Analysis of ulixacaltamide (PRAX-944) clinical data

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I believe Praxis Precision Medicines has been deceitful with its communications of the results of its phase 2 trial for PRAX-944 (now marketed as "ulixacaltamide") and its phase 3 trial, due Q1 2025, is unlikely to show statistically significant results.

1 The bad science of ulixacaltamide (PRAX-944)

The FDA recommended the primary endpoint be mADL, which is defined mADL tests 1 through 11 (mADL without social impact) plus TETRAS-PS6 (spirals) and TETRAS-PS7 (handwriting). This measurement has been used for previous trials submitted to the FDA. The results for the primary endpoint were not statistically significant at $p = 0.126$.

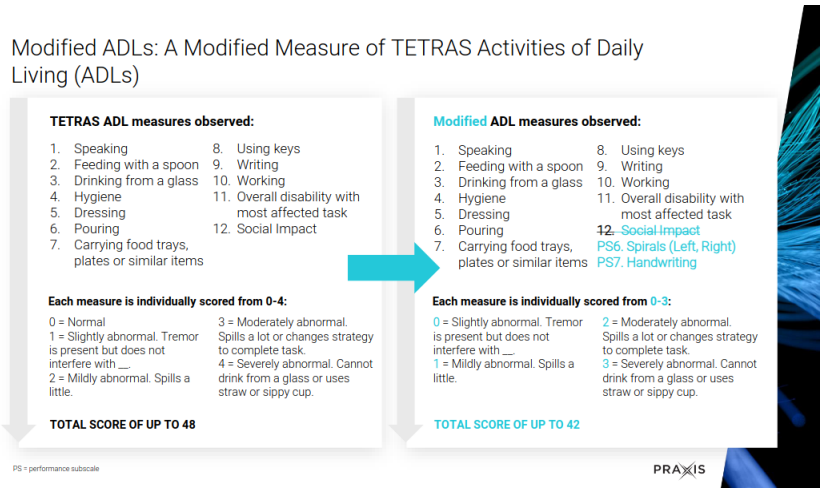

Figure 1: mADL as defined by the FDA

Not deterred, Praxis reported $p = 0.026$ for ADL, a measurement that was picked after the fact.

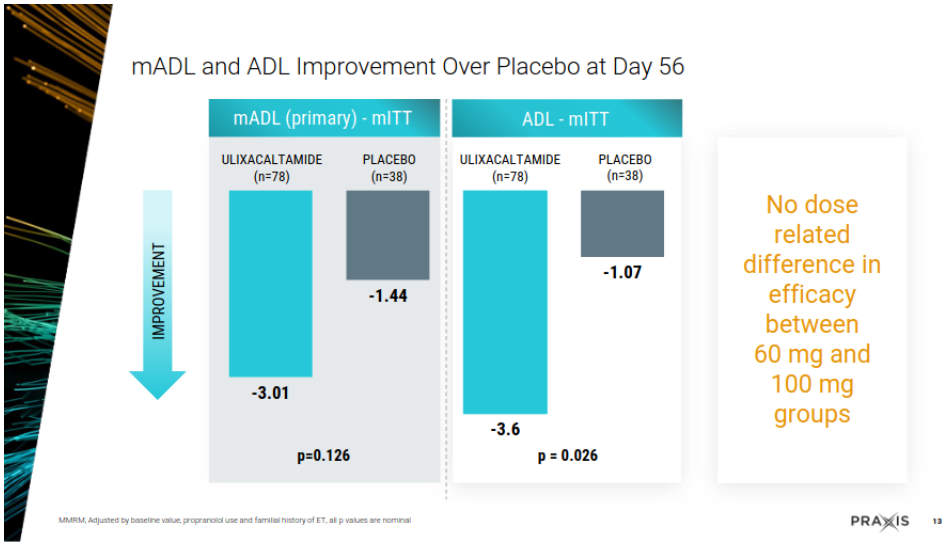

Figure 2: mADL vs ADL

Luckily enough, ADL (which the FDA specifically recommended against) is made up entirely of subjective measurements at which PRAX-944 did well at, while removing the objective measurements where it did worse than placebo.

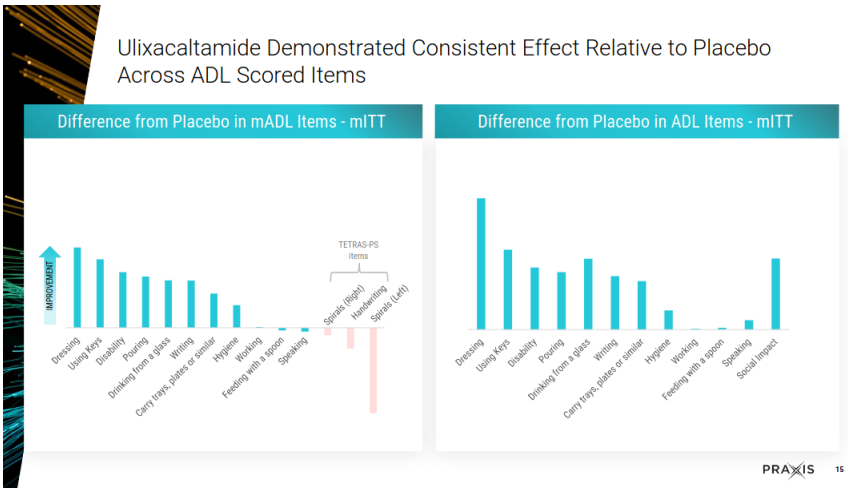

Figure 3: TETRAS-PS data did not perform well