

Acadia Pharmaceuticals: How to Commit After Mixed Phase 2 Evidence?

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Decision scope: Evidence and capital-release gates for Acadia's announced continuation of two ongoing Phase 3 remlifanserin studies in Alzheimer's disease psychosis (ADP)

Case convention: The role and alternatives below are a classroom exercise. Company disclosures are historical and attributed. The case does not represent a private management debate.

The decision

On September 24, 2026, Acadia Pharmaceuticals announced topline results from RADIANT, a Phase 2 study of remlifanserin for ADP. The 60 mg dose narrowly missed the study's primary endpoint, while a key secondary measure was nominally significant. Acadia said it would continue enrollment in two ongoing Phase 3 studies, remove the 30 mg arm, and present detailed Phase 2 results at the November CTAD meeting. [C3]

Assume you are advising Acadia's development leadership as it reviews the next commitments for the program. The company has announced a path forward, but public materials do not disclose the updated Phase 3 protocols, complete topline tables, the Food and Drug Administration's feedback, or the program's full cost. The question is how to govern commitments while obtaining and interpreting that information.

Decision question: What evidence and capital-release gates should govern the announced continuation of the two Phase 3 studies?

Consider three approaches:

1. **Proceed under the amended plan.** Continue the 60 mg-only Phase 3 studies under ordinary trial oversight, using complete Phase 2 results and standard safety monitoring as they become available.
2. **Continue while staging discretionary commitments.** Maintain ongoing study activity, but condition additional discretionary resources or design changes on review of complete data, clinical relevance, safety, and regulatory discussion.
3. **Schedule a formal reassessment.** Continue only those activities needed to protect the ongoing studies and review the full dataset, then reassess the program against other portfolio uses before making further commitments.

These are hypothetical governance paths, not options Acadia publicly disclosed. The case does not assume that a pause is operationally or contractually available, that the program has a fixed budget, or that other programs compete for a binding pool of cash.

Reading the RADIANT result

Exhibit 1. Phase 2 RADIANT topline at week six

Company-reported change from baseline; lower scores are reported as improvement. Full arm denominators and confidence intervals were not included in the topline release.

Measure	60 mg	Placebo	Reported effect size	Reported p-value / status
SAPS-H+D (primary endpoint)	-12.6	-10.4	0.26	p=.0603; primary endpoint not met
CGI-S-ADP (key secondary endpoint)	-1.3	-0.9	0.37	p=.0077; nominally significant
30 mg dose pattern	-	-	-	Acadia reported minimal improvement

Source: Acadia's September 24 release and furnished Exhibit 99.1 [C3]. Acadia said analyses used its prespecified modified full analysis set. The release did not provide full study tables, arm sample sizes, confidence intervals, detailed multiplicity strategy, all subgroup results, or independent regulatory interpretation.

The company also described adverse events, serious adverse events, and discontinuations due to adverse events as occurring at similar rates to placebo across doses; it reported no QT-prolongation signal and no deaths in the treatment arms. These are topline statements from the company. The release did not give event denominators or full safety tables. [C3]

The results leave more than one interpretation. The primary measure did not cross the conventional statistical threshold, while the secondary measure favored 60 mg and the 30 mg dose showed little improvement. The public release does not give enough detail to assess the precision and robustness of those results or the clinical importance of the observed differences.

The company's announced next step

Acadia said enrollment would continue in two ongoing Phase 3 ADP studies and the program would be amended to remove the 30 mg arm. The release characterized RADIANT as "Phase 3 enabling" and said detailed results would be presented at CTAD, scheduled for November 16-19, after this case's cutoff. [C3]

Acadia had already received FDA Fast Track designation for remlifanserin in ADP. Fast Track is a development designation; the cited release does not disclose FDA agreement with a specific Phase 3 design or a regulatory conclusion on RADIANT. [C6]

Portfolio and financial context

Exhibit 2. Selected company financial context

USD millions; Q2 and H1 are periods ended June 30, 2026. Guidance is management's FY2026 outlook as of August 4.

Measure	Reported amount	Period / basis
Cash and cash equivalents	\$384.985	June 30 balance sheet
Available-for-sale investment securities	\$571.489	June 30 balance sheet
Cash plus available-for-sale securities	\$956.474	Calculated sum; excludes restricted cash
Restricted cash	\$7.846	Separately reported
Operating cash flow	\$134.762	Six months ended June 30
Net product sales	\$307.959	Three months ended June 30
Net product sales	\$576.021	Six months ended June 30
FY2026 GAAP total revenue guidance	\$1,240-\$1,300	Management guidance
FY2026 GAAP R&D expense guidance	\$355-\$380	Management guidance; lowered from \$385-\$410

Sources: Acadia's Q2 2026 Form 10-Q, printed pp. 1-5, 24-25 [C1], and August 4 results release [C2]. The company said cash, investments, and anticipated product-sale funds were expected to support planned operations through and beyond 12 months. That statement is management's liquidity outlook, not a dedicated remlifanserin budget. The cash-plus-securities sum excludes restricted cash and does not indicate the amount available for a particular program.

Acadia's marketed portfolio included NUPLAZID (pimavanserin) and DAYBUE products (trofinetide). The company reported Q2 product sales of \$183 million for NUPLAZID and \$125 million for DAYBUE products, and raised full-year revenue guidance while lowering consolidated R&D guidance. The guidance covers the company as a whole; it does not identify a remlifanserin budget or explain which project's resources changed. [C1, C2]

Other pipeline programs provide context for portfolio review. At the Q2 filing, remlifanserin also had a Phase 2 study in Lewy body dementia psychosis; ACP-211 was in Phase 2 for major depressive disorder; ACP-711 Phase 2 for essential tremor was expected in 2027 after a successful Phase 1; and ACP-271 entered a first-in-human study in Q1 2026. The public sources do not disclose comparative program budgets, probabilities, or returns. [C1, p. 19; C2]

Exhibit 3. R&D expense visibility

USD millions; six months ended June 30, 2026.

Reported R&D category	Amount
Total GAAP R&D expense	\$158.423
Direct external-provider costs	\$106.719
Internal costs	\$42.816
Stock-based compensation	\$8.888

Reported R&D category	Amount
Of direct external-provider costs: remlifanserin	\$53.965
Of direct external-provider costs: early-stage programs	\$38.114

Source: Q2 2026 Form 10-Q, printed pp. 20-21 [C1]. The \$53.965 million is only external-provider cost for remlifanserin, not total program spending. Acadia says project-level internal R&D is not reported and non-project-specific costs are proportionally allocated. The filing does not state full Phase 3 cost, marginal cost, or expected cost by trial.

What should happen next?

Prepare a short recommendation to Acadia's development leadership. State which approach you would use and explain:

- how much weight to give the missed primary endpoint, nominal secondary finding, dose pattern, and company-reported safety summary;
- which missing results or analyses should be reviewed before the next material commitment;
- how to sequence information, regulatory discussion, trial design, and spending without assuming that delay is automatically valuable; and
- what evidence would lead you to continue, change the plan, or reallocate resources.

The evidence cutoff is October 3, 2026. Do not use CTAD results or any later regulatory or clinical outcome. Do not assign Acadia a probability of success, trial cost, market size, price, or return that is not in the cited sources. Any proposed quantitative decision threshold must be clearly labeled **[A] hypothetical**.

Sources and conventions

- **[C1]** Acadia Pharmaceuticals, Q2 2026 Form 10-Q, filed August 5, 2026; quarter ended June 30; SEC accession 0001193125-26-333243. [SEC filing](#)
- **[C2]** Acadia Pharmaceuticals, Q2 2026 results release, August 4, 2026; furnished as Exhibit 99.1 to Form 8-K accession 0001193125-26-332858. [Issuer release](#)
- **[C3]** Acadia Pharmaceuticals, September 24, 2026 Form 8-K accession 0001193125-26-401157, Items 7.01, 8.01 and 9.01; clinical topline in furnished Exhibit 99.1. [SEC filing](#) · [Issuer release](#)
- **[C4]** Acadia Pharmaceuticals, September 28, 2026 U.S. patent allowance release. [Issuer release](#)
- **[C5]** Acadia Pharmaceuticals, European Commission approval of DAYBU, August 24, 2026. [Issuer release](#)
- **[C6]** Acadia Pharmaceuticals, FDA Fast Track designation for remlifanserin in ADP, July 20, 2026. [Issuer release](#)

All clinical topline statements are attributed to Acadia. GAAP expense and balance-sheet figures are company-reported. The case is a historical teaching exercise and not a statement about subsequent outcomes.