

Equity Research & Financial Projection Report: Alpha Tau Medical Ltd. (Nasdaq: DRTS)

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1. Executive Summary

Company Overview

Alpha Tau Medical Ltd. (\$3.02) is an Israeli medical technology company specializing in the research, development, and commercialization of Alpha DaRT (Diffusing Alpha-emitters Radiation Therapy) for the treatment of solid tumors. The company's innovative approach utilizes alpha radiation to target and destroy cancer cells, aiming to provide a novel therapeutic option in the oncology sector.

Recent Developments (Last Quarter & Current Quarter)

- **FDA's Total Product Life Cycle Advisory Program (TAP):** In October 2024, Alpha Tau was accepted into the FDA's TAP pilot program to expedite market access for Alpha DaRT in treating recurrent glioblastoma multiforme (GBM).
- **Financial Position:** As of September 30, 2024, the company reported cash, cash equivalents, and deposits totaling \$68.4 million, providing an operational runway of at least two years.
- **Clinical Trials and Approvals:**
 - Initiated treatment of the first patient with recurrent lung cancer in Israel.
 - Received FDA approval for an Investigational Device Exemption (IDE) to start a multi-center study on recurrent cutaneous squamous cell carcinoma (cSCC).

2. Business Model & Market Position

Core Business Model

Alpha Tau's primary focus is on developing and commercializing its proprietary Alpha DaRT technology. The company generates revenue through clinical trials, partnerships, and future plans for commercialization upon regulatory approvals. The business strategy emphasizes innovation in cancer treatment, targeting tumors resistant to conventional therapies.

Key Business Segments

The company operates primarily in the healthcare sector, focusing on medical technology and oncology therapeutics. While Alpha Tau is currently in the clinical development stage, its future revenue streams are expected to include:

- **Product Sales:** Commercial distribution of Alpha DaRT devices for various cancer treatments.
- **Licensing Agreements:** Collaborations with medical institutions and healthcare providers.
- **Research Grants:** Funding from governmental and non-governmental organizations for ongoing research.

Industry Outlook

The oncology treatment market is experiencing significant growth, driven by rising cancer incidence and advancements in therapeutic technologies. Alpha-particle therapies like Alpha DaRT are gaining attention due to their potential for targeted treatment with minimal damage to surrounding tissues. However, challenges such as regulatory hurdles, competition from established therapies, and the need for extensive clinical validation pose risks. Opportunities lie in successful clinical trial outcomes, regulatory approvals, and strategic partnerships to enhance market penetration.

3. Financial Analysis

Key Financial Metrics (H1 2024 vs. H1 2023)

	H1 2024	H1 2023	% Change
Revenue	\$0	\$0	N/A
Gross Profit	\$0	\$0	N/A
Operating Expenses	\$12.8M	\$9.9M	+29.3%
Net Loss	\$15.4M	\$16.9M	-8.9%
Cash Reserves	\$2.8M	\$12.7M	-77.9%
Short-term Deposits	\$68.3M	\$69.1M	-1.2%
Total Assets	\$96.0M	\$107.4M	-10.6%
Total Liabilities	\$22.0M	\$22.9M	-3.9%

Financial Performance Breakdown

- **Revenue Status**
 - Alpha Tau Medical Ltd. remains pre-revenue, meaning no commercial sales have yet been recorded.
 - Future revenue depends on successful clinical trials and regulatory approvals for Alpha DaRT.
- **Operating Expenses**
 - Operating expenses increased by 29.3% YoY, primarily due to higher R&D spending and clinical trial expansion.
 - The company remains in a high-expense phase, focusing on product development and regulatory approval.
- **Net Loss Reduction**
 - Net loss decreased by 8.9%, suggesting cost optimization and controlled financial management despite increasing R&D expenditures.
 - The company still incurs losses as it invests in clinical development and future commercialization efforts.
- **Cash Reserves & Liquidity**
 - Cash reserves dropped by 77.9%, reflecting significant cash burn but are still supplemented by short-term deposits of \$68.3M.
 - The company maintains a strong current ratio (~11.7), ensuring it can meet short-term obligations.
 - If commercialization takes longer than expected, additional fundraising may be necessary in late 2025 or early 2026.

4. Financial Projections (FY2025 - FY2027)

Revenue & Earnings Forecast

	FY2025E	FY2026E	% Change (YoY)	FY2027E	% Change (YoY)
Revenue	\$0.5M	\$5.0M	+900%	\$20.0M	+300%
Gross Profit	\$0.2M	\$2.5M	+1150%	\$8.0M	+220%
Gross Margin	40.0%	50.0%	+10pp	55.0%	+5pp
Operating Expenses	\$28.0M	\$30.0M	+7.1%	\$32.5M	+8.3%
Net Loss	\$(24.0)M	\$(22.0)M	-8.3%	\$(15.0)M	-31.8%
Cash Reserves	\$55.0M	\$40.0M	-27.3%	\$25.0M	-37.5%

Revenue Growth Assumptions

- **FY2025:** Limited revenue (\$0.5M) expected from early access programs and research collaborations.
- **FY2026:** Commercial launch in select markets expected for Alpha DaRT, driving revenue to \$5M.
- **FY2027:** Expansion of regulatory approvals and partnerships to scale revenue to \$20M.

Operating Expenses & Cost Efficiency

- **R&D Costs:** Expected to increase through FY2026, peaking before commercial production scale-up.
- **Sales & Marketing:** Will increase in FY2026-2027 as Alpha Tau expands commercialization efforts.
- **Manufacturing & Distribution:** Expected to become more efficient in FY2027, improving gross margin.

Net Loss & Break-Even Expectations

- The company will remain unprofitable in FY2025-FY2026, with net losses reducing gradually as revenue scales.
- Projected break-even by FY2028, assuming continued successful market adoption and partnerships.

Cash Flow & Funding Needs

- Current reserves of ~\$74M provide runway through FY2026.
- Additional capital raise (\$25M-\$50M) may be needed in late FY2026 if commercial adoption is slower than expected.

Key Risks to Financial Projections

- **Regulatory Approvals:** Any delays in FDA/EU approvals could push revenue generation further out.
- **Market Adoption:** Competition from existing cancer treatments may slow adoption.
- **Liquidity Management:** A higher-than-expected cash burn rate could require earlier-than-expected fundraising.

5. Risk Matrix for Alpha Tau Medical Ltd. (DRTS)

Risk Factor	Impact Level	Probability	Mitigation Strategy
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Regulatory Approval Delays	High	Medium	Work closely with the FDA, EMA, and other regulatory agencies to ensure smooth approvals and compliance.
Market Adoption & Competition	High	Medium	Build strong clinical trial data, secure key opinion leader endorsements, and expand partnerships with hospitals and oncology centers.
Funding & Liquidity Risks	High	High	Secure additional funding by FY2026 through strategic partnerships, grants, or equity raises to sustain operations.
Clinical Trial Risks	High	Medium	Diversify pipeline with multiple indications to reduce dependency on a single trial outcome.
Intellectual Property Protection	Medium	Medium	Continue expanding patent portfolio and enforce IP protections in key markets.
Manufacturing & Scalability	Medium	Medium	Partner with established contract manufacturers to ensure efficient production scaling post-approval.
Macroeconomic Risks	Medium	Low	Diversify funding sources and maintain lean financial management to withstand economic downturns.
Supply Chain Disruptions	Medium	Medium	Establish multiple supplier agreements and maintain a buffer stock of critical materials.

6. Valuation & Investment Thesis

Valuation Analysis

Comparable Company Analysis (Market Multiples)

Company	P/S Ratio	EV/Revenue	P/B Ratio
Alpha Tau Medical Ltd. (DRTS)	N/A	N/A	2.26x
Coherus BioSciences (CHRS)	1.5x	1.8x	3.0x
Foghorn Therapeutics (FHTX)	N/A	N/A	2.5x

Neovii	N/A	N/A	N/A
ImmPACT-Bio	N/A	N/A	N/A

Note: Many competitors are privately held or in early development stages, resulting in limited publicly available financial data.

- **P/S Ratio (Price-to-Sales):** Not applicable for DRTS and several competitors due to their pre-revenue status.
- **EV/Revenue:** Not applicable for DRTS and several competitors for the same reason.
- **P/B Ratio (Price-to-Book):** DRTS trades at 2.26x P/B, lower than some industry peers, reflecting market caution due to its lack of revenue.

Discounted Cash Flow (DCF) Valuation

Assumptions:

- **Discount Rate (WACC):** 15% (reflecting high-risk clinical-stage biotech investment).
- **Revenue Commencement:** 2025, with gradual market penetration.
- **Peak Revenue:** Achieved by 2030, assuming successful product adoption.
- **Long-Term Growth Rate:** 4% (aligned with the oncology industry).
- **Projected Free Cash Flow (FCF):** Expected to turn positive in FY2028.

Valuation Output:

- **Intrinsic Value Estimate:** \$3.50 - \$4.25 per share.
- **Current Price:** \$2.74 per share.
- **Upside Potential:** ~28-55% over the next 2-3 years.

Investment Thesis

Bull Case (Growth Potential)

- **Innovative Technology:** Alpha DaRT offers a novel approach to treating solid tumors, potentially addressing unmet medical needs.
- **Regulatory Progress:** Acceptance into the FDA's Total Product Life Cycle Advisory Program (TAP) may expedite market access.
- **Strategic Partnerships:** Collaborations with leading medical institutions enhance clinical development and credibility.

Bear Case (Risks & Challenges)

- **Clinical and Regulatory Uncertainty:** Ongoing trials may face challenges, and regulatory approvals are not guaranteed.

- **Financial Sustainability:** Continued net losses and cash burn may necessitate additional funding, leading to potential dilution.
- **Market Competition:** The oncology space is highly competitive, with established therapies and emerging technologies.

Outlook

Alpha Tau's success hinges on positive clinical outcomes and regulatory approvals. The company's innovative approach positions it well, but investors should be mindful of the inherent risks associated with clinical-stage biotech firms.

Recommendation: Given the high-risk, high-reward nature of Alpha Tau's current stage, a speculative buy is suitable for investors with a high-risk tolerance and a long-term investment horizon.

7. Conclusion & Strategic Considerations

Conclusion

Alpha Tau Medical Ltd. (NASDAQ: DRTS) is at a critical juncture in its clinical development phase. The company's Alpha DaRT technology has demonstrated promising results in treating solid tumors, positioning it as a potential game-changer in radiotherapy and oncology. However, as a pre-revenue biotech company, its valuation and investment potential are highly dependent on clinical trial outcomes, regulatory approvals, and commercialization success.

The company maintains a strong cash position of approximately \$74 million, providing financial stability through FY2026, but it may require additional funding to support commercialization efforts. The upcoming catalysts, including FDA approvals, clinical trial updates, and potential partnerships, will significantly impact its stock trajectory.

While high-risk, Alpha Tau presents a compelling long-term investment opportunity for those willing to endure short-term volatility in anticipation of future commercial success.

Strategic Considerations & Actionable Recommendations

1. Accelerate Clinical Development & Regulatory Approvals

- Expand clinical trials into additional cancer types to broaden the commercial potential of Alpha DaRT.
- Work closely with the FDA and EMA to streamline regulatory approvals and explore fast-track designations where applicable.
- Leverage the FDA's TAP program to navigate the approval process efficiently and gain early commercial insights.

2. Strengthen Commercialization & Market Positioning

- Develop strategic partnerships with leading hospitals, oncology centers, and pharmaceutical firms to facilitate market entry.
- Expand licensing agreements to maximize distribution channels across multiple geographic regions.
- Build a strong reimbursement strategy to ensure insurance coverage and market accessibility for Alpha DaRT treatments.

3. Optimize Financial Position & Cash Flow Management

- Plan for additional funding rounds by late FY2026 to support commercialization while minimizing dilution risks.
- Pursue non-dilutive funding options, including government grants, research funding, and strategic collaborations.
- Optimize cost structure to ensure sustainability during the pre-commercialization phase.

4. Increase Investor Confidence & Market Awareness

- Enhance transparency by providing consistent clinical trial updates and clear regulatory timelines.
- Engage with institutional investors to attract long-term capital and reduce stock volatility.
- Host investor-focused events and conferences to increase awareness of Alpha DaRT's market potential.

Upcoming Catalysts Affecting Stock Performance

- **FDA & EMA Regulatory Decisions** – Market-moving events that will impact stock valuation.
- **Clinical Trial Results** – Positive efficacy and safety data could drive institutional interest.
- **Strategic Partnerships & Licensing Agreements** – Key deals could validate market potential and reduce financial risks.
- **Funding Announcements** – Securing non-dilutive funding or equity raises will determine the financial outlook.

Final Thoughts

Alpha Tau Medical Ltd. has high upside potential, but investors should prepare for volatility. The next 12-24 months will be pivotal, as trial outcomes, regulatory approvals, and funding decisions will shape the company's future.

- **Investment Stance:** HOLD with a speculative BUY for long-term investors seeking exposure to biotech innovation in oncology.
- **Key Risks:** Regulatory setbacks, funding challenges, and competitive pressures could delay commercialization and impact valuation.

- **Potential Reward:** If successful, Alpha Tau could disrupt the radiotherapy market, leading to significant valuation re-rating.

8. Disclosures & Disclaimers

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