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Contents

EMERGING TECH RESEARCH

Key Takeaways From Medtech MVP Venture & Partnering

PitchBook is a Morningstar company providing the most comprehensive, most accurate, and hard-to-find data for professionals doing business in the private markets.

Key takeaways

- Reimbursement has replaced regulatory review as the greatest hurdle for successful commercialization. While the proliferation of devices in the FDA's breakthrough program has reduced its exclusivity, designation can lead to meaningfully shorter review periods for devices in de novo and PMA pathways.

- Strategics will continue using M&A as a key lever to maintain growth, and there has been a rise in acquisitions of public medtech companies this year, as valuations have been more favorable for buyers.

- Despite the potential liquidity benefit of an acquisition, complex cap tables can incentivize a decision to IPO, as public listings effectively wipe the investor slate clean. Attendees expect a busy period for IPOs in 2025, although many were less optimistic for the rest of this year.

- VCs and startups shared candid views about the pros and cons of accepting minority investment from strategics; having a potential acquirer lined up can be offset by C-suite strategy changes and shifting corporate priorities.

- Medtech has not been significantly affected by hype for weight loss drugs and generative AI, although these topics came up occasionally during the conference. Areas such as precision medicine, connected devices, and portable therapies appear set to fuel the next decade of medtech innovation.

Introduction

The 23rd annual Medtech MVP Venture & Partnering Conference was held in Minneapolis from June 16-17. The event was organized by Cambridge VIP, an entity that hosts other healthtech events such as the Digital Health Innovation East Coast and West Coast summits. Startups, strategics, and investors attended Medtech MVP, considered to be one of the top annual medtech gatherings focused on private investment. Early-stage investment, exit considerations, and regulatory strategies were all key agenda themes, and investor and strategic-led panel sessions formed the core of the event schedule. Beyond discussions on national and global medtech investment, the conference also placed an emphasis on investment in the Twin Cities area, a region that is a bedrock for medtech innovation but often does not have the same level of investment as other metro areas. For further analysis from our team on the medtech sector, see our recently published research reports: Q1 Medtech Report, Q1 Medtech Public Comp Sheet and Valuation Guide, and our Organ Transplant Tech innovation report.

FDA insights

The US Food and Drug Administration's (FDA) Breakthrough Devices Program has become an important pathway for medical device companies to engage early with regulators, distinguish themselves in crowded markets, and accelerate review processes. At Medtech MVP, a key takeaway was that the FDA has become a better and more effective partner over the past decade—as shown by the more than 900 devices that have received breakthrough device designation since 2015.[1] During a conference session dedicated to discussing the breakthrough program, panelists cited the cardiovascular space as one area where the FDA has been able to provide strong guidance in bringing new devices to market through accelerated review pathways. This is supported by cardiovascular having the greatest number of breakthrough devices across all clinical areas, with nearly 200 in the program.

While receiving breakthrough device designation does not guarantee FDA approval, it is an important recognition of having an innovative device with plausible market potential given that the criteria include being more effective than current treatment options. And the designation can be an important milestone for current investors and future fundraising purposes. However, panelists hinted that the benefits of having the designation might be moderating since multiple innovations within a specific treatment area can receive the designation—at least until one of these successfully achieves FDA approval—especially since the qualification criteria is nebulous by design (for example, "must represent" breakthrough technology). The rapid expansion of this program in recent years has also affected policy decisions: In January 2021, the Centers for Medicare and Medicaid Services announced automatic coverage for devices with FDA breakthrough designation, but the new administration rescinded that decision later that same year.[2]

1: "Breakthrough Devices Program," US Food & Drug Administration, March 21, 2024.
2: "CMS Scraps Coverage Rule for Breakthrough Devices," MedCity News, Elise Reuter, November 12, 2021.

Attendees' attention was captured by preliminary data presented during the panel, which compared FDA decision time for 510(k), de novo, and premarket approval (PMA) pathways by breakthrough device status. Average time-to-decision was meaningfully lower for de novo and PMA devices, with a difference of 2.8 and 6.5 months, respectively. However, this benefit was effectively negligible for 510(k) with a difference of just a half-month, and one panelist remarked that the "jury was still out" on the benefits of seeking FDA breakthrough designation for devices with 510(k) submissions. However, the general conclusion from the panel discussion was that there remains a strong upside to applying for the program, and at minimum, early engagement with the FDA can be beneficial for approval efforts later. Panelists agreed that given the FDA's strong support for innovative technologies via this program and others, and in contrast to the dynamic from previous decades, reimbursement now often represents a greater hurdle for successful commercialization compared to the FDA review process.

M&A, IPO, or no

The current down market has resulted in more complex cap tables, which can increase the desire for an IPO that can wipe the cap-table slate clean.

Medtech historically leans toward M&A as a common exit outcome for VC-backed startups, with large strategics often using a "buy and build" strategy to maintain growth in relatively tepid markets. Even when startups go public, being acquired is still a real possibility, as seen by recent deals this year for Shockwave Medical, Axonics, Abiomed, and Silk Road Medical, among others. Still, a public listing remains an attractive exit point when available. During conference sessions, we heard from investors such as Garheng Kong, founder at HealthQuest Capital, about things to consider when deciding whether to seek an acquisition, IPO, or remain private for longer. Kong pointed out that the current down market has resulted in more complex cap tables, which can increase the desire for an IPO that can wipe the cap-table slate clean. Several panelists also shared that there remain meaningful bid-ask valuation spreads and that certain startups are still holding on to outdated valuations. We attribute this partly to recency and anchoring bias; however, valuation spreads are unlikely to exist forever, as an evolving market cycle should eventually push the two sides closer together.

While there is no arguing that we have fully emerged from the investment down market, optimism permeated the conference, as attendees and panelists alike expect the investment landscape to materially pick up over the next 12 months. To accentuate the theme that we are expected to emerge from the market winter soon, the AV team played the Spring portion of Vivaldi's Four Seasons during a conference session on M&A and IPO decisions. From our perspective, while it does appear we are out of the deepest winter frost, we do not expect a significant deal rebound in the near term, and we see early-to-mid 2025 as the most likely time horizon for a spike in public listings.

Strategics' strategy

At Medtech MVP, we heard that corporates are "still buying, they have money, and they will (eventually) come into the market."

Large medtech strategics have continued to accumulate dry powder for M&A opportunities even as deal activity has remained slow. At Medtech MVP, we heard that corporates are "still buying, they have money, and they will (eventually) come into the market," and on the first day of the conference, Boston Scientific announced the pending acquisition of carotid artery disease device maker Silk Road Medical for $1.2 billion in a deal expected to close in the second half of 2024. This transaction is in our view representative of other deals that could occur, with corporates looking for acquisitions in the high hundred-million dollars to low billion-dollar range.

While many panels at the conference had engaging speakers, Chris Eso, Global Head of Corporate and Business Development, M&A, and Ventures at Medtronic, was certainly a notable speaker, and he shared several helpful insights from the perspective of a top strategic. As a counterpoint to VCs' hope that the IPO window will reopen, Eso shared that a slower reopening could benefit strategics, as startups could be more willing to be acquired at a potentially more reasonable multiple. Another insight from Eso was that about 25% to 30% of Medtronic's corporate venture investments lead to an eventual strategic acquisition—with a higher likelihood for investments with built-in acquisition rights versus minority investments. This is perhaps a tad lower than we would have forecast but still indicates that strategic investment is a positive indication of future M&A interest. From the opposite perspective, investor panelists mentioned some potential downsides to accepting strategic capital because corporate leadership can change. Firms' strategic priorities can shift over time, and Eso mentioned that renegotiations with portfolio companies are common given the normal shifts in market dynamics and investment strategy changes over time.

The innovation horizon

"If you're not fundraising, you should be 'friendraising'"

—Josh Baltzell

Although the audience demographics at Medtech MVP were diverse, event speakers often spoke directly to startups in the crowd and aimed to provide helpful guidance for emerging companies. Various discussions centered on the benefit of engaging early and often with the FDA. Along these lines, we heard from a former FDA reviewer that startups "should not be afraid" to engage directly even without a formal proposal in place. Further, Josh Baltzell, Partner at Sightline Partners, provided the timely advice that connecting with strategics and other market players can be highly useful even in a difficult fundraising environment, as regardless of market conditions, building a network between funding rounds can provide value down the road. Baltzell provided a memorable line: "If you're not fundraising, you should be 'friendraising'"—and the concept of "friendraising" was referenced several times in panel sessions later during the conference.

There were a few opportunities at the event for emerging startups to pitch their companies, and on day two of the conference, Ponte Biosciences, Heart Failure Solutions, and Sparta Biomedical participated in a live-pitch contest. Although the prize amount ($20,000) won by Ponte Biosciences was not large, there were

unquantifiable benefits for these companies' pitches considering the high-quality investors and strategics in the audience. Of these startups, cartilage implant maker Sparta Biomedical had raised the most VC funding (more than $5 million). Other VC-backed startups in the bone graft & support subsector are in the table below. While there haven't been many exits in this space, one recent exit was Artelon's acquisition by Stryker on June 3.

Select VC-backed bone graft & support startups*

Company	HQ location	Total raised ($M)	Last financing type	Last financing date	Last financing amount ($M)
Cerapedics	Westminster, US	$343.5	Debt financing	September 30, 2023	$2.3
Conventus Flower Orthopedics	Horsham, US	$87.9	Late-stage VC	May 18, 2020	$69.8
Shoulder Innovations	Grand Rapids, US	$116.1	Debt financing	August 7, 2023	$45.0
OSSIO	Woburn, US	$82.5	Series C	October 17, 2022	$38.5
b-ONE Ortho	Cedar Knolls, US	$60.5	Series B	December 29, 2022	Undisclosed
EpiBone	Jersey City, US	$58.5	Late-stage VC	December 27, 2022	$18.5
CurvaFix	Bellevue, US	$53.8	Series C	July 14, 2023	$39.0
AgNovos Bioscience	Rockville, US	$51.5	Late-stage VC	March 11, 2024	$13.4
Catalyst OrthoScience	Naples, US	$49.0	Late-stage VC	April 18, 2024	$1.5
Just Medical	Tianjin, China	$48.0	Series B	May 6, 2021	$33.8

Source: PitchBook • Geography: Global • *As of June 20, 2024

Yōni.Fit, an Oklahoma-based women's health startup, was another company that had an opportunity to present at Medtech MVP. Founder Allison L. Watkins gave a presentation that held attendees' attention during the normally sluggish early afternoon timeslot, as Watkins spoke candidly about her own health experiences. Yoni-fit is fundraising and will launch its device for stress urinary incontinence commercially this summer with a national roll-out expected later this year. Longer-term, Yōni.Fit intends to build a platform product model with applications for diagnostics and drug delivery. More broadly, there has been rising recognition of the market and investment potential in women's health, and the sector has been a key thematic focus at several recent conferences, as investors purposefully seek out opportunities in the space. A comprehensive market map of women's health startups is also available in the PitchBook Platform.