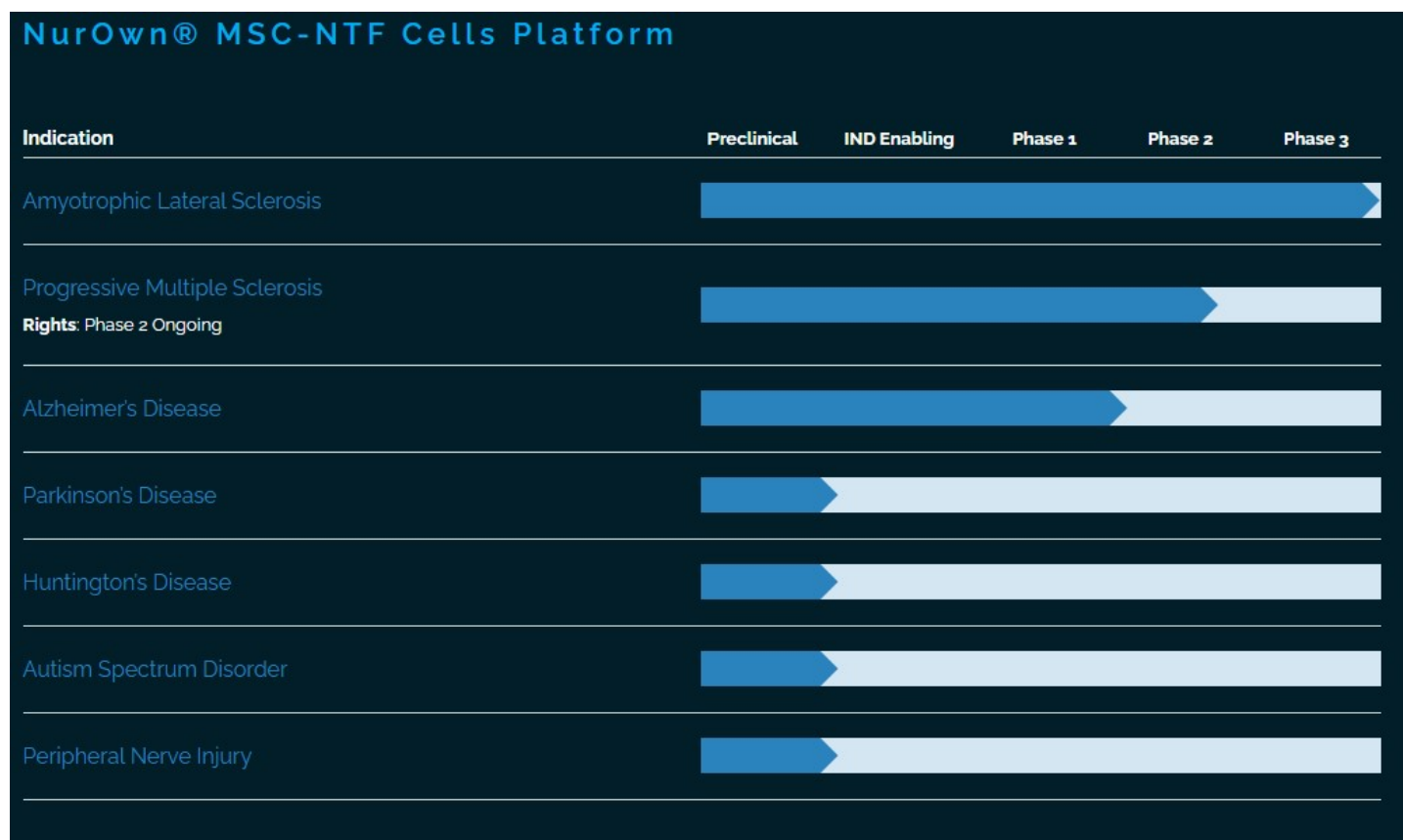


## Brainstorm's go or no-go decision



[Lisa Urquhart](#)

Brainstorm Cell Therapeutics is today facing a monumental decision: quit all developmental work on its lead asset in its most advanced indication or press on with a regulatory filing despite a dire warning from the US FDA on the project's chances of success. However, this might feel like déjà vu for investors. Back in November Brainstorm decided to try to file its autologous cell therapy treatment NurOwn in ALS despite the [unequivocal failure of its pivotal trial](#). Today the agency made its position clear, stating that the clinical data Brainstorm has submitted did not meet its threshold for filing. However, in what must be an acknowledgement of what a terrible disease ALS is, the agency did not preclude Brainstorm from proceeding with a BLA submission. But, even with the support of patient groups desperate for a cure, it is hard to see how Brainstorm will succeed without further clinical trials and, with only \$42m in the bank, funding those trials and its other work in multiple sclerosis might be a struggle. However, while Brainstorm's next move might be slightly opaque, investors were very clear where they stood, with shares falling by 30% in early trading today.



### [More from Evaluate Vantage](#)

Evaluate HQ  
[44-\(0\)20-7377-0800](tel:44-020-7377-0800)

Evaluate Americas  
[+1-617-573-9450](tel:+1-617-573-9450)

Evaluate APAC  
[+81-\(0\)80-1164-4754](tel:+81-080-1164-4754)

© Copyright 2022 Evaluate Ltd.

