Corporate Intelligence Brief

Avadel Pharmaceuticals plc (AVDL)

(Report generated January 20, 2026)

Executive Summary

Avadel Pharmaceuticals has evolved from a clinical-stage developer into a commercial-stage biopharmaceutical entity focused on the sleep disorder market. This transformation centers on the approval and commercialization of LUMRYZ (formerly FT218), a once-nightly sodium oxybate formulation for narcolepsy. The company successfully navigated existential legal challenges and complex regulatory hurdles to challenge the incumbent market leader, Jazz Pharmaceuticals.

Strategic execution was defined by overcoming the "REMS Patent" barrier. Through aggressive litigation and a counter-offensive against Jazz, Avadel secured the delisting of blocking patents and obtained a critical FDA determination of "Clinical Superiority" based on dosing convenience. This designation granted Orphan Drug Exclusivity (ODE), shielding LUMRYZ from generic competition and validating its core value proposition.

Financially, Avadel transitioned from capital preservation to revenue scaling. After divesting legacy hospital products, the company funded launch preparations through royalty-based financing to minimize equity dilution. Since the June 2023 launch, Avadel has scaled annualized net product revenues and expanded its patient base, though the cost structure has shifted heavily toward sales, marketing, and patient support.

Looking forward, the company is pivoting to lifecycle management. With adult narcolepsy established, Avadel has secured pediatric approval and is pursuing an indication for Idiopathic Hypersomnia (IH). Having settled outstanding patent litigation and stabilized its supply chain, Avadel now operates as a commercial entity with a growing revenue base and protected intellectual property, focused on capturing market share in the sodium oxybate space.

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Methodology and Limitations

What This Report Provides: This intelligence brief systematically extracts and synthesizes strategic disclosures from Avadel 103 SEC filings (10-K, 10-Q, 8-K) published between February 17, 2021 and January 20, 2026. The system identifies strategic themes, competitive positioning, business model evolution, and management priorities as disclosed by management in regulatory filings. Every factual claim is traceable to source documents through links to specific filing excerpts and to the filings themselves. Users are encouraged to review source excerpts and independently verify material claims before relying on this analysis (See Audit Table);

What This Report Does NOT Provide: - Financial performance calculations, projections, or forecasts - Valuation analysis or price targets - Investment recommendations (buy/sell/hold) - Predictive modeling of future outcomes - Comparison to consensus estimates or peer benchmarks - Verification of management claims against external data sources

Analytical Approach: The analysis is fully automated using large language models with structured extraction protocols and quality assurance validation. The system synthesizes narrative patterns and strategic shifts across multiple years of filings without manual analyst interpretation. While rigorous quality assurance protocols are applied, AI systems can misinterpret ambiguous language, fail to capture unstated context, synthesize patterns that reflect correlation rather than causation, and reflect biases in training data or extraction algorithms. Users bear responsibility for verifying AI-generated analysis and management's claims before relying on them for investment decisions.

Known Limitations:

- Extraction is limited to narrative prose sections of SEC filings (e.g., Management's Discussion & Analysis, Business Description, Risk Factors, Strategy sections). Financial statements, GAAP data tables, performance metrics tables, charts, and structured data exhibits are not processed.
- Analysis reflects filing language as of publication dates; rapid market changes after filing dates are not incorporated
- Segment definitions, reporting structures, and terminology may change over time, affecting year-over-year comparability
- The selection of 'strategic themes' involves algorithmic judgment on materiality. Significant disclosures may be omitted if they do not align with the system's thematic extraction definitions
- Management tone and emphasis may reflect positioning rather than operational reality
- Automated extraction may miss subtle contextual signals that human analysts would detect

Note on monetary values: All monetary values are presented verbatim from source materials or LLM analysis without automated correction. We do not attempt to normalize apparent inconsistencies (e.g., $20,000 where $20M may be intended) as programmatic interpretation can introduce errors. In case of doubt, users must verify material amounts against original SEC filings using the provided hexid references.

Intended Use: This report is designed as a **starting point for investment research**, not a substitute for comprehensive due diligence. Users should:

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Strategic Intelligence Report: Avadel Pharmaceuticals

LUMRYZ Commercial Execution & Financial Performance

Strategic Pivot and Resource Reallocation Avadel shifted its primary focus from clinical development to the commercial execution of LUMRYZ following the mid-2020 divestiture of its legacy Hospital Products business. This reset allowed for capital reallocation toward the U.S. launch [1]. To support this transition, Selling, General, and Administrative (SG&A) expenses ramped aggressively, surging 74.5% year-over-year by mid-2021 and rising by over $36 million in 2021 [2]. These investments funded marketing, legal costs, and the build-out of U.S. commercial systems [3].

The expense structure evolved further upon FDA approval in May 2023. The subsequent June launch triggered a 177.8% spike in Q3 2023 SG&A expenses [4]. Conversely, R&D production costs declined as the company moved from development to execution [5]. By early 2025, while total expenses grew, the mix shifted: legal fees associated with litigation decreased, offset by continued investment in medical education and market access [6].

Financial Performance and Revenue Trajectory LUMRYZ is now the sole source of product revenue, creating a high reliance on the asset's performance [7]. Revenue scaling has been rapid, growing from ~$28 million in 2023 to over $169 million in 2024 [8]. This trajectory persisted into 2025, with nine-month revenues reaching $198.1 million, up from $118.7 million in the prior year [9]. Performance correlates directly with patient uptake; the active patient base expanded from ~1,900 in June 2024 to 3,400 by September 2025 [10].

Post-approval accounting shifts included capitalizing manufacturing costs as inventory rather than expensing them as R&D, contributing to a ~30% decline in R&D expenses in H1 2023 [11]. While this aids gross margins as pre-approval inventory depletes, Cost of Products Sold (COGS) has increased due to volume and royalty obligations [12].

Commercial Model and Market Access To manage market entry complexities, Avadel pursued a bifurcated commercial strategy. In the U.S., the company built internal sales and marketing infrastructure, despite acknowledging risks related to field team sizing and physician targeting [13]. Ex-U.S., the strategy relies on third-party collaborations, accepting lower margins for broader access [14].

Commercial success faces a challenging reimbursement environment. Avadel recognizes that dosing convenience—LUMRYZ's primary differentiator—is historically insufficient for reimbursement without demonstrating therapeutic improvement or cost reduction [15]. Revenue recognition is impacted by significant gross-to-net adjustments, including Medicaid rebates and specialty pharmacy fees [16]. Furthermore, distribution concentration creates counterparty risk; as of late 2023, 100% of gross accounts receivable and sales were held by just three customers: Caremark, Accredo, and Optum [17].

Legal Proceedings & Intellectual Property Strategy

The REMS Patent Litigation and Regulatory Standoff From 2022 to early 2023, Avadel's market entry was blocked by the "REMS Patent" (No. 8,731,963) held by Jazz Pharmaceuticals. An FDA determination compelled Avadel to certify against this patent "under protest," triggering a Jazz infringement lawsuit and an automatic

regulatory stay [18]. While LUMRYZ received "tentative approval," final authorization remained contingent on resolving this litigation [19].

Avadel countered with an aggressive multi-front legal campaign. The company filed a **Renewed Motion for Judgment on the Pleadings** to delist the REMS patent, sued the FDA to vacate the certification decision, and alleged trade secret misappropriation by Jazz [20]. This offensive strategy succeeded in early 2023 when a Federal Circuit order compelled Jazz to request the delisting of the REMS patent, enabling Avadel to amend its NDA for final approval [21].

Antitrust Counter-Offensive and Final Settlement Litigation persisted post-approval through 2025, with Jazz alleging infringement of the '782 patent [22]. Avadel leveraged antitrust mechanisms, successfully defeating Jazz's motion to dismiss counterclaims in May 2024 [23]. Following complex appellate maneuvers and injunctions that granted Jazz a 3.85% royalty but permitted continued sales, the conflict culminated in a definitive **Settlement and License Agreement in October 2025** [24].

Financial Impact and Resource Allocation This legal strategy was a primary driver of operating expense growth. Legal fees surged by ~$11.4 million in 2022 and continued to rise through H1 2023 [25]. A financial inflection point occurred in 2024; while early quarters saw elevated costs, legal expenses declined significantly by Q3 and Q4 as the company pivoted from litigation to commercial execution [26].

Competitive Positioning & Clinical Differentiation

Core Value Proposition and Market Disruption Avadel aims to disrupt the **$1.8 billion annualized sodium oxybate market** with LUMRYZ, the only once-nightly formulation [27]. Leveraging proprietary **Micropump technology**, the product eliminates the middle-of-the-night dosing required by the standard of care [28]. Management positions this profile as a solution to compliance and safety limitations of twice-nightly regimens [29].

Regulatory Victory: Clinical Superiority and Exclusivity Differentiation was solidified via a regulatory finding of superiority. The FDA's May 2023 approval included Orphan Drug Exclusivity (ODE) through May 2030, based on the determination that LUMRYZ makes a **"major contribution to patient care"** by eliminating nocturnal arousal [30]. This victory was essential to overcoming competitor exclusivity barriers [31]. The exclusivity shield was strengthened in October 2024 with pediatric approval, extending protection through October 2031 [32].

Strategic Evolution: From Efficacy to Preference Acknowledging that dosing convenience alone might not secure reimbursement, Avadel initiated the **RESTORE Open Label Extension (OLE) switch study** to demonstrate "significant therapeutic improvements" [33]. The study reported that **94% of patients** switching from twice-nightly oxybates preferred the once-nightly LUMRYZ regimen, providing critical data for market access negotiations [34].

Competitive Landscape and Generic Defense The market landscape shifted in 2023 with the entry of **authorized generics (AG)** for twice-nightly sodium oxybate [35]. Avadel relies on its IP estate (expiring 2037-2042) and the "major contribution to patient care" designation to insulate LUMRYZ from price-based generic erosion [36].

Capital Structure & Liquidity Management

Navigating "Going Concern" Risks (2022) Prior to approval, Avadel's liquidity was tightly coupled with the regulatory timeline. Facing net losses of $110 million in the first nine months of 2022, management acknowledged substantial doubt regarding the company's ability to continue as a going concern [37]. To preserve capital, the company executed a Corporate Restructuring Plan in 2022, reducing its workforce by approximately 50% [38].

Commercialization Financing and Stabilization (2023) In 2023, the strategy shifted from survival to securing a commercial runway. Management alleviated the going concern doubt through a multi-pronged financing approach designed to minimize dilution [39]. A cornerstone was a royalty purchase agreement with RTW Investments providing up to $75 million, secured by LUMRYZ assets without subjective acceleration clauses [40]. This was complemented by a public offering yielding ~$117 million and $40 million in Series B Preferred Shares [41].

Post-Launch Capital Structure (2023–2024) Avadel leveraged non-dilutive financing to support the launch, accessing a $30 million tranche from RTW in August 2023 and a second tranche contingent on revenue milestones [42]. This structure increased the cost of products sold due to royalty obligations [43]. Additionally, the liability profile evolved in late 2024 following the Jazz litigation; Avadel recorded estimated liabilities for court-mandated royalties, which now sit alongside standard capital commitments as long-term obligations [44].

Operational Infrastructure & Regulatory Compliance

Manufacturing Strategy and Supply Chain Evolution Avadel employs a fully outsourced manufacturing model, utilizing Contract Development and Manufacturing Organizations (CDMOs) for LUMRYZ supply [45]. This required significant upfront investment, including a dedicated production suite with long-term fee commitments [46].

Initially, the supply chain relied on high-risk single-source partners for both API and finished product [47]. By 2024-2025, Avadel mitigated this risk by diversifying its network to include two U.S.-based API suppliers and dual finished product manufacturers [48]. To accelerate launch, the company utilized the Pre-launch Activities Importation Request (PLAIR) program in March 2023 to import product prior to final approval [49].

Regulatory Pathway and REMS Implementation Commercialization is governed by a rigid regulatory infrastructure. Following approval, Avadel activated the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS), a closed distribution system restricting access to certified prescribers and pharmacies [50]. This system strictly controls sales and marketing [51]. Between 2023 and 2024, the REMS infrastructure expanded to support the pediatric indication [52].

Controlled Substance Compliance Operations are further constrained by the Controlled Substances Act. While LUMRYZ is Schedule III, the API is Schedule I, necessitating strict adherence to DEA manufacturing quotas and site-specific registrations [53]. This compliance burden extends to all third-party partners, who must maintain valid DEA registrations and state licenses [54].

Pipeline Expansion & Lifecycle Management

Lifecycle Management: Pediatric Expansion Avadel expanded its addressable market by securing FDA approval for LUMRYZ in pediatric narcolepsy (ages 7+) in October 2024 [55]. Utilizing **Liquitime technology** for patients with swallowing difficulties, this approval extended Orphan Drug Exclusivity through October 2031, reinforcing the product's lifecycle [56].

Pipeline Expansion: Idiopathic Hypersomnia (IH) Building on the narcolepsy foundation, Avadel is targeting Idiopathic Hypersomnia (IH) as a strategic priority [57]. The company posits that once-nightly dosing offers a "major contribution to patient care" for IH, supporting an Orphan Drug Designation [58]. The pivotal Phase 3 REVITALYZ trial began dosing in July 2024, driving a shift in resource allocation back toward active clinical development [59].

Geographic Strategy and Portfolio Diversification Avadel pursues diversification through externalization and inorganic growth. International commercialization relies on third-party collaborations to minimize internal infrastructure costs [60]. To mitigate single-asset reliance, the company acquired a license for valiloxybate from XWPharma for a $20 million upfront fee, broadening the portfolio beyond the LUMRYZ franchise [61].

Strategic Trajectory and Outlook

Avadel Pharmaceuticals has successfully navigated a critical inflection point, transitioning from a development-stage company facing existential legal threats to a commercial entity with a scaling flagship product. The successful defense against REMS patent litigation and the regulatory recognition of LUMRYZ's clinical superiority have established a defensible market position protected by exclusivity through 2031.

Strategic focus has shifted from survival to execution. With adult narcolepsy revenue generating significant cash flow, growth vectors now lie in the pediatric indication and potential expansion into Idiopathic Hypersomnia. Financially, the company has stabilized its capital structure through non-dilutive financing, though it remains reliant on LUMRYZ's commercial success to fund pipeline obligations. The settlement of major litigation removes a significant overhang, allowing management to focus on maximizing the sodium oxybate franchise and diversifying via disciplined business development.

Audit Trail Table

Back to Methodology

Main Report Text (Top Section) - Strategic narrative with citation numbers in brackets: [1], [2], [3], etc. - Example: "Intel's manufacturing strategy transformed... [1]" - These numbers link to evidence below

In the Audit Trail Table, each numbered entry contains:

1. **Citation number** - [1], [2], [3]
2. **Claim being supported** - The specific statement from the main text (often slightly paraphrased/ excerpted)
3. **Source entries** - One or more blocks showing:
    - **Document type & date**: "10-K::2021-01-22"
    - **Hexid**: "5388f3375ce4e512" (snippet unique hexadecimal identifier)
    - **Snippet text**: Extracted passage from SEC filing
    - **(More..)** link to Google search query derived from snippet

Forward reference (reading report):

- See [29] in main text ⇒ Jump to appendix entry [29] and check supporting snippets
    - Then either jump back to [29] location in text
    - Or use the "More.." Google Search Feature to get the source document and related context. In most cases, clicking on "Read more" on the Google entry for the original SEC document will return the exact original text of the snippet

Additional Formats:

- HTML version: Interactive document with bidirectional links between narrative claims and supporting evidence. Recommended for manual verification workflows.
- Chronological audit trail: All evidence organized by filing date rather than thematic structure. Available as:
    - HTML for browsing
    - JSON for programmatic access and LLM integration (see example use cases)

Paragraph 1		
[1]		Avadel shifted its primary focus from clinical development to the commercial execution of LUMRYZ following the mid-2020 divestiture of its legacy Hospital Products business. This reset allowed for capital reallocation toward the U.S. launch
	10-K::2022-03-16 2c8d3f5e305ec242	The Company will no longer be responsible for these payments. NOTE 5 Revenue Recognition Prior to June 30 2020 the Company generated revenue primarily from the sale of pharmaceutical products to customers. On June 30 2020 the Company sold the Hospital Products. See Note 4 Disposition of the Hospital Products. Product Sales and Services Prior to June 30 2020 the Company sold products primarily through wholesalers and considered these wholesalers to be its customers. (More..)
	10-K::2022-03-16 2a7820cc8add4e10	Operating income for the year ended December 31 2020 was driven by the gain on sale of the Hospital Products on June 30 2020 of $45,760. Selling general administrative expenses increased in the current year by $36,090, driven by the Company s continued commercial preparations and launch readiness activities for the potential approval of FT218. Net loss was $77,329 for the year ended December 31 2021 compared to net income of $7,028 in the same period last year. (More..)
[2]		To support this transition, Selling, General, and Administrative (SG&A) expenses ramped aggressively, surging 74.5% year-over-year by mid-2021 and rising by over $36 million in 2021
	10-Q::2021-08-09 4752178138d4cd91	SG A expenses increased $11,178 or 74.5 during the six months ended June 30 2021 as compared to the same prior year period driven by the Company s continued commercial preparations and launch readiness activities for potential approval of FT18. These activities included an increase in marketing and market research activities of approximately $3,800, and an increase in other launch planning and preparation activities totaling approximately $2,300. (More..)
	10-K::2022-03-16 2a7820cc8add4e10	Operating income for the year ended December 31 2020 was driven by the gain on sale of the Hospital Products on June 30 2020 of $45,760. Selling general administrative expenses increased in the current year by $36,090, driven by the Company s continued commercial preparations and launch readiness activities for the potential approval of FT218. Net loss was $77,329 for the year ended December 31 2021 compared to net income of $7,028 in the same period last year. (More..)

[3]		These investments funded marketing, legal costs, and the build-out of U.S. commercial systems
	10-Q::2021-08-09 87531120034c6cda	These activities included an increase in marketing and market research costs of approximately $3,000 and an increase in other launch planning and preparation activities totaling $1,400. Compensation costs increased by approximately $2,100 due to an increase in headcount primarily in commercial and medical affairs and legal and insurance costs increased by approximately $1,400. (More..)
	10-K::2021-03-09 633cf2e7bf5f9cc6	We are continuing to build the systems processes policies relationships and materials necessary for launch of FT218 in the U.S. for the treatment of cataplexy or EDS in adults with narcolepsy. (More..)

Paragraph 2

[4]		The expense structure evolved further upon FDA approval in May 2023. The subsequent June launch triggered a 177.8% spike in Q3 2023 SG&A expenses
	10-Q::2023-11-08 58c2ff04c553119c	We began capitalizing API purchases to inventory in May 2023 upon FDA approval of LUMRYZ and prior to FDA approval API purchases were recorded as research and development expense. Selling general and administrative expenses increased $25,062 or 177.8 during the three months ended September 30 2023 as compared to the same period in the prior year. (More..)
	10-Q::2023-08-09 6c4547df036997c5	In June 2023 the Company commercially launched LUMRYZ in the U.S. In approving LUMRYZ the FDA approved a risk evaluation and mitigation strategy REMS for LUMRYZ to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing misuse abuse and diversion of the drug. (More..)

[5]		Conversely, R&D production costs declined as the company moved from development to execution
	10-Q::2022-11-09 5a1f9834eea7adee	This decrease was driven by lower research and development production costs during the current period of approximately $1,300 and share based compensation costs of approximately $400, partially offset by higher API purchases of $1,200, the majority of which were purchased in the three months ended March 31 2022. (More..)

[6]		By early 2025, while total expenses grew, the mix shifted: legal fees associated with litigation decreased, offset by continued investment in medical education and market access
	10-Q::2025-05-07 5700194741df0ab1	This increase was driven primarily by costs associated with the Phase 3 REVITALYZ clinical trial for LUMRYZ in treating IH. Selling general and administrative expenses decreased $3,042 or 6.3 during the three months ended March 31 2025 as compared to the same period in the prior year. This decrease was driven by lower legal costs of $9,600. (More..)
	10-Q::2025-08-07 3ac66d9911ebbf8c	This decrease was driven by lower legal costs of $10,600 and nonrecurring fees associated with terminating our American Depository Receipt program ADR Program of American Depositary Shares ADSs in the prior year of $5,500. The decrease was offset by LUMRYZ commercial costs including higher employee related costs of $5,500 due to increased headcount and recruiting higher patient and market access of $4,700, higher selling and marketing costs of $1,300, and higher medical education of $1,200. (More..)

Paragraph 3

[7]		LUMRYZ is now the sole source of product revenue, creating a high reliance on the asset's performance
	10-Q::2023-08-09 0d58c0ef703c38d5	Results for interim periods are not necessarily indicative of the results to be expected during the remainder of the current year or for any future period. NOTE 2 Revenue Recognition The Company s source of net product revenue during the three and six months ended June 30 2023 consists solely of sales of LUMRYZ. For the three and six months ended June 30 2023 three customers accounted for 100 of sales. (More..)
	10-K::2025-03-03 443f956dd6eff11d	LUMRYZ is the only commercialized product in our portfolio and we will incur substantial expenses to continue our commercial launch of LUMRYZ. Financial Highlights Highlights of our consolidated results for the year ended December 31 2024 are as follows Net product revenue was $169,117 for the year ended December 31 2024 compared to net product revenue of $27,963 for the year ended December 31 2023. (More..)

[8]		Revenue scaling has been rapid, growing from ~$28 million in 2023 to over $169 million in 2024
	10-K::2025-03-03 443f956dd6eff11d	LUMRYZ is the only commercialized product in our portfolio and we will incur substantial expenses to continue our commercial launch of LUMRYZ. Financial Highlights Highlights of our consolidated results for the year ended December 31 2024 are as follows Net product revenue was $169,117 for the year ended December 31 2024 compared to net product revenue of $27,963 for the year ended December 31 2023. (More..)

[9]		This trajectory persisted into 2025, with nine-month revenues reaching $198.1 million, up from $118.7 million in the prior year
	10-Q::2025-11-04 e360171cef2648d7	Financial Highlights Highlights of our consolidated results for the three and nine months ended September 30 2025 are as follows Net product revenue was $77,467 and $198,107 during the three and nine months ended September 30 2025 respectively compared to net product revenue of $50,025 and $118,707 for the three and nine months ended September 30 2024. The increase in net product revenue is driven by the early phases of LUMRYZ launch in the prior period and patient uptake throughout launch. (More..)

[10]		Performance correlates directly with patient uptake; the active patient base expanded from ~1,900 in June 2024 to 3,400 by September 2025
	10-Q::2025-08-07 60d23926ac3a2368	The increase in cost of products sold during the period was due to higher sales of LUMRYZ and inclusion of an estimated royalty on net product revenue in the current period. Net product revenue increased $51,958 during the six months ended June 30 2025. The increase in net product revenue is driven by continual increases in the number of patients treated with LUMRYZ. As of June 30 2025 approximately 3 100 patients were on LUMRYZ compared to approximately 1 900 patients as of June 30 2024. (More..)
	10-Q::2025-11-04 a9f50456a60f3281	Net product revenue increased $79,400 during the nine months ended September 30 2025. The increase in net product revenue is driven by continual increases in the number of patients treated with LUMRYZ. As of September 30 2025 approximately 3 400 patients were on LUMRYZ compared to approximately 2 300 patients as of September 30 2024. Cost of products sold decreased $2,638 during the nine months ended September 30 2025 as compared to the same period in the prior year. (More..)

Paragraph 4

[11]		Post-approval accounting shifts included capitalizing manufacturing costs as inventory rather than expensing them as R&D, contributing to a ~30% decline in R&D expenses in H1 2023
	10-Q::2023-08-09 613af8958b8b56d8	This decrease was driven by lower active pharmaceutical ingredients API purchases during the current period of approximately $700. The decrease in research and development expense was offset by a $500 cumulative adjustment for certain compensation awards tied to the achievement of performance conditions which became probable in the period. Research and development expenses decreased $3,479 or 30.2 during the six months ended June 30 2023 as compared to the same period in the prior year. (More..)
	10-Q::2023-08-09 c0ddd7c664290a8c	The Company capitalizes inventory costs associated with products when future is considered probable and the future economic benefit is expected to be realized which is typically when regulatory approval is obtained for a drug candidate. As such the Company began capitalizing costs related to inventory in May 2023 upon FDA approval of LUMRYZ. Manufacturing costs associated with inventory purchased or produced prior to FDA approval were recorded as research and development expense in prior periods. (More..)

[12]		While this aids gross margins as pre-approval inventory depletes, Cost of Products Sold (COGS) has increased due to volume and royalty obligations
	10-K::2024-02-29 6b002a3b91179ea7	This decrease was driven by lower pre commercial LUMRYZ related costs of $11,500 that we began capitalizing to inventory in May 2023 upon FDA approval of LUMRYZ. Prior to FDA approval these costs were recorded as research and development expense. (More..)
	10-Q::2025-08-07 ce17e4033aeb8c03	Cost of products sold increased during the three and six months ended June 30 2025 compared to the three and six months ended June 30 2024 due to higher sales of LUMRYZ and the inclusion of an estimated royalty on net product revenue in the current period. Total operating expense was $52,879 and $102,814 for the three and six months ended June 30 2025 respectively compared to total operating expense of $51,457 and $103,148 for the three and six months ended June 30 2024 respectively. (More..)

Paragraph 5

[13]		To manage market entry complexities, Avadel pursued a bifurcated commercial strategy. In the U.S., the company built internal sales and marketing infrastructure, despite acknowledging risks related to field team sizing and physician targeting
	10-K::2023-03-29 840e16afb75abd9b	We may face other limitations or issues related to the price of LUMRYZ. Our results may also be negatively impacted if we have not adequately sized our field teams or our physician segmentation and targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. (More..)
	10-K::2023-03-29 af4eb9cb48c6b99d	We may encounter issues delays or other challenges in launching or LUMRYZ. We have limited experience in building and managing a commercial team conducting a comprehensive market analysis obtaining state licenses and reimbursement or managing distributors and a sales force for our medicines. (More..)

[14]		Ex-U.S., the strategy relies on third-party collaborations, accepting lower margins for broader access
	10-K::2022-03-16 7f70e95860ab47c3	We may rely on collaborations with third parties to commercialize FT218 outside of the U.S. if approved and certain of our future product candidates and such strategy involves risks that could impair our prospects for realizing profits from such products. We expect that the of FT218 outside of the U.S. if approved or future product candidates may require collaboration with third party partners involving strategic alliances licenses product divestitures or other arrangements. (More..)
	10-K::2022-03-16 21feaf6d979715e2	Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized FT218 ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our medicines. (More..)

Paragraph 6

[15]		Commercial success faces a challenging reimbursement environment. Avadel recognizes that dosing convenience—LUMRYZ's primary differentiator—is historically insufficient for reimbursement without demonstrating therapeutic improvement or cost reduction
	10-K::2021-03-09 27b48ebd84da79c5	Market Opportunities In today s pharmaceutical market a drug has to demonstrate significant therapeutic improvements over the current standard of care in order to obtain third party payer coverage. Alternatively changes in the delivery of a drug must create a demonstrable reduction in costs. Dosing convenience by itself is not sufficient to gain reimbursement acceptance.companies must demonstrate through extensive clinical trials the therapeutic efficacy of their new formulations. (More..)

[16]		Revenue recognition is impacted by significant gross-to-net adjustments, including Medicaid rebates and specialty pharmacy fees
	10-Q::2023-11-08 0cbc2cb79d85a944	Reserves for Variable Consideration Revenues from product sales are recorded at the estimated net selling price which includes reserves for estimated variable consideration to reduce gross product sales to net product revenue resulting from payment discounts specialty pharmacy fees patient financial assistance programs rebates and product returns. (More..)
	10-K::2022-03-16 2bdd46ae8f34d238	Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 or collectively the ACA. If drugs are made available to authorized users of the Federal Supply Schedule of the General Services Administration additional laws and requirements apply. (More..)
	10-K::2025-03-03 331b2a6f591e5227	These adjustments include estimates of payment discounts specialty pharmacy fees patient financial assistance programs rebates and product returns and are estimated based on contractual arrangements historical trends expected utilization of such products and other judgments and analysis. (More..)

[17]		Furthermore, distribution concentration creates counterparty risk; as of late 2023, 100% of gross accounts receivable and sales were held by just three customers: Caremark, Accredo, and Optum
	10-K::2024-02-29 0d4119cf4b227048	As of December 31 2023 three customers accounted for 100 of gross accounts receivable Caremark LLC Caremark which accounted for 52 of gross accounts receivable Accredo Health Group Inc. Accredo which accounted for 28 of gross accounts receivable and Optum Frontier Therapies LLC Optum which accounted for 20 of gross accounts receivable. As of December 31 2022 the Company did not have accounts receivable. (More..)
	10-K::2024-02-29 81cf2ae28dd58eae	Adoption of ASU 2023 09 will not have a material effect on the Company s financial position or results of operations. NOTE 3 Revenue Recognition The Company s source of net product revenue during the year ended December 31 2023 consists solely of sales of LUMRYZ in the U.S. For the year ended December 31 2023 three customers accounted for 100 of sales. (More..)

Paragraph 7

[18]		From 2022 to early 2023, Avadel's market entry was blocked by the "REMS Patent" (No. 8,731,963) held by Jazz Pharmaceuticals. An FDA determination compelled Avadel to certify against this patent "under protest," triggering a Jazz infringement lawsuit and an automatic regulatory stay
	10-Q::2022-11-09 040ab82776c1c840	The FDA required Avadel CNS to file a Paragraph IV certification against the REMS Patent which Avadel CNS did under protest consistent with its Renewed Motion for Judgment on the Pleadings for the de listing of the REMS Patent from the Orange Book which is pending in response to the above First Jazz Complaint action. Avadel CNS provided the required notice of its Paragraph IV certification to Jazz and Jazz reasserted the REMS Patent in a separate action following receipt of that notice. (More..)
	10-Q::2022-08-09 ce4a35e08e06d3ff	The filing of that lawsuit triggers a regulatory stay on FDA approval of LUMRYZ. On July 18 2022 we received tentative approval from the FDA for LUMRYZ for the treatment of cataplexy or EDS in adults suffering from narcolepsy. (More..)
	10-Q::2022-11-09 58c93a5b372cb498	Tentative approval indicates that LUMRYZ has met all required quality safety and efficacy standards necessary for approval in the U.S. The Company is primarily focused on obtaining final FDA approval of LUMRYZ. A decision on final FDA approval of LUMRYZ is pending disposition of U.S. Patent No.8731963 the REMS Patent which is listed in the FDA s Orange Book. (More..)

[19]		While LUMRYZ received "tentative approval," final authorization remained contingent on resolving this litigation
	10-Q::2022-11-09 58c93a5b372cb498	Tentative approval indicates that LUMRYZ has met all required quality safety and efficacy standards necessary for approval in the U.S. The Company is primarily focused on obtaining final FDA approval of LUMRYZ. A decision on final FDA approval of LUMRYZ is pending disposition of U.S. Patent No.8731963 the REMS Patent which is listed in the FDA s Orange Book. (More..)
	8-K::2022-11-18 c2e33a2dd8258f14	With the issuance of this ruling the Company intends to seek final FDA approval for LUMRYZ upon removal of the REMS Patent. (More..)

Paragraph 8

[20]		Avadel countered with an aggressive multi-front legal campaign. The company filed a **Renewed Motion for Judgment on the Pleadings** to delist the REMS patent, sued the FDA to vacate the certification decision, and alleged trade secret misappropriation by Jazz
	10-Q::2022-11-09 040ab82776c1c840	The FDA required Avadel CNS to file a Paragraph IV certification against the REMS Patent which Avadel CNS did under protest consistent with its Renewed Motion for Judgment on the Pleadings for the de listing of the REMS Patent from the Orange Book which is pending in response to the above First Jazz Complaint action. Avadel CNS provided the required notice of its Paragraph IV certification to Jazz and Jazz reasserted the REMS Patent in a separate action following receipt of that notice. (More..)
	10-Q::2022-08-09 8443abd96e7169a7	This suit alleges that the FDA s decision requiring Avadel CNS to file a patent certification concerning the REMS Patent was arbitrary capricious and contrary to law and asks the DC Court to vacate the FDA s decision and order the FDA to take final action on the LUMRYZ NDA. On July 28 2022 the DC Court granted Jazz s unopposed motion to intervene in the case to defend the FDA s decision. (More..)
	10-Q::2022-08-09 4c115abff6ffe824	Avadel Complaint On April 14 2022 Avadel CNS and Avadel plc collectively the Avadel Plaintiffs filed a formal complaint the Avadel Complaint initiating a lawsuit in the Court against Jazz and Jazz Ireland Ltd.collectively the Jazz Parties. In the Avadel Complaint the Avadel Plaintiffs allege that the Jazz Parties breached certain confidential disclosure agreements and certain of the Avadel Plaintiffs trade secrets. (More..)

[21]		This offensive strategy succeeded in early 2023 when a Federal Circuit order compelled Jazz to request the delisting of the REMS patent, enabling Avadel to amend its NDA for final approval
	10-K::2023-03-29 1c6073b12410c611	On February 28 2023 Jazz complied with the order of the Federal Circuit and provided a written submission to the FDA requesting delisting of the REMS Patent from FDA s Orange Book. On March 1 2023 we submitted an amendment to our NDA for LUMRYZ requesting final FDA approval for LUMRYZ. Our receipt of tentative approval and filing of our amendment requesting final approval does not mean we will receive final FDA approval for the LUMRYZ NDA in a timely manner or at all. (More..)

Paragraph 9

[22]		Litigation persisted post-approval through 2025, with Jazz alleging infringement of the '782 patent
	10-Q::2023-05-04 7b9105f9835f1964	On September 7 2022 the case was reassigned to a new judge. Third Jazz Complaint On November 10 2021 Jazz filed another formal complaint the Third Complaint initiating a lawsuit in the Court against the Avadel Parties. In the Third Complaint Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS will infringe at least one claim of U.S. Patent No.11147782. (More..)
	10-Q::2025-11-04 2977e4c0d4a63568	Settlement Agreement with Jazz On October 21 2025 our subsidiary Avadel CNS LLC Avadel CNS entered into a Settlement and License Agreement the Settlement Agreement with Jazz Inc.to resolve the previously disclosed actions captioned Jazz Inc.v. Avadel CNS LLC C. A. No.21 691 Jazz Inc.et al v. Avadel CNS LLC C. A. No.21 1138 Jazz Inc.et al v. Avadel CNS LLC C. A. No.21 1594 Avadel CNS LLC et al v. Jazz Inc.et al C. A. No.22 487 Avadel CNS LLC v. (More..)

[23]		Avadel leveraged antitrust mechanisms, successfully defeating Jazz's motion to dismiss counterclaims in May 2024
	10-Q::2024-08-08 7ca3ee9867369130	On December 9 2022 Jazz filed a Motion to Dismiss Avadel s Antitrust Counterclaims. Avadel filed its opposition brief on December 27 2022 and Jazz filed its reply brief on January 6 2022. On January 11 2023 Avadel filed a request for oral argument on the motion. On May 24 2024 the Court denied Jazz s Motions to Dismiss. On June 7 2024 Jazz filed its Answer to Avadel s Counterclaims. (More..)

[24]		Following complex appellate maneuvers and injunctions that granted Jazz a 3.85% royalty but permitted continued sales, the conflict culminated in a definitive **Settlement and License Agreement in October 2025**
	8-K::2025-09-17 0847b335853180ee	the Court issued an opinion and order requiring Avadel CNS to pay a future ongoing royalty of 3.85 on sales of LUMRYZ to Jazz through. (More..)
	10-Q::2025-11-04 4c91a5a2e4df310e	That injunction excluded certain categories of conduct including permitting Avadel to continue making using and selling LUMRYZ for the treatment of narcolepsy and for use in ongoing clinical trials and studies. The August 27 2024 opinion and order also granted Jazz s motion for an ongoing royalty pending additional briefing on the appropriate royalty rate. That briefing closed on September 23 2024. (More..)
	10-Q::2025-11-04 2977e4c0d4a63568	Settlement Agreement with Jazz On October 21 2025 our subsidiary Avadel CNS LLC Avadel CNS entered into a Settlement and License Agreement the Settlement Agreement with Jazz Inc.to resolve the previously disclosed actions captioned Jazz Inc.v. Avadel CNS LLC C. A. No.21 691 Jazz Inc.et al v. Avadel CNS LLC C. A. No.21 1138 Jazz Inc.et al v. Avadel CNS LLC C. A. No.21 1594 Avadel CNS LLC et al v. Jazz Inc.et al C. A. No.22 487 Avadel CNS LLC v. (More..)

Paragraph 10

[25]		This legal strategy was a primary driver of operating expense growth. Legal fees surged by ~$11.4 million in 2022 and continued to rise through H1 2023
	10-K::2023-03-29 6a3ae1e896a8186f	This change is driven by a $4,800 increase in active pharmaceutical ingredient purchases in the current year offset by a $1,000 reduction in clinical studies spend. Selling general and administrative expenses increased by $6,021 or 8.8 during the year ended December 31 2022 as compared to the prior year. This increase was driven primarily by higher legal costs of approximately $11,400 and debt issuance costs of approximately $5,450 related to the Exchange Transaction. (More..)
	10-Q::2023-08-09 3f369e34e192cb21	Selling general and administrative expenses increased during the six months ended June 30 2023 by $27,807 compared to the six months ended June 30 2022 driven by higher legal fees of $8,600, higher marketing and market research activities of $3,900, higher costs associated with the commercial launch of LUMRYZ of $3,500, and higher compensation costs of $2,600 due to increased headcount. (More..)

[26]		A financial inflection point occurred in 2024; while early quarters saw elevated costs, legal expenses declined significantly by Q3 and Q4 as the company pivoted from litigation to commercial execution
	10-Q::2024-05-08 341dc8b9edb670a8	Selling general and administrative expenses increased $24,155 during the three months ended March 31 2024 compared to the three months ended March 31 2023 driven by increased headcount and costs associated with the commercial launch of LUMRYZ and higher legal fees. Net loss was $27,342 for the three months ended March 31 2024 compared to net loss of $30,784 in the same period last year. (More..)
	10-Q::2024-11-12 6aff7435eb2a41cf	Selling general and administrative expenses increased $1,236 or 3.2 during the three months ended September 30 2024 as compared to the same period in the prior year. This increase was driven by higher compensation costs of $2,700 due to increased headcount and higher costs associated with the commercial launch of LUMRYZ of $600, offset by lower legal costs of $2,300. (More..)

Paragraph 11

[27]		Avadel aims to disrupt the **$1.8 billion annualized sodium oxybate market** with LUMRYZ, the only once-nightly formulation
	10-K::2021-03-09 2c944a71e177e69e	The current market size for the twice nightly administration of sodium oxybate is estimated at an annualized revenue run rate of $1.8B. 46 Micropump Drug Delivery Technology Our Micropump drug delivery technology allows for the controlled delivery of small molecule drugs taken orally which has the potential to reduce safety issues and improve a number of things like efficacy dosing compliance and patient satisfaction. (More..)
	10-K::2022-03-16 0a2a030d6c146120	FT218 FT218 is a once nightly formulation of sodium oxybate that uses our Micropump controlled release drug delivery technology for the treatment of EDS or cataplexy in adults suffering from narcolepsy. Sodium oxybate is the sodium salt of gamma an endogenous compound and metabolite of the gamma aminobutyric acid. (More..)

[28]		Leveraging proprietary **Micropump technology**, the product eliminates the middle-of-the-night dosing required by the standard of care
	10-Q::2021-05-10 30101095bd736d74	As of March 31 2021 we do not have any approved and commercialized products in our portfolio. We are registered as an Irish public limited company. Our headquarters are in Dublin Ireland and we have operations in St. Louis Missouri U.S. FT218 FT218 is a once nightly formulation of sodium oxybate that uses our Micropump controlled release drug delivery technology for the treatment of EDS and cataplexy in adults suffering from narcolepsy. (More..)
	10-Q::2021-11-08 2c676534d515fa81	Sodium oxybate is the sodium salt of gamma an endogenous compound and metabolite of the gamma aminobutyric acid. Sodium oxybate is approved in the U.S. for the treatment of EDS and cataplexy in patients with narcolepsy and is approved in Europe for the treatment of cataplexy in patients with narcolepsy. Since 2002 sodium oxybate has only been available as a formulation that must be taken twice nightly first at bedtime and then again 2.5 to 4 hours later. (More..)

[29]		Management positions this profile as a solution to compliance and safety limitations of twice-nightly regimens
	10-K::2021-03-09 2951b3f10660a394	We believe FT218 has the potential to demonstrate improved dosing compliance safety and patient satisfaction over the current standard of care for EDS and cataplexy in patients with narcolepsy which is a twice nightly sodium oxybate formulation. If approved we believe FT218 has the potential to take a significant share of the sodium oxybate market. (More..)
	10-Q::2021-08-09 544a5bc354d2319a	If approved we believe FT218 has the potential to take a significant share of the oxybate market. The current market size for the twice nightly administration of oxybate products is an estimated $1.8B annually. Micropump Drug Delivery Technology Our Micropump drug delivery technology allows for the controlled delivery of small molecule drugs taken orally which has the potential to improve dosing compliance reduce toxicity and improve patient compliance. (More..)

Paragraph 12

[30]		Differentiation was solidified via a regulatory finding of superiority. The FDA's May 2023 approval included Orphan Drug Exclusivity (ODE) through May 2030, based on the determination that LUMRYZ makes a **"major contribution to patient care"** by eliminating nocturnal arousal
	10-Q::2023-08-09 1a6f92dc836133f3	LUMRYZ formally known as FT218 is an extended release formulation of sodium oxybate indicated to be taken once at bedtime for the treatment of cataplexy or excessive daytime sleepiness EDS in adults with narcolepsy. LUMRYZ was approved by the U.S. Food and Drug Administration FDA on May 1 2023. The FDA also granted Orphan Drug Exclusivity ODE to LUMRYZ for a period of seven years until May 1 2030. (More..)
	10-Q::2023-05-04 09ff2cc6effae3a0	Additionally with its approval the FDA also granted seven years of orphan drug exclusivity to LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy due to a finding of clinical superiority of LUMRYZ relative to currently marketed oxybate treatments. In particular FDA found that LUMRYZ makes a major contribution to patient care over currently marketed twice nightly oxybate treatments by providing a once nightly dosing regimen that avoids nocturnal arousal to take a second dose. (More..)

[31]		This victory was essential to overcoming competitor exclusivity barriers
	10-K::2023-03-29 77768037be625e56	In addition because LUMRYZ would not be the first sodium oxybate product to be approved for the treatment of narcolepsy we must demonstrate that LUMRYZ is clinically superior to any previously approved same drug in order to obtain orphan drug exclusivity for LUMRYZ and we may be required to demonstrate clinical superiority for the approval and exclusivity of other product candidates in the future. (More..)
	10-K::2023-03-29 a8b487b0bf2a410d	For instance marketing approval for LUMRYZ could be delayed due to unexpired orphan drug exclusivity for an approved product in the event the FDA determines LUMRYZ to be the same drug as such approved product unless we are able to demonstrate LUMRYZ is clinically superior to or not the same drug as such approved product. (More..)

[32]		The exclusivity shield was strengthened in October 2024 with pediatric approval, extending protection through October 2031
	10-Q::2024-11-12 10fb47cf5008acd4	The FDA also granted Orphan Drug Exclusivity ODE to LUMRYZ for treatment of cataplexy or EDS in adults with narcolepsy for a period of seven years until May 1 2030. In June 2023 the Company commercially launched LUMRYZ in the U. S for the treatment of cataplexy or EDS in adults living with narcolepsy. LUMRYZ was approved by the FDA for use in the treatment of cataplexy or EDS in the pediatric narcolepsy population seven years and older on October 16 2024 and was granted ODE through October 16 2031. (More..)

Paragraph 13

[33]		Acknowledging that dosing convenience alone might not secure reimbursement, Avadel initiated the **RESTORE Open Label Extension (OLE) switch study** to demonstrate "significant therapeutic improvements"
	10-K::2021-03-09 27b48ebd84da79c5	Market Opportunities In today s pharmaceutical market a drug has to demonstrate significant therapeutic improvements over the current standard of care in order to obtain third party payer coverage. Alternatively changes in the delivery of a drug must create a demonstrable reduction in costs. Dosing convenience by itself is not sufficient to gain reimbursement acceptance.companies must demonstrate through extensive clinical trials the therapeutic efficacy of their new formulations. (More..)
	10-K::2021-03-09 177cd3264fb2eb99	In July 2020 we announced that the first patient was dosed initiating an open label extension OLE switch study of FT218 as a potential treatment for EDS and cataplexy in patients with narcolepsy. (More..)

[34]		The study reported that **94% of patients** switching from twice-nightly oxybates preferred the once-nightly LUMRYZ regimen, providing critical data for market access negotiations
	10-Q::2023-11-08 af806f97361b736a	Subsequent interim data showed a preference 94.0 for the once nightly dosing regimen. (More..)
	10-K::2025-03-03 18169a97ef2f989b	The last patient visit occurred in October 2023. RESTORE results for the largest cohort those who switched from twice nightly oxybates have been published which include the 94 preference for the once nightly dosing regimen that LUMRYZ provides. We believe LUMRYZ has the potential to demonstrate improved dosing compliance safety and patient satisfaction over other treatment options for cataplexy or EDS in patients seven years of age and older with narcolepsy. (More..)

Paragraph 14

[35]		The market landscape shifted in 2023 with the entry of **authorized generics (AG)** for twice-nightly sodium oxybate
	10-Q::2023-11-08 936c4dce0991872c	LUMRYZ may face competition from manufacturers of generic twice nightly sodium oxybate formulations. In January 2023 Hikma plc announced that it launched an authorized generic version of Jazz plc s Jazz Xyrem sodium oxybate. In July 2023 Amneal Inc.announced that it launched an authorized generic version of Jazz s Xyrem sodium oxybate. (More..)
	10-Q::2025-08-07 b1a13cac0e84f90e	In January 2023 Hikma plc announced the launch of an authorized generic version of Jazz s Xyrem sodium oxybate. In July 2023 Amneal Inc.announced that it launched an authorized generic version of Jazz s Xyrem sodium oxybate. There are other potential future competitive products that could impact the marketplace. (More..)

[36]		Avadel relies on its IP estate (expiring 2037-2042) and the "major contribution to patient care" designation to insulate LUMRYZ from price-based generic erosion
	10-Q::2023-08-09 8cd285c76f39ce38	The orphan exclusivity will continue until May 1 2030. In June 2023 we announced the U.S. commercial launch of LUMRYZ for the treatment of cataplexy or EDS in adults living with narcolepsy. Thirteen LUMRYZ related U.S. patents have been issued having expiration dates spanning from mid 2037 to early 2042 and there are additional patent applications currently in development and or pending at the U.S. Patent and Trademark Office USPTO as well as foreign patent offices. (More..)
	10-Q::2023-05-04 09ff2cc6effae3a0	Additionally with its approval the FDA also granted seven years of orphan drug exclusivity to LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy due to a finding of clinical superiority of LUMRYZ relative to currently marketed oxybate treatments. In particular FDA found that LUMRYZ makes a major contribution to patient care over currently marketed twice nightly oxybate treatments by providing a once nightly dosing regimen that avoids nocturnal arousal to take a second dose. (More..)

Paragraph 15

[37]		Prior to approval, Avadel's liquidity was tightly coupled with the regulatory timeline. Facing net losses of $110 million in the first nine months of 2022, management acknowledged substantial doubt regarding the company's ability to continue as a going concern
	10-Q::2022-11-09 5605d59d5d911439	Net loss was $20,146 and $110,014 for the three and nine months ended September 30 2022 respectively compared to net loss of $22,002 and $55,028 in the same periods last year respectively. Diluted net loss per share was $0.33 and $1.85 for the three and nine months ended September 30 2022 respectively compared to diluted net loss per share of $0.38 and $0.94 in the same period last year respectively. (More..)
	10-K::2023-03-29 9643b1af7f885502	As a result we have concluded that management s plans are probable of being achieved to alleviate the substantial doubt about our ability to continue as a going concern. The sources of financing described above that could be available to us and the timing and probability of obtaining sufficient capital depends in part on obtaining final FDA approval of LUMRYZ resolving any legal and regulatory matters that could preclude us from launching LUMRYZ and future capital market conditions. (More..)

[38]		To preserve capital, the company executed a Corporate Restructuring Plan in 2022, reducing its workforce by approximately 50%
	10-Q::2022-08-09 ed4ed6cc835fc62d	The Company s cost structure optimization efforts will include a nearly 50 reduction in its workforce by the end of August 2022 the 2022 Corporate Restructuring Plan. Restructuring charges of $ 3 592 associated with this plan comprised primarily of severance related costs were recorded in the three months ended June 30 2022. (More..)

Paragraph 16

[39]		In 2023, the strategy shifted from survival to securing a commercial runway. Management alleviated the going concern doubt through a multi-pronged financing approach designed to minimize dilution
	10-Q::2023-05-04 26d738192ffef8f8	The $40,000 of net proceeds received prior to the completed public offering was included in the unaudited condensed consolidated balance sheet as p roceeds received in advance of Series B Preferred Shares issuance at March 31 2023. As a result of the 2023 Exchange Transaction and public offering we have concluded that cash on hand provides sufficient capital to meet our operating debt service and capital requirements for the next twelve months following the date of this Quarterly Report. (More..)
	10-K::2023-03-29 198820b75361c968	In response to these conditions and events we are evaluating various financing strategies to obtain sufficient additional liquidity to meet its operating debt service and capital requirements for the next twelve months following the date of this Annual Report. The potential sources of financing that we are evaluating include one or any combination of royalty financing as described above secured or unsecured debt convertible debt and equit y. (More..)

[40]		A cornerstone was a royalty purchase agreement with RTW Investments providing up to $75 million, secured by LUMRYZ assets without subjective acceleration clauses
	10-Q::2023-08-09 175bd8e7c498eac9	On March 29 2023 the Company and Avadel CNS LLC an indirect wholly owned subsidiary of the Company Avadel CNS entered into a royalty purchase agreement RPA with RTW Investments L. P. that could provide the Company up to $75 000 of royalty financing in two tranches. (More..)
	10-Q::2023-11-08 d5c3557901b5a2db	The RPA is recorded as a royalty financing obligation on the unaudited condensed consolidated balance sheet based on the Company s evaluation of the terms of the RPA. The accounts receivable and inventory balances of LUMRYZ are pledged as collateral for the RPA. There are no subjective acceleration clauses or provisions and there are no covenants in violation or other clauses that would cause the full amount of the royalty financing obligation to be callable. (More..)

[41]		This was complemented by a public offering yielding ~$117 million and $40 million in Series B Preferred Shares
	8-K::2023-03-30 c8940b7aa3e0fbdc	The net proceeds to the Company are expected to be approximately $117.0M after deducting underwriting discounts and commissions and estimated offering expenses. The Company has granted the Underwriters. (More..)
	10-Q::2023-05-04 26d738192ffef8f8	The $40,000 of net proceeds received prior to the completed public offering was included in the unaudited condensed consolidated balance sheet as p roceeds received in advance of Series B Preferred Shares issuance at March 31 2023. As a result of the 2023 Exchange Transaction and public offering we have concluded that cash on hand provides sufficient capital to meet our operating debt service and capital requirements for the next twelve months following the date of this Quarterly Report. (More..)

Paragraph 17

[42]		Avadel leveraged non-dilutive financing to support the launch, accessing a $30 million tranche from RTW in August 2023 and a second tranche contingent on revenue milestones
	10-Q::2024-05-08 3222d8bb7463d473	The first tranche of $ 30 000 became available upon satisfaction of certain conditions which included the Company s first shipment of LUMRYZ. The second tranche is now available to use at the Company s election as the Company has achieved quarterly net revenue of $ 25 000 prior to the quarter ending June 30 2024. The second tranche expires if the Company does not elect to use it by August 31 2024. On August 1 2023 the Company received the first tranche of $ 30 000. (More..)
	10-K::2025-03-03 a540874f98106a68	On March 29 2023 we entered into a royalty purchase agreement RPA with RTW Investments L. P. RTW for up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 became available upon satisfaction of certain conditions which included our first shipment of LUMRYZ. The second tranche became available to use at our election when we achieved quarterly net revenue of $25,000 prior to the quarter ending June 30 2024. (More..)

[43]		This structure increased the cost of products sold due to royalty obligations
	10-Q::2025-08-07 ce17e4033aeb8c03	Cost of products sold increased during the three and six months ended June 30 2025 compared to the three and six months ended June 30 2024 due to higher sales of LUMRYZ and the inclusion of an estimated royalty on net product revenue in the current period. Total operating expense was $52,879 and $102,814 for the three and six months ended June 30 2025 respectively compared to total operating expense of $51,457 and $103,148 for the three and six months ended June 30 2024 respectively. (More..)
	10-K::2024-02-29 48ac4850c90fd759	As such the RPA is recorded as a long term obligation on the consolidated balance sheet. The Company imputes interest using the effective interest method and records interest expense based on the unamortized royalty financing obligation. The Company s estimate of the interest rate under the RPA is based primarily on forecasted net revenue and the calculated amounts and timing of net royalty payments to reach the total payback of $ 75 000. (More..)

[44]		Additionally, the liability profile evolved in late 2024 following the Jazz litigation; Avadel recorded estimated liabilities for court-mandated royalties, which now sit alongside standard capital commitments as long-term obligations
	10-Q::2024-11-12 0bc24099bdd7151a	The August 27 2024 opinion and order also granted Jazz s motion for an ongoing royalty pending additional briefing on the appropriate royalty rate. That briefing closed on September 23 2024. While a future ongoing royalty is pending briefing and a decision by the Court the Company recorded an estimated liability for a royalty based on information available as of September 30 2024. (More..)
	10-K::2024-02-29 c8efdb73807bd09d	For the twelve month period ending December 31 2024 we project that our fixed commitments will include i payments on our royalty financing obligation ii capital commitments and iii lease payments. We project that our long term fixed commitments will include i payments on our royalty financing obligation ii capital commitments and iii lease payments. (More..)

Paragraph 18

[45]		Avadel employs a fully outsourced manufacturing model, utilizing Contract Development and Manufacturing Organizations (CDMOs) for LUMRYZ supply
	10-K::2023-03-29 a26155fde569e0a4	Currently we use single source providers for the development supply of clinical materials and supply of commercial batches for our lead product candidate LUMRYZ. We do not own or operate manufacturing facilities for clinical or commercial manufacture of LUMRYZ. We have limited personnel with experience in drug manufacturing and we lack the capabilities to manufacture LUMRYZ clinical or commercial scale. (More..)
	10-K::2025-03-03 4bc2f6a7ed2290b3	We rely and expect to continue to rely on third parties for the manufacture of LUMRYZ for clinical testing and commercial manufacture of LUMRYZ as well as any other future products and product candidates we develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality which could delay prevent or impair our development and efforts. (More..)

[46]		This required significant upfront investment, including a dedicated production suite with long-term fee commitments
	10-K::2021-03-09 7cff423f960d6933	The Company also has a commitment with a contract manufacturer related to the construction and preparation of a production suite at the contract manufacturer s facility which is substantially complete at December 31 2020. Subsequent to the initial build and preparation of the production suite this commitment also includes annual fees which would commence at the start of production of validation batches and continue thereafter for five years. (More..)

Paragraph 19

[47]		Initially, the supply chain relied on high-risk single-source partners for both API and finished product
	10-K::2023-03-29 a26155fde569e0a4	Currently we use single source providers for the development supply of clinical materials and supply of commercial batches for our lead product candidate LUMRYZ. We do not own or operate manufacturing facilities for clinical or commercial manufacture of LUMRYZ. We have limited personnel with experience in drug manufacturing and we lack the capabilities to manufacture LUMRYZ clinical or commercial scale. (More..)
	10-K::2023-03-29 70c03258f1eac35c	Nevertheless for LUMRYZ we currently rely on one supplier for sourcing active pharmaceutical ingredients API. The API in LUMRYZ sodium oxybate is a Schedule I controlled substance in the U.S. and LUMRYZ if granted final approval by the FDA is anticipated to be a Schedule III controlled substance in the U.S. per current federal regulations. (More..)

[48]		By 2024-2025, Avadel mitigated this risk by diversifying its network to include two U.S.-based API suppliers and dual finished product manufacturers
	10-K::2024-02-29 9651cc2c2eba7c1a	The API is currently manufactured by two source contract development and manufacturing organizations CDMOs in the U.S. The drug product for commercial lots is manufactured by one source CDMO in the U.S. and one source CDMO outside of the U.S. Revenue. Revenue includes sales of LUMRYZ. ASC 606 applies to all contracts with customers except for contracts that are within the scope of other standards such as leases insurance collaboration arrangements and financial instruments. (More..)

[49]		To accelerate launch, the company utilized the Pre-launch Activities Importation Request (PLAIR) program in March 2023 to import product prior to final approval
	10-Q::2023-05-04 6a49644b9e668088	We are advancing our preparations for the commercial launch of LUMRYZ. For example on March 15 2023 we were notified by the FDA that we are permitted to conduct certain pre launch activities including the importation of foreign manufactured product under the Pre launch Activities Importation Request PLAIR Program. (More..)

Paragraph 20

[50]		Commercialization is governed by a rigid regulatory infrastructure. Following approval, Avadel activated the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS), a closed distribution system restricting access to certified prescribers and pharmacies
	10-Q::2023-08-09 6c4547df036997c5	In June 2023 the Company commercially launched LUMRYZ in the U.S. In approving LUMRYZ the FDA approved a risk evaluation and mitigation strategy REMS for LUMRYZ to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing misuse abuse and diversion of the drug. (More..)
	10-Q::2023-05-04 301aa78c71eb2786	Under this REMS healthcare providers must be specially certified pharmacies practitioners or health care settings that dispense the drug must be specially certified and the drug must be dispensed to patients with documentation of safe use conditions. The FDA also granted Orphan Drug Exclusivity ODE to LUMRYZ for a period of seven years until May 1 2030. Outside of LUMRYZ the Company continues to evaluate opportunities to expand its product portfolio. (More..)

[51]		This system strictly controls sales and marketing
	10-K::2024-02-29 09a8d56b1b9ce87f	Under this REMS healthcare providers who prescribe the drug must be specially certified pharmacies that dispense the drug must be specially certified and the drug must be dispensed only to patients who have enrolled in the LUMRYZ REMS and completed all REMS requirements including documentation of safe use conditions among other requirements. (More..)
	10-K::2025-03-03 3a9eea58eeb78af3	The FDA has required implementation of a REMS to help ensure the benefits of the drug outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing misuse abuse and diversion of the same. (More..)

[52]		Between 2023 and 2024, the REMS infrastructure expanded to support the pediatric indication
	10-K::2024-02-29 aaf5f92ee01fd34d	LUMRYZ LUMRYZ was approved by the FDA on May 1 2023 for the treatment of cataplexy or EDS in adults with narcolepsy. In approving LUMRYZ the FDA required a REMS for LUMRYZ to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in adults with narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing misuse abuse and diversion of the drug. (More..)
	10-Q::2025-05-07 f59a389462280258	LUMRYZ was approved by the FDA for use in the treatment of cataplexy or EDS in the pediatric narcolepsy population seven years of age and older on October 16 2024 and was granted ODE for this patient population through October 16 2031. The FDA required implementation of a Risk Evaluation and Mitigation Strategy REMS to help ensure the benefits of the drug outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing misuse abuse and diversion of the same. (More..)

Paragraph 21

[53]		Operations are further constrained by the Controlled Substances Act. While LUMRYZ is Schedule III, the API is Schedule I, necessitating strict adherence to DEA manufacturing quotas and site-specific registrations
	10-K::2023-03-29 6f202dc8b6f78bb8	The API in LUMRYZ sodium oxybate is a Schedule I controlled substance in the U.S. and LUMRYZ if granted final FDA approval will be a Schedule III controlled substance in the U.S. For drugs manufactured in the U.S. the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the U.S. based on the DEA s estimate of the quantity needed to meet legitimate medical scientific research and industrial needs. (More..)
	10-K::2022-03-16 7ca453f2c15e0b5f	The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year and individual manufacturing or procurement quotas from time to time during the year although the DEA has substantial discretion in whether or not to make such adjustments for individual companies. (More..)

[54]		This compliance burden extends to all third-party partners, who must maintain valid DEA registrations and state licenses
	10-K::2025-03-03 8a3a587c0c2452d7	In addition the third parties who perform our clinical and commercial manufacturing distribution dispensing and clinical studies for LUMRYZ are required to maintain necessary DEA registrations and state licenses. (More..)

Paragraph 22

[55]		Avadel expanded its addressable market by securing FDA approval for LUMRYZ in pediatric narcolepsy (ages 7+) in October 2024
	10-Q::2024-11-12 10fb47cf5008acd4	The FDA also granted Orphan Drug Exclusivity ODE to LUMRYZ for treatment of cataplexy or EDS in adults with narcolepsy for a period of seven years until May 1 2030. In June 2023 the Company commercially launched LUMRYZ in the U. S for the treatment of cataplexy or EDS in adults living with narcolepsy. LUMRYZ was approved by the FDA for use in the treatment of cataplexy or EDS in the pediatric narcolepsy population seven years and older on October 16 2024 and was granted ODE through October 16 2031. (More..)

[56]		Utilizing **Liquitime technology** for patients with swallowing difficulties, this approval extended Orphan Drug Exclusivity through October 2031, reinforcing the product's lifecycle
	10-K::2024-02-29 0b8f9d732e7942f4	MICROPUMP. Our MICROPUMP technology allows for the development of modified release solid oral dosage formulations of drugs. A version of our MICROPUMP technology is being employed in LUMRYZ. LIQUITIME. Our LIQUITIME technology allows for development of modified release oral products in a liquid suspension formulation which may make such formulations particularly well suited for children and or patients having issues swallowing tablets or capsules. (More..)
	10-K::2025-03-03 0621d67d93b48194	In June 2023 we announced the U.S. commercial launch of LUMRYZ for the treatment of cataplexy or EDS in adults living with narcolepsy. LUMRYZ was approved by the FDA for use in the treatment of cataplexy or EDS in the pediatric narcolepsy population seven years of age and older on October 16 2024 and was granted ODE for this patient population through October 16 2031. (More..)

Paragraph 23

[57]		Building on the narcolepsy foundation, Avadel is targeting Idiopathic Hypersomnia (IH) as a strategic priority
	10-K::2024-02-29 ea3ba23655500757	Because we have limited financial managerial and research and development resources we must prioritize our research programs and will need to focus LUMRYZ on the potential treatment of certain indications or in certain populations. As a result we may forego or delay pursuit of opportunities for other populations or indications that later prove to have greater commercial potential. For example we anticipate initiating a clinical trial for LUMRYZ in idiopathic hypersomnia in 2024. (More..)

[58]		The company posits that once-nightly dosing offers a "major contribution to patient care" for IH, supporting an Orphan Drug Designation
	10-Q::2025-08-07 bba95fd38c088b51	Specifically ODD was granted based on the plausible hypothesis that LUMRYZ may be clinically superior to the same drug s already approved for the same indication because LUMRYZ may provide a major contribution to patient care due to its once nightly dosing for patients with IH a chronic sleep disorder that requires potentially lifelong treatment. (More..)

[59]		The pivotal Phase 3 REVITALYZ trial began dosing in July 2024, driving a shift in resource allocation back toward active clinical development
	10-K::2025-03-03 41c9c558ef0073db	For example we initiated a pivotal trial in IH REVITALYZ which is a double blind placebo controlled randomized withdrawal multicenter Phase 3 study designed to evaluate the efficacy and safety of LUMRYZ given as a once at bedtime dose in treating IH. We expect to enroll approximately 150 adults in the study who are diagnosed with IH. On July 31 2024 we announced that the first patient was dosed in this study. (*More..*)
	10-Q::2024-11-12 518e43b097687765	Research and development expenses increased $954 during the three months ended September 30 2024 compared to the three months ended September 30 2023 due to new clinical work to evaluate the efficacy and safety of LUMRYZ given as a once at bedtime dose in IH offset by lower pre commercial related expenses. (*More..*)

Paragraph 24

[60]		Avadel pursues diversification through externalization and inorganic growth. International commercialization relies on third-party collaborations to minimize internal infrastructure costs
	10-K::2023-03-29 363fe6d60e86ae14	We expect that the of LUMRYZ and our future product candidates outside of the U.S. if granted the necessary approvals or authorizations may require collaboration with third party partners involving strategic alliances licenses product divestitures or other arrangements. (*More..*)

[61]		To mitigate single-asset reliance, the company acquired a license for valiloxybate from XWPharma for a $20 million upfront fee, broadening the portfolio beyond the LUMRYZ franchise
	10-Q::2025-11-04 088538c874430a89	This increase was driven primarily by the $20,000 upfront license fees to XWPharma and development costs of the valiloxybate drug candidate.34 Research and development expenses increased $24,697 or 226.1 during the nine months ended September 30 2025 as compared to the same period in the prior year. (*More..*)