Six Trends Reshaping Medtech

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The healthcare industry is constantly evolving, driven by technological advancements, regulatory changes, and shifting healthcare paradigms. A primary driver of modern healthcare is medical technology (medtech) innovation, which plays a crucial role in improving patient outcomes, reducing costs, and enhancing overall patient care quality.

In the last decade, the medtech sector has experienced both peaks and valleys. For example, while the COVID-19 pandemic accelerated the adoption of telemedicine and remote monitoring technologies, it also diverted attention and resources away from non-COVID-related diseases and devices, which has impacted medtech development and commercialization.

Today, the medtech industry is well-positioned for continued growth with an aging world population that has large unmet medical needs. The forecast for the medical device market is strong, with expected global revenue of $595 billion in 2024 and an estimated 6.1% Compound Annual Growth Rate from 2022 to 2030.[1] The medtech sectors with the largest prospective profits include cardiovascular, orthopedic, neurological, urological, and diabetes.

Several key trends are reshaping medtech's future, presenting many opportunities and challenges for both early-stage and established companies. From raising capital to artificial intelligence's growing influence, there presently are six major trends impacting medtech.

1. Funding Challenges

Current global economic uncertainty has cast a shadow over medical technology investments. Today, venture capitalists are highly selective and more discerning in their medtech investment valuations. Fundraising is challenging, particularly for early-stage companies, as institutional investors are prioritizing existing investments, risk mitigation, and more immediate returns on their investment capital.

While the potential for high returns remains enticing, investors are placing greater emphasis on such factors as clinical evidence, large market opportunity, product differentiation, and scalability. Medtech companies with innovative technologies backed by robust clinical data for a major unmet medical need are more likely to secure funding, while those lacking substantive evidence may face heightened skepticism and difficulty in raising capital.

Despite this challenging backdrop, the investment community continues to be interested in disruptive and best-in-class products. When traditional venture capital (VC) is scarce, medtech innovators should explore alternative funding sources to fuel their growth. Family offices, strategic partnerships, government grants, disease foundations, and non-dilutive funding opportunities offer alternatives to VC financing. By diversifying funding sources, medtech companies can secure financing to advance product development, mitigate risk, maintain greater control over their intellectual property, and access capital that may otherwise be unavailable through conventional channels.

Given the challenging fundraising environment, medtech companies must focus on optionality for funding. No matter which funding source is most viable, medtech companies must prove the value proposition of their products and the potential impact on patient outcomes.

2. M&A Remains the Most Common Exit

As the IPO window in the public stock markets remains closed for the medtech sector, and fundraising becomes increasingly challenging, mergers and acquisitions (M&A) has become the primary exit strategy for companies. In the second half of 2024, expect M&A activity to intensify as companies seek strategic alliances to drive growth and market expansion.

Several factors are driving M&A deals, including:

- **Market consolidation:** Larger medtech companies are actively seeking to expand their product portfolios, technological capabilities, and market share. M&A allows medtech giants to achieve these objectives rapidly by acquiring innovative startups or smaller medtech companies with specialized expertise.
- **Access to innovation:** The demand for more sophisticated medical solutions is always a market driver. M&A deals provide access to advanced technology, new product pipelines, and IP rights that can fuel growth and maintain a competitive advantage.
- **Regulatory and compliance costs:** Navigating the complex regulatory landscape, including U.S. Food and Drug Administration approval and reimbursement, requires substantial time, resources, and financial investment. By acquiring medtech companies, larger firms can streamline product development and reduce time to market.
- **Global expansion:** In an increasingly globalized healthcare industry, expanding into new markets is important for sustained growth. M&A enables companies to enter new geographical regions, penetrate untapped markets, and leverage local distribution networks. This strategic expansion enhances market reach, diversifies revenue streams, and reduces dependency on any single market

or region, thereby mitigating risks associated with market fluctuations or regulatory changes.

- **Creating value:** For the target, M&A transactions can deliver more immediate returns to investors through premium valuations, cash payouts, or stock swaps. Moreover, strategic acquisitions can enhance the acquiring firm's overall growth trajectory and financial performance, further bolstering investor confidence and value.

To position themselves as attractive M&A targets, medtech companies must prioritize de-risking their commercial, regulatory, and IP strategies. Thorough due diligence will be essential for both buyers and sellers, necessitating a comprehensive understanding of market dynamics, the competitive landscape, and potential synergies. Companies that proactively address these considerations will be better equipped to navigate the M&A process.

3. IP Drives Investment and M&A

In a competitive market landscape, intellectual property (IP) serves as a cornerstone for differentiation and value creation. Building a strategic IP portfolio encompassing patents, trademarks, and trade secrets is essential for attracting investments and facilitating M&A transactions. A well-protected IP portfolio not only de-risks technology, but also enhances company valuation for investment and M&A.

Investors are drawn to companies with strong IP portfolios. These portfolios not only signify a commitment to innovation, but also represent potential revenue streams through product sales, licensing agreements, or royalties. Additionally, a robust patent portfolio is a barrier to entry for competitors, safeguarding market share and bolstering the attractiveness of investment opportunities. Investors recognize that companies with a solid IP foundation are better positioned to weather market uncertainties and capitalize on market trends, making them compelling prospects for funding.

Similarly, IP serves as a key driver of M&A transactions. Acquiring emerging companies with valuable patents or proprietary technologies can provide immediate access to cutting-edge innovations, accelerating the acquirer's time-to-market and enhancing its competitive advantage. Additionally, IP assets can be leveraged as bargaining chips during negotiations, influencing deal terms and increasing valuation.

For smaller medtech companies, acquisition offers a pathway to liquidity and scalability, allowing them to monetize their intellectual assets and gain access to resources and expertise that can fuel further innovation and growth. By strategically acquiring companies with complementary IP portfolios, larger players can consolidate their market positions and fortify their place as industry leaders.

Companies should adopt a proactive approach to IP management, focusing on innovation, patent filing strategies, and enforcement measures. Collaborations with research institu-

tions and strategic partners can further bolster IP assets, fostering a culture of innovation and driving growth.

4. AI Is Everywhere

Artificial intelligence (AI) is transforming the medtech industry, offering unprecedented opportunities to streamline healthcare delivery and improve clinical trials, patient testing, diagnostics, and personalized treatments. By harnessing AI's power, medtech companies can develop innovative solutions that enhance patient outcomes, optimize resource utilization, and revolutionize the way healthcare is delivered.

From streamlining R&D processes to enabling personalized medicine, AI-powered solutions are driving innovation and efficiency. Connected devices and telehealth platforms are becoming increasingly prevalent, facilitating remote patient monitoring and enhancing accessibility to healthcare services.

Despite the numerous benefits though, AI's integration into the medtech industry presents unique challenges. Privacy and security concerns regarding patient data must be addressed to ensure compliance with regulatory standards, such as HIPAA. Additionally, there is a need for robust validation and testing processes to ensure the safety, reliability, and effectiveness of AI-powered medical devices. The increasing use of AI may also cause the emergence of mass tort claims rooted in defective product design, unreliable code, or training data bias.

As AI continues to evolve, medtech companies must embrace technological advancements and harness the power of data analytics to drive actionable insights and improve clinical decision-making. Investing in AI capabilities is important to stay competitive in an increasingly digitalized healthcare landscape.

5. Data Security, Privacy, and Regulatory Concerns

With technological advancements come inherent risks, particularly in the realm of data security, privacy, and regulatory compliance. As data breaches and cyber threats abound, medtech companies must prioritize strong cybersecurity measures to safeguard sensitive information and protect patient privacy. Regulatory enforcement actions pose additional challenges, necessitating a thorough understanding of compliance requirements and proactive engagement with regulatory authorities.

Addressing these risks requires a multifaceted approach. Device manufacturers must prioritize cybersecurity throughout the product lifecycle, from design and development to post-market surveillance. This includes implementing robust encryption protocols, access controls, and intrusion detection systems to safeguard against cyber threats. Regular security assessments and audits can help identify vulnerabilities and ensure compliance with regulatory requirements. By implementing comprehensive risk mitigation strategies, companies can navigate these challenges effectively and uphold their commitment to patient safety and regulatory compliance.

Furthermore, collaboration between industry stakeholders (including manufacturers, healthcare providers, regulators, and cybersecurity experts) is essential for sharing best practices and fostering a culture of security awareness. Education and training programs can empower healthcare professionals to recognize and respond to cybersecurity threats effectively, minimizing the risk of data breaches and patient harm.

6. Reducing Litigation Through Risk Mitigation

The rapid pace of innovation and rise of new technologies and AI in medtech compounds the fertile risk of litigation, including claims that arise in the aftermath of data breaches and regulatory enforcement and/or inquiry, as well as more typical claims relating to product liability and commercial and consumer actions. The wide availability of both information and misinformation also impacts the pace and scope of litigation, as well as the use of litigation as a tool to gain market share.

Not surprisingly, there remains a robust filing of product liability claims, as well as litigation using other creative theories against medtech companies, including consumer class action efforts, unfair competition/false advertising-type actions, and attacks on the components and materials used in products and therapies. Risk mitigation should start with a foundational understanding and evaluation of what those risks look like for a company individually. While general advice is useful, it is critical to assess how risk applies in a company's specific field and how litigation might be impacted by various factors, including a company's physical location, product type(s), sales method, customer or patient interactions, and labeling and internal processes, to comply with regulatory oversight. Risk can then be reduced and mitigated by training, processes, and simple awareness of areas of potential exposure. Given the types of cases that are on the rise, it is more important than ever for a company to implement strong and coordinated responses to information coming from the field and its evaluation. It remains a good practice to consider what your website and customer (and/or patient) facing or publicly available materials say and how that information is understood and used in litigation, both in the present and with hindsight.

Even small efforts in mitigation can help reduce risk. Focusing on factual documentation concerning outcomes and adverse events and implementing robust and compliant systems and processes, as well as never letting the basics fall out of fashion remains important. Litigation is likely not entirely avoidable, but understanding how choices can impact legal defenses remains a valuable mitigation strategy. For example, PMA versus 510(k) still makes a difference in traditional product liability cases, and as noted, understanding the structure and processes of one's own place in medtech can be a significant benefit toward risk reduction. Additionally, risk reduction increases business value and helps in

any funding or exit strategy.

Preparing for the Future

These trends will continue to shape the medtech landscape for years to come. By embracing innovation, prioritizing strategic partnerships, and implementing a proactive approach to risk management and AI adoption, medtech companies can navigate these trends and emerge stronger in an evolving healthcare ecosystem. Staying agile and responsive to market dynamics will be essential for driving sustainable growth and delivering value to patients and stakeholders alike. ❖

Reference

[1] *Nicole Sheynin, "Top Medical Device Trends & Outlook for 2024," AlphaSense, October 6, 2023, https://www.alpha-sense.com/blog/trends/medical-device-trends-outlook/.*

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