

Cassava Sciences: clinical evidence, disclosure failures, and the transition to Filana Therapeutics

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1. Executive assessment: three questions that require different answers

Cassava Sciences changed its legal name to Filana Therapeutics on 10 March 2026. Its historical name remains appropriate for examining the simufilam Alzheimer's program and the disclosures made while it operated as Cassava. The name change does not identify an acquisition or a different corporation: the company's own filing records an amendment to its certificate of incorporation and a new trading symbol, FLNA.¹ This report therefore follows one corporate entity across two names.

The evidence supports a serious, specific criticism of clinical-trial disclosure. In September 2024 the Securities and Exchange Commission brought a civil case concerning representations about blinding, investigator conflicts, and selected cognitive data from a Phase 2 trial. Cassava agreed to a \$40 million civil penalty without admitting or denying the allegations. The company described the resolved charges as negligence-based disclosure charges and reported remedial governance measures.^{2,3} This is a civil regulatory resolution, not a corporate criminal conviction.

The scientific question has a separate answer. Cassava reported that its Phase 3 Alzheimer's studies did not demonstrate the intended benefit and announced the discontinuation of that development program. Failure in a large controlled trial is important evidence about the tested treatment, population, dose, and duration. It does not by itself prove that earlier researchers intentionally fabricated results. Conversely, a civil settlement cannot establish that a drug works.^{4,5}

A third question concerns criminal allegations against former scientific collaborator Hoau-Yan Wang. The Justice Department announced an indictment in June 2024. A subsequent company SEC filing reports that the court dismissed that indictment with prejudice on 23 October 2025.^{6,7} An account that mentions the indictment while omitting this disposition would materially mislead readers. The dismissal also should not be presented as a finding that simufilam is effective: it concerns a prosecution, not clinical validation.

This report's assessment is consequently bounded. The documented record warrants scrutiny of evidence selection and investor communication, while requiring explicit treatment of later clinical results, legal dispositions, and the current development program. The July 2026 company update describes an investigational TSC-related epilepsy program under an FDA clinical hold.⁸ There is no verified commercial simufilam price in this source set. Access analysis therefore concerns research participation, information quality, and development resources rather than an established medicine's retail affordability. No conclusion about individual treatment or investment suitability is offered.

2. Timeline: why the order of events changes the interpretation

The key sequence begins with public claims about a 2020 Phase 2 study, rather than with the later Phase 3 failure. The SEC’s 2024 account says Cassava represented the earlier study as blinded and described improvement in episodic memory without adequately disclosing the treatment of the full patient dataset. The agency also alleged inadequate disclosure of the therapeutic co-inventor’s involvement and interests.² These are claims about how evidence was communicated at a particular time; they should not be reconstructed solely from hindsight after a negative trial.

Date	Verified development	Appropriate interpretation
September 2020	Disclosures later challenged by SEC	Historical communication under scrutiny
June 2024	DOJ announces Wang indictment	Allegation, not conviction
September 2024	SEC announces negotiated civil resolution	Settlement without admission or denial
November 2024	RETHINK-ALZ failure disclosed	Negative confirmatory clinical result
March 2025	REFOCUS-ALZ results and program discontinuation	Further negative Alzheimer’s evidence
October 2025	Wang indictment dismissed with prejudice	Criminal case terminated
March 2026	Legal name becomes Filana Therapeutics	Corporate continuity under new name
July 2026	Company reports continuing FDA clinical hold	New indication remains investigational

Sources for the timeline are the corresponding agency releases and company filings.^{1,2,4,5,6,7,8}

On 25 November 2024 Cassava disclosed that RETHINK-ALZ missed the prespecified co-primary, secondary, and exploratory biomarker endpoints. It also announced the discontinuation of REFOCUS-ALZ and the open-label extension.⁴ The later availability of REFOCUS results matters because “discontinued” does not mean that no interpretable observations had been collected. The company said many participants had completed their final visit before termination and subsequently reported analyses from that program.⁵

By March 2025 management stated that it would stop all Alzheimer’s development efforts for simufilam. The July 2026 update says that phase-out was completed in the second quarter of 2025.^{5,8} Readers should therefore reject descriptions of an ongoing successful Alzheimer’s Phase 3 program based on older promotional material.

The timeline also prevents a misleading fusion of separate proceedings. The SEC disclosure case, the criminal grant-fraud indictment against Wang, and private securities litigation involved different parties, legal issues, and outcomes. A fine, dismissal, and escrow deposit cannot be added together as though they were three confirmations of the same factual proposition. Chronological reporting is an analytical safeguard: it identifies what was known when, which authority acted, and whether a statement described a completed event or a future expectation.

3. Principal evidence: blinding, selection, and confirmatory trials

The central SEC allegation was not simply that optimistic scientific predictions proved wrong. The agency alleged that Cassava and Lindsay Burns misled investors by describing the Phase 2 trial as blinded when the scientist testing samples had been unblinded. It further alleged that the full episodic-memory dataset showed no measurable improvement, whereas the company publicized results derived from a selected subset. The reported interests of the co-inventor were also relevant to assessing independence.²

Analytically, these issues affect different parts of the evidence chain. Blinding limits the influence of knowledge about treatment assignment on measurement or interpretation. Dataset selection changes which observations enter the advertised result. A financial or professional interest does not automatically make a result false, but it increases the importance of transparent procedures and independent checking. A credible response must address these mechanisms individually rather than rely on a general statement that research is difficult.

The company resolved negligence-based disclosure charges without admitting or denying the allegations.³ Accordingly, this report attributes the disputed factual assertions to the SEC. It does not convert the settlement into a judicial determination of intentional fabrication by Cassava's entire workforce. Nor does it treat the company's statement of cooperation and remediation as an independent audit demonstrating that every underlying problem was corrected.

The larger Alzheimer's studies supply a different category of evidence. REFOCUS-ALZ enrolled 1,125 patients and compared two simufilam doses with placebo. In the company's published topline table, cognition and daily-function comparisons did not reach the prespecified efficacy objectives. Management characterized the two Phase 3 results as showing no treatment benefit and ended the program.⁵ That sponsor acknowledgment is particularly relevant because it does not depend on a critic's interpretation of a stock-price movement.

The disclosed trial findings can support the conclusion that benefit was not established in those studies. They cannot, without participant-level records and statistical reconstruction, establish the cause of every earlier discrepancy. Possible issues in an early dataset and lack of efficacy in a later trial may coexist, but one should not be offered as automatic proof of the other.

A proper scientific review would examine the protocol, statistical analysis plan, missing-data assumptions, inclusion rules, laboratory custody, and original measurements. This report did not obtain that complete record. Its narrower contribution is to identify the material disclosure allegations, describe the sponsor's subsequent confirmatory results, and maintain the distinction between a regulator's civil claim and an independent reanalysis of clinical data.

4. Access and quantitative context: no defensible commercial price estimate

The source record describes simufilam as investigational; the current program concerns TSC-related epilepsy and remains subject to a clinical hold in the latest substantive update located.⁸ This makes a conventional “price gouging” calculation inappropriate. A proposed medicine without a verified marketed price does not have an observed list-price increase, net-price trend, or patient copayment that this report can analyze. Inventing one would confuse research controversy with commercial pricing conduct.

The available monetary figures instead concern enforcement and corporate resources. Cassava’s civil SEC penalty was \$40 million; the negotiated individual penalties were \$175,000 for former CEO Remi Barbier and \$85,000 for Burns.² Those amounts describe sanctions. They are not estimates of patient injury, of the company’s profit from simufilam, or of the total social cost of the episode. Because the product remained investigational, an inference from penalty dollars to sales revenue would be especially unsound.

In its July 2026 update, Filana reported \$82.7 million in cash and equivalents at 30 June 2026 and said it paid \$31.25 million into escrow on 23 July toward potential resolution of securities litigation, with final court approval still outstanding as described in that release.⁸ The dates are essential: the quarter-end cash balance precedes the escrow funding. A reader should not subtract the same payment from both figures or describe the escrow as a second SEC fine. The source does not establish that any investor received a distribution by the research date.

Access also depends on what patients and families are told. When a sponsor presents preliminary findings, a responsible explanation distinguishes measured clinical outcomes from biological hypotheses. Participation in research can entail time, travel, caregiver effort, and uncertain benefit even when no marketed medicine is purchased. This report has no participant-level information with which to quantify those burdens or assign them to particular communications. It identifies them as relevant questions rather than calculated damages.

There is a further resource-allocation issue. Decisions about later studies depend on the credibility of earlier measurements. Independent replication and reliable reporting can help avoid committing research capacity on the strength of a selected result. That is an analytical implication, not a claim that every dollar spent on this program was wasted. Negative trials themselves can produce useful knowledge when transparently reported. Public value depends partly on whether complete results become available to researchers rather than disappearing after an unsuccessful commercial program.

5. Outcomes, company position, and the current regulatory boundary

The SEC settlement is one completed resolution in a broader history. Cassava stated that it cooperated with the investigation, implemented remedial measures, and appointed new leadership. It also stated in September 2024 that it did not then anticipate criminal charges or a resolution with DOJ against the company.³ The time qualifier matters: a contemporaneous corporate expectation is not a permanent government assurance, and this report does not treat it as one.

The criminal matter concerned Wang, a former collaborator. DOJ's June 2024 release alleged that grant applications involving research for an Alzheimer's treatment and diagnostic test contained fabricated or falsified data and resulted in approximately \$16 million in NIH awards. Those were allegations made at indictment.⁶ The October 2025 SEC filing states that the district court granted the government's unopposed motion to dismiss the indictment with prejudice.⁷ This report relies on the company filing for that disposition and has not independently inspected a complete criminal docket. Nothing in the filing establishes a clinical efficacy finding or supplies a judicial explanation for dismissal.

Corporate identity is equally important. The March 2026 name change to Filana was formally disclosed, together with the new ticker and website.¹ Historical allegations should remain attached to the relevant period and entity, while current descriptions should use the current name. A renamed company does not become exempt from historical examination, but the fact of renaming alone supplies no evidence of concealment or misconduct.

The latest detailed update located was the company's 29 July 2026 report. It said Filana continued discussions with FDA to address requested information and lift the clinical hold on its proposed TSC-related epilepsy proof-of-concept trial.⁸ That is evidence of the company's reported regulatory status, not access to FDA's complete review file. The source does not permit this report to infer the undisclosed reasons for every regulatory concern.

A different disease indication also creates a fresh evidentiary question. Lack of demonstrated efficacy in Alzheimer's disease does not logically settle efficacy in TSC-related epilepsy. At the same time, a new mechanistic rationale or preclinical signal cannot establish clinical benefit in that population. The practical position is therefore neither blanket endorsement nor blanket scientific impossibility. Filana's future claims should be assessed against indication-specific human evidence, regulatory permissions, and the same standards of transparent analysis that were central to the earlier controversy. Trial plans remain plans until enrollment and results are independently documented.

6. Implications, research method, and limitations

This new research edition was prepared for the Pharma Foundation library in September 2026. The previously linked report was unavailable. No text from that missing report was recovered, verified, or represented as the Foundation's earlier work. The present account is based on the cited primary sources and does not reconstruct historical authorship or establish past publication.

Research prioritized original SEC and DOJ material and the company's own disclosures. Agency releases establish what an agency alleged or announced; company filings establish the registrant's disclosed position and status. Neither source category is automatically a substitute for the complete evidentiary record. The references intentionally include the original indictment announcement and later dismissal filing, as well as both the SEC's account and the company's settlement response, so readers can inspect material developments that cut in different directions.

The analysis did not reproduce patient-level statistics, estimate damages, or attribute a specific death or medical outcome to the program. It did not verify every historical research paper, image dispute, shareholder lawsuit, or commentator's claim. Search results and social-media summaries were used only to locate primary material, not as proof. The latest-status search was conducted on 9 September 2026; the latest substantive corporate update located was dated 29 July. A subsequent court order or FDA development could supersede that status, but cannot be inferred from elapsed time.

Three distinctions shape this account. First, the SEC disclosure matter settled without admission or denial, and the \$40 million is a civil penalty. Second, the account of Wang includes the dismissal with prejudice alongside the indictment. Third, the current company profile uses Filana Therapeutics and describes simufilam as investigational, with the clinical-hold status attributed to the dated company update. These distinctions prevent an old allegation from becoming an inaccurate present-tense description.

For research governance, the case illustrates the importance of preserving full datasets, documenting who was blinded and when, disclosing consequential exclusions, and separating investor communication from confirmatory scientific conclusions. These are this report's analytical implications. They do not presume a universal explanation for failed drug development. The strongest supported public-interest conclusion is narrower and more useful: readers need an auditable connection between an advertised result, the population analyzed, the legal status of claims about it, and the most recent clinical outcome. That connection is the appropriate basis for a fair report.

References

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