Evaluate Vantage

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Focus turns to Rett as panel gives Acadia's Nuplazid a thumbs down

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Acadia's attempt to expand Nuplazid's label into Alzheimer's disease psychosis looks to have failed, following an FDA panel vote last Friday that went 9 to 3 against the idea. This was always a long shot after the complete response letter for the group's previous application in the wider dementia-related psychosis setting; the Alzheimer's submission relied heavily on a subgroup analysis and the FDA had already said it wanted another trial conducted. The company has yet to say whether this will happen; Alzheimer's disease psychosis might have big commercial potential but investors are unlikely to want to see more money spent here. Either way, another CRL looks to be on the way, making negative symptoms of schizophrenia Acadia's next label expansion bid; Nuplazid managed only a very narrow win in the first pivotal trial conducted here. Regarding the psychosis panel, the most supportive comments that Stifel analysts could muster were that the absence of negative surprises validated management's credibility, though the logic that this is "incrementally positive" for the group's next project, trofinetide in Rett syndrome, is pretty hard to follow. A filing for trofinetide is due mid-year, making acceptance from the FDA the next big event for Acadia.

Up next for Acadia		
Project	**Setting**	**Details**
Trofinetide	Rett syndrome	Submission due mid-2022, priority review expected (Lavender trial succeeded Dec' 21)
Nuplazid	Negative symptoms of schizophrenia	Ph3 Advance-2 trial due to read out Q1'23 (Advance narrowly succeeded)
ACP-044	Osteoarthritis pain	Ph2 trial due to read out H1'23 (Failed in post-surgical pain in Apr' 22)
Source: Evaluate Pharma.		