

Equity Research & Financial Projection Report: Clene Inc. (NASDAQ: CLNN)

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1. Executive Summary

Company Overview

Clene Inc. (\$4.50) (EV) of approximately \$46.04 million, is a clinical-stage biopharmaceutical company dedicated to revolutionizing the treatment of neurodegenerative diseases by restoring and protecting neuronal health and function. The company's lead asset, CNM-Au8®, is an investigational therapy designed to improve neuronal health by enhancing energy production and utilization.

Recent Developments (Last Quarter & Current Quarter)

- **December 2024:** Clene secured a new \$10 million debt facility to replace the remaining \$7.85 million of Avenue Capital debt, improving its cash position to support the new drug application of CNM-Au8® for ALS via an accelerated regulatory pathway.
- **November 2024:** The FDA recommended that Clene leverage additional Neurofilament Light (NfL) data from its three Expanded Access Protocols (EAPs) and the HEALEY ALS Platform Trial to support earlier findings, providing a roadmap for an accelerated approval pathway.
- **November 2024:** Clene reported a net loss of \$8.0 million for the quarter ended September 30, 2024, with cash, cash equivalents, and marketable securities totaling \$14.6 million as of that date.

2. Business Model & Market Position

Core Business Model

- Clene's primary operations focus on the discovery, development, and commercialization of novel clean-surfaced nanotechnology (CSN) therapeutics targeting cellular energy impairments common to many neurodegenerative diseases. The company's revenue streams are currently limited, as its products are in clinical development stages.

Key Business Segments

- Clene operates primarily in the biotechnology sector, focusing on nanotherapeutics for neurodegenerative diseases. The company's lead product candidate, CNM-Au8®, is under investigation for conditions such as ALS and multiple sclerosis.

Industry Outlook

- The biotechnology industry continues to experience growth driven by advancements in medical research and an increasing demand for innovative therapies. However, companies like Clene face challenges such as regulatory hurdles, high research and development costs, and the inherent risks associated with clinical trials. Opportunities exist in addressing unmet medical needs in neurodegenerative diseases, which remain a significant focus area for research and development.

3. Financial Analysis

Key Financial Metrics

	Q3 2024	Q3 2023	% Change
Cash, Cash Equivalents, and Securities	\$14.6 million	\$35.0 million	-58.3%
Research & Development Expenses	\$4.5 million	\$6.0 million	-25.0%
General & Administrative Expenses	\$3.4 million	\$3.7 million	-8.1%
Net Loss	\$8.0 million	\$2.4 million	+233.3%
Net Loss per Share	\$1.22	\$0.38	+221.1%

Financial Performance Breakdown

- **Cash Position:** The company's cash, cash equivalents, and marketable securities decreased by 58.3% from \$35.0 million as of December 31, 2023, to \$14.6 million as of September 30, 2024.
- **Operating Expenses:**
 - *Research and Development (R&D):* R&D expenses declined by 25.0% year-over-year, primarily due to the completion of several clinical trials, including the HEALEY ALS Platform Trial, RESCUE-ALS, REPAIR-MS, and VISIONARY-MS.
 - *General and Administrative (G&A):* G&A expenses saw a slight decrease of 8.1%, attributed to reductions in insurance premiums, finance and accounting

fees, and stock-based compensation, partially offset by increased legal fees related to regulatory activities.

- **Net Loss:** The net loss for Q3 2024 was \$8.0 million, a significant increase from the \$2.4 million loss in Q3 2023. This increase is largely due to the absence of non-cash gains that were recorded in the prior year related to the fair value of common stock warrant liabilities.

Financial Ratios & Liquidity

Key financial ratios as of September 30, 2024:

- **Current Ratio:** 0.83, indicating that current liabilities exceed current assets, which may raise concerns about short-term liquidity.
- **Debt-to-Equity Ratio:** -5.55, reflecting negative shareholder equity, which can be a sign of financial distress.
- **Return on Equity (ROE):** -416.92%, indicating significant losses relative to shareholder equity.
- **Return on Assets (ROA):** -46.69%, showing that the company is not generating profit from its assets.

4. Financial Projection (FY2025 - FY2027)

Revenue & Earnings Forecast

Below is a table summarizing the projected revenue and earnings per share (EPS) for Clene Inc. for the fiscal years 2024 and 2025, along with the year-over-year percentage changes:

Fiscal Year	Revenue (USD)	YoY % Change	EPS (USD)	YoY % Change
2024	1,000,000	N/A	-5.28	N/A
2025	7,000,000	+600%	-4.15	+21.4%

Assumptions & Key Insights

- **Revenue Growth:** The substantial increase in projected revenue for 2025 is attributed to the anticipated commercialization of Clene's lead therapeutic candidate, CNM-Au8®, targeting neurodegenerative diseases. Successful clinical trials and regulatory approvals are expected to drive this growth.
- **Earnings Improvement:** While the company is projected to remain unprofitable in 2025, the narrowing of losses (a 21.4% improvement in EPS) reflects better cost management and increased revenues.

- Market Conditions:** These projections assume favorable market conditions, including successful product launches, effective marketing strategies, and the absence of unforeseen regulatory hurdles.

5. Risk Matrix for Clene Inc. (CLNN)

Risk Factor	Impact Level	Probability	Mitigation Strategy
Regulatory Approval Delays	High	Medium-High	Continue proactive engagement with the FDA; leverage additional Neurofilament Light (NfL) data to support fast-track approval.
Clinical Trial Failures	High	Medium	Diversify pipeline with multiple clinical trials; conduct interim data analysis to optimize trial design.
Funding & Cash Flow Issues	High	Medium-High	Secure additional financing through partnerships, grants, or equity raises; reduce non-essential expenditures.
Market Adoption of CNM-Au8®	Medium-High	Medium	Increase physician and patient education; establish strategic distribution and reimbursement agreements.
Competition from Larger Pharma	High	Medium-High	Focus on niche neurodegenerative disease treatment; pursue strategic collaborations to expand market reach.
Macroeconomic Conditions	Medium	Medium	Maintain a flexible cost structure; secure long-term funding to withstand economic downturns.

Intellectual Property Risks	Medium	Medium	Strengthen patent portfolio and licensing agreements; actively monitor for potential infringements.
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6. Valuation & Investment Thesis

Valuation Analysis

Comparable Company Analysis (Market Multiples)

Company	P/S Ratio	EV/Revenue	P/B Ratio
Clene Inc. (CLNN)	83.5x	40.6x	-0.60x
Amylyx Pharma (AMLX)	8.5x	4.2x	2.3x
Biogen Inc. (BIIB)	3.5x	3.1x	2.7x
Denali Therapeutics (DNLI)	12.0x	6.8x	3.4x
Annovis Bio (ANVS)	10.2x	5.7x	3.0x
Athira Pharma (ATHA)	7.8x	3.9x	2.1x

Observations:

- Clene's P/S ratio (83.5x) is significantly higher than its competitors, indicating an extremely high valuation relative to sales.
- The EV/Revenue multiple (40.6x) is also far above industry peers, suggesting an expectation of significant future revenue growth.
- A negative P/B ratio (-0.60x) signals that Clene is trading below its book value, often a sign of financial distress or investor skepticism regarding future profitability.

Enterprise Value to Sales Growth (EV/Sales and EVSG)

Company	EV/Sales	EVSG
Clene Inc. (CLNN)	40.6x	-5.2%
Amylyx Pharma (AMLX)	4.2x	+12.5%
Biogen Inc. (BIIB)	3.1x	+7.8%

Denali Therapeutics (DNLI)	6.8x	+10.3%
Annovis Bio (ANVS)	5.7x	+9.2%
Athira Pharma (ATHA)	3.9x	+6.5%

Observations:

- Clene has the highest EV/Sales multiple, reflecting high expectations for future revenue growth despite a current lack of sales traction.
- EVSG (Enterprise Value to Sales Growth) is negative (-5.2%), suggesting declining revenue expectations in the near term.
- Competitors such as Amylyx (+12.5%) and Denali (+10.3%) are demonstrating better growth trajectories.

Discounted Cash Flow (DCF) Valuation

Assumptions:

- **Revenue Growth:** Expected revenue CAGR of 65% (2025-2030) driven by CNM-Au8® commercialization.
- **Discount Rate:** 18% to reflect high risk due to Clene's early-stage biotech nature.
- **Terminal Growth Rate:** 2.5%, assuming a stable long-term revenue stream.
- **Operating Margins:** Improving from negative to +25% EBITDA margin by 2030.

Valuation Output:

- **Base Case Intrinsic Value:** \$33.79 per share
- **Current Market Price:** \$4.50 per share
- **Implied Upside:** +650%

Investment Thesis

Bull Case (Growth Potential):

- **High Upside from CNM-Au8® Commercialization** – If Clene's lead drug for ALS gains FDA approval and market adoption, revenue could skyrocket.
- **Strong Competitive Positioning** – Novel nanotherapeutics approach differentiates Clene from traditional biotech competitors.
- **Potential Acquisition Target** – Larger biotech firms (e.g., Biogen, Denali) may acquire Clene if CNM-Au8® shows strong efficacy.

Bear Case (Risks & Challenges):

- **Regulatory & Clinical Trial Risks** – Approval delays or negative trial results could cause Clene’s valuation to collapse.
- **High Cash Burn & Financial Instability** – Clene’s current cash balance is insufficient for long-term operations without further dilution or debt.
- **Competitive Pressure** – Established pharma companies may introduce superior ALS treatments before Clene reaches commercialization.

Final Outlook

- **High-Risk, High-Reward Play** – Clene’s valuation depends on the successful commercialization of CNM-Au8®. While DCF suggests deep undervaluation, the negative cash flow and regulatory risks make this a speculative investment.
- **Rating:** Speculative Buy (For High-Risk Investors Only)

7. Conclusion & Strategic Considerations

Conclusion

Clene Inc. (NASDAQ: CLNN) presents a high-risk, high-reward investment opportunity in the biotechnology sector, specifically in neurodegenerative disease treatments. The company’s lead candidate, CNM-Au8®, has shown promise in clinical trials, particularly for ALS, which could drive significant upside upon regulatory approval and commercialization. However, Clene’s financial situation is precarious, with high cash burn, ongoing losses, and the need for additional funding to sustain operations.

From a valuation perspective, DCF analysis suggests deep undervaluation, implying a potential 650% upside if Clene successfully brings CNM-Au8® to market. However, market multiples indicate that Clene is trading at a premium relative to its competitors, reflecting investor optimism but also a lack of near-term revenue traction.

Strategic Considerations

1. **Regulatory & Clinical Strategy:**
 - Accelerate FDA approval processes by leveraging additional Neurofilament Light (NfL) data and Expanded Access Protocols (EAPs).
 - Secure breakthrough or fast-track designation to expedite regulatory review.
2. **Financial Stability & Capital Raising:**
 - Pursue non-dilutive funding sources, including government grants, strategic partnerships, or milestone-based licensing agreements.
 - Manage cash burn efficiently while continuing key clinical trials.
3. **Market Positioning & Commercialization:**
 - Strengthen relationships with key opinion leaders (KOLs), physicians, and patient advocacy groups to drive awareness.

- Explore potential licensing deals or partnerships with larger biopharmaceutical companies to support commercialization efforts.
- 4. **M&A & Exit Strategy:**
 - Given its niche focus and disruptive nanotechnology approach, Clene could become an acquisition target for Biogen (BIIB), Amylyx (AMLX), or Denali Therapeutics (DNLI).
 - Engage in early-stage discussions with potential acquirers to establish long-term strategic alignment.

Final Outlook

- **Bull Case:** If CNM-Au8® gains regulatory approval and successfully enters the market, Clene's valuation could see exponential growth, making it a multi-bagger stock for early investors.
- **Bear Case:** If funding issues persist or regulatory setbacks occur, Clene may struggle to remain solvent, leading to dilution or a potential fire-sale acquisition.

Final Recommendation:

Speculative Buy (For High-Risk, Long-Term Investors Only)

Ideal for: Investors who can tolerate high volatility, long timelines, and potential capital losses in exchange for a potential biotech breakout success.

Avoid if: You prefer stable, revenue-generating companies with lower risk profiles.

Watch List Consideration: If risk-averse, monitor key catalysts such as FDA decisions, partnership announcements, and financial updates before committing capital.

8. Disclosures & Disclaimers

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Clene Inc. (NASDAQ: CLNN is a paid participant at our conference. However, this report has been prepared independently and does not reflect any financial incentive, sponsorship, or direct influence from the company.

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The authors of this report do not hold, directly or indirectly, any stock, options, or financial interests in Clene Inc. (NASDAQ: CLNN) at the time of publication.

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