309	27,337	57,364	57,421	42,358	57,565	57,796	58,027	58,260	58,493	58,727	58,963	59,199

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

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	# of Companies	% of Total	# of Companies	% of Totals
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Market Perform (Neutral)	3	12%	1	33%
Market Underperform (Sell)	0	0%	0	0%
Total	26	100%	4	15%

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