

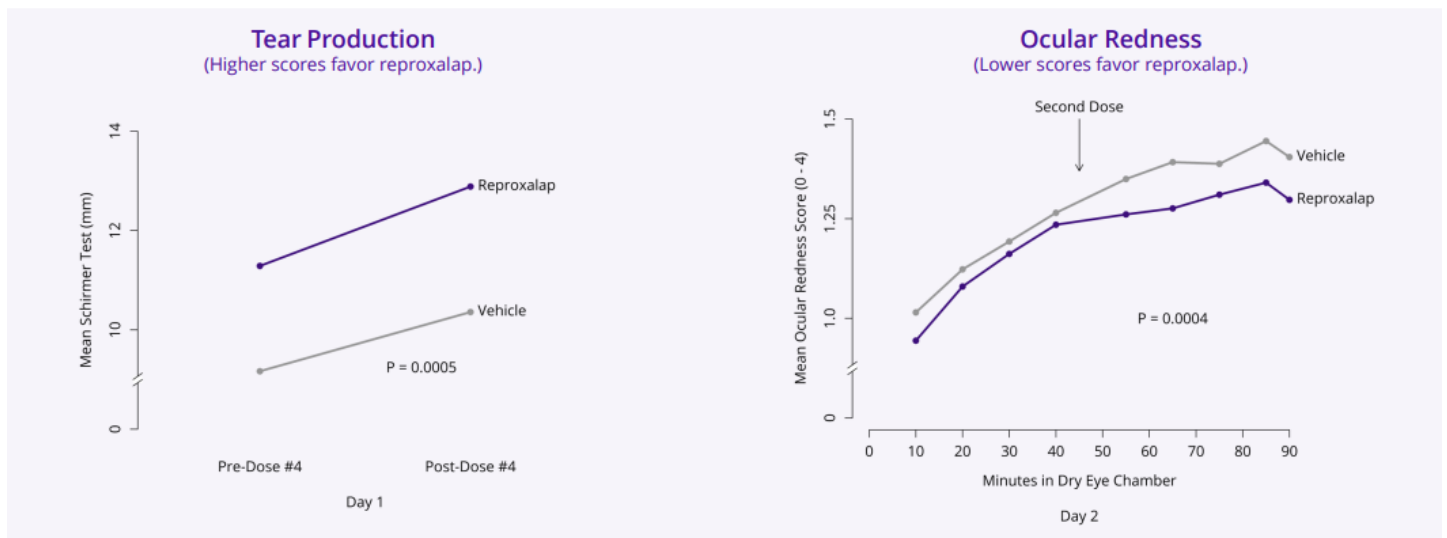
## Aldeyra eyes its next phase



Madeleine Armstrong

Aldeyra Therapeutics reckons it has put questions about the approvability of its dry eye disease project reproxalap to bed with its latest data drop. Indeed, the group described the results from a crossover study as “possibly the most important we’ve generated”. The trial entailed two days of either reproxalap or vehicle sandwiched either side of a two-week washout period – the idea being that patients acted as their own control, thereby cutting down inter-patient variability. And the crossover study achieved what Aldeyra’s pivotal trials, Tranquility and [Tranquility-2, could not](#), by showing improvement on both ocular redness and tear production, measured by the Schirmer test. Still, the group’s stock opened flat this morning after being up as much as 14% premarket. Perhaps investors are unconvinced by the prospect of Aldeyra launching into a market dominated by Novartis’s Xiidra and Abbvie’s Restasis; the latter [got its first generic competition in February](#). Aldeyra, which had \$217m in the bank at the last count, hopes to submit reproxalap for approval this quarter following a pre-NDA meeting with the FDA. If the project is approved, the company will need to buck the trend of [lacklustre launches for small developers](#).

### In the Dry Eye Disease Crossover Trial, Both Primary Endpoints Were Statistically Significant in Favor of Reproxalap over Vehicle



P values derived from mixed effect model of repeated measures of change from baseline. **Source:** Dry eye disease crossover clinical trial results on file. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,800 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

Source: Company presentation

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