Evaluate Vantage

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Intercept’s Nash exit feels inevitable

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Another complete response letter for Intercept and its Nash project seems inevitable in the wake of Friday’s advisory committee drubbing. On the question of whether the benefits of Ocaliva outweigh its risks 12 panelists voted no and two yes, with two abstaining. On a call today Intercept executives held back from completely pulling the plug on further work in Nash ahead of the FDA’s final verdict, due by 22 June, but they made it pretty clear that this was on the cards. “We will immediately pivot to profitability” if accelerated approval is turned down, said the group's chief executive, Jerry Durso. This will presumably involve shutting down the large Regenerate trial, from which outcome data are still being collected, and unwinding any commercial investments already made. Some analysts project a move into the black for Intercept by 2025; with $337m in debt due by 2026, generating cash is already an important consideration. Executives attempted to turn attention to Ocaliva in its already approved indication, primary biliary cholangitis, but investors clearly have doubts about this planned pivot. Intercept stock sank 29% in morning trade, plumbing a record low.

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