

MARCH 2024 | Vol. 11, No. 3

MedTech STRATEGIST

**AAOS 2024 Takeaways:
Evolving Practice
Models, Implantable
Sensors, and the Role
of AI in Orthopedics**

Wendy Diller

**Standout Strategies
for Next-Gen Venous
Devices**

Mary Stuart

**A Current Affair:
MTI Start-Ups'
Novel Solutions in
Neurostimulation**

Colin Miller

**DIGITAL
HEALTH
FUNDING:
EXPERTS
FORESEE
CHALLENGES
AHEAD**

Mary Thompson



[MYSTRATEGIST.COM/MEDTECH-STRATEGIST](https://mystrategist.com/medtech-strategist)



DIGITAL HEALTH FUNDING: EXPERTS FORESEE CHALLENGES AHEAD

Digital health funding soared in 2021, at the height of the pandemic, but a year later began a precipitous decline. Now, with valuations way down and investors harder to come by, some digital health start-ups are struggling. We take a deep dive into the current funding environment, and what is on the radar for 2024 and beyond, with the help of Janke Dittmer of Gilde Healthcare, Karl Hess of Outcome Capital, Paul Grand of MedTech Innovator, and Jonathan Norris of HSBC Innovation Banking.

► MARY THOMPSON

Coming off a pandemic-driven (and in hindsight, clearly frothy) high in 2021, venture funding for digital health start-ups continued to slide in 2023, reaching its lowest level since 2019, and the fallout is creating upheaval in the industry. With valuation resets well underway, a handful of high-profile company failures, and investors now harder to come by, many digital health start-ups are facing a difficult year ahead. Those with a strong value proposition and a solid business plan, with coverage and reimbursement in place and/or a clear pathway to profitability, are in the best position to weather the storm.

But it's not all doom and gloom. Demand for digital solutions in healthcare remains strong and opportunities still abound. And with a renewed emphasis on the fundamentals, the industry could come out of this reset stronger than ever.

To understand how we got here and where we might be headed, it's necessary to take a step back. We did so with the help of four thought leaders well versed in the healthcare and digital health funding space: Janke Dittmer, general partner and head of European investments for Gilde Healthcare, one of Europe's most active investors in medical devices and healthtech; Karl Hess, managing director with Outcome Capital, a life sciences and healthcare advisory and investment banking firm, and leader of Outcome's healthtech and digital health practices; Paul Grand, founder and CEO of MedTech Innovator, the world's largest life sciences accelerator; and Jonathan Norris, managing director of HSBC Innovation Banking, who tracks healthcare venture investing in the US and Europe.

2021: A Digital Health Gold Rush

During the first two years of the pandemic, companies with technologies that promised to help enable remote care, such as remote monitoring, telehealth, and digital therapeutics, attracted a huge amount of investor interest and dollars. In 2021, at the height of this digital health gold rush, equity investors poured \$52.7 billion into digital health companies worldwide, according to CB Insights' report "State of Digital Health, Global 2023 Recap," and nearly \$30 billion into US digital health companies, according to Rock Health (see Figures 1-3).

Many of the investors who flooded into digital health during this time came from outside the healthcare arena

and had little or no experience with the intricacies and challenges of bringing new technologies into the healthcare space. They bet big on a wide range of companies, often with an expectation of tech-like returns and little concern for the business model or the pathway to profitability. As a result, valuations soared while accountability did not.

"The amount of investment [during this time] was just astounding in terms of both the number of deals and the dollars invested," Jon Norris told *MedTech Strategist* recently. "There were a lot of investors really excited about where healthcare was going and the application of technology in healthcare, so the deal sizes and valuations these companies were getting were really, really aggressive compared to historical pre-money valuations and dollars raised." However, by mid-2022, as the pandemic frenzy eased and the market outlook soured, the bubble had burst, leaving a field littered with companies that were "stuck with really aggressive valuations and investors that lacked the experience set needed to integrate that into the healthcare system."

The Bubble Bursts

The downturn in healthcare investment began in 2022 when the US stock market, under the threat of rising inflation and growing geopolitical concerns, suffered its worst performing year since 2008. This negatively impacted the entire healthcare investment arena, but it hit the digital health segment particularly hard.

As the impact spread, a few digital health companies that were once the darlings of the industry collapsed in high-profile fire sales. These included Pear Therapeutics, which went public in December 2021 in a \$1.6 billion SPAC deal and raised more than \$400 million in venture capital, but in May of 2023 sold its assets for \$6 million at auction. In 2017, Pear was the first to gain FDA clearance for a digital therapeutic (for substance abuse), but ultimately failed to obtain reimbursement for its offerings, burned through an enormous amount of cash in the process, and waited too long to address its crisis.

Babylon Health was another company that suffered a similar fate, although its demise was surrounded by controversy and claims that the company had overstated the abilities of its AI-based tool. At its IPO debut (via SPAC) in 2021, Babylon was valued at \$4.2 billion and had over 2,000 employees, but less than

two years later the company filed for bankruptcy, with assets valued at only about \$35 million.

Babylon was once considered a unicorn, as was Olive, which offered a revenue-cycle AI suite for health systems. Olive shut down last fall after raising more than \$800 million in venture capital and achieving a peak valuation of \$4 billion, selling its assets for pennies on the dollar. All three companies succumbed to the frothy era of easy money and growth at any cost that characterized the early pandemic years and that many believe was exacerbated by a proliferation of SPAC-enabled IPOs.

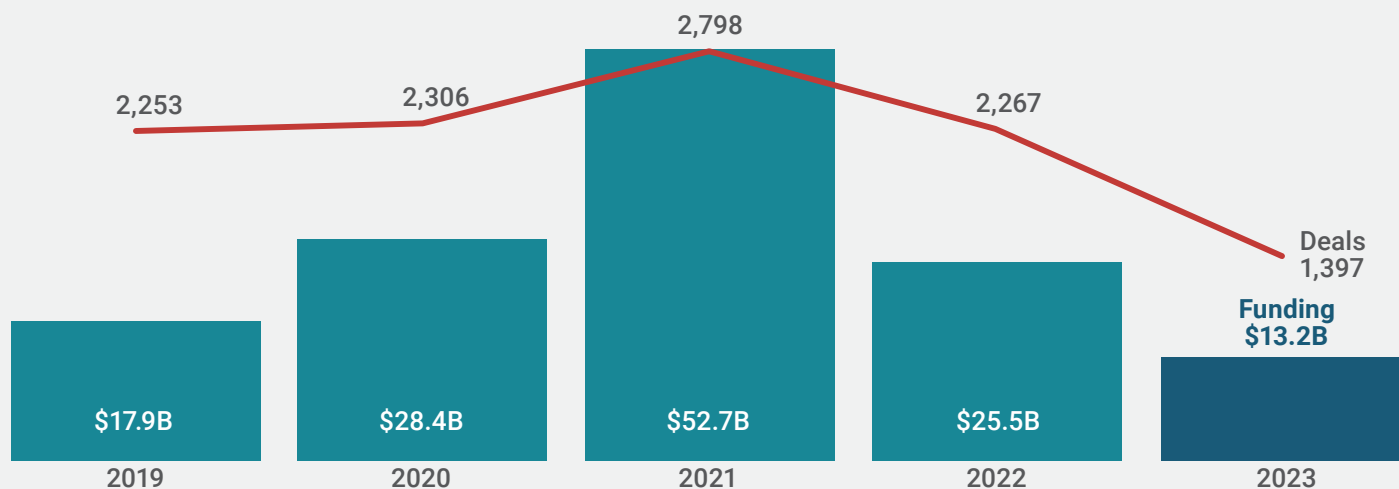
These types of high-profile failures are unsettling for investors, to say the least, who are dealing with their own problems related to economic uncertainty and high interest rates. Even though the situation has stabilized somewhat, the rate of new investments in healthcare overall still fell 28% last year, according to Norris. Only the top 10% of VC-backed healthcare companies secured a substantial funding round with a step-up valuation in 2023, he noted in HSBC’s latest Venture Healthcare Report, released in January, while others either raised new rounds at flat or lower valuations or obtained insider rounds to bridge the gap (almost half of 2023 financings were insider rounds, according to Norris’ analysis, defined as equity/convertible financings from existing investors, typically involving smaller amounts than traditional funding rounds). Meanwhile, some VCs were forced to downsize, and many turned away from new healthcare investments to concentrate their resources on supporting their existing portfolios.

The fallout particularly impacted digital health/healthtech. Although Norris doesn’t break out digital health, per se, as a separate category (he breaks the market into healthtech, med device, Dx/tools, and biopharma, all of which could contain digital elements), his analysis, like others that focus specifically on digital health, points to some common elements that can help explain how the current situation evolved and what might be coming down the road in the future.

Early-stage VC funding in 2023 was down 18% across the board in the medical device sector, compared to the previous year, Norris found, while there was evidence of more corporate involvement in early-stage device companies. One area of devices that was particularly hard hit and that falls squarely under the digital health umbrella was noninvasive monitoring (NIM), which saw a 75% decline in first-financing investments and an overall funding decline of more than 40%, according to the report. Meanwhile, other, more traditional medtech device segments, such as neuro and imaging, did well last year, with neuro hitting record investment levels. Still, nearly one in three Series B and later deals involving new investors during 2023 were down rounds, according to Norris, and in the healthtech space, first-financings were focused primarily on provider operations and alternative care.

Norris expects the downturn to continue in 2024. “We’re not out of the woods yet,” he writes. Although top companies will be able to secure large rounds and perhaps achieve “noteworthy” M&A exits, the upcoming year will be “crucial,” he says, as many will need to secure new rounds or “face

Figure 1
Global Digital Health Annual Equity Funding & Deal Volume, 2019-2023



tough consequences.” He anticipates an uptick in consolidation going forward, along with more VC/corporate build-to-buy collaborations, and in some cases shutdowns as some companies reach the end of their cash runway.

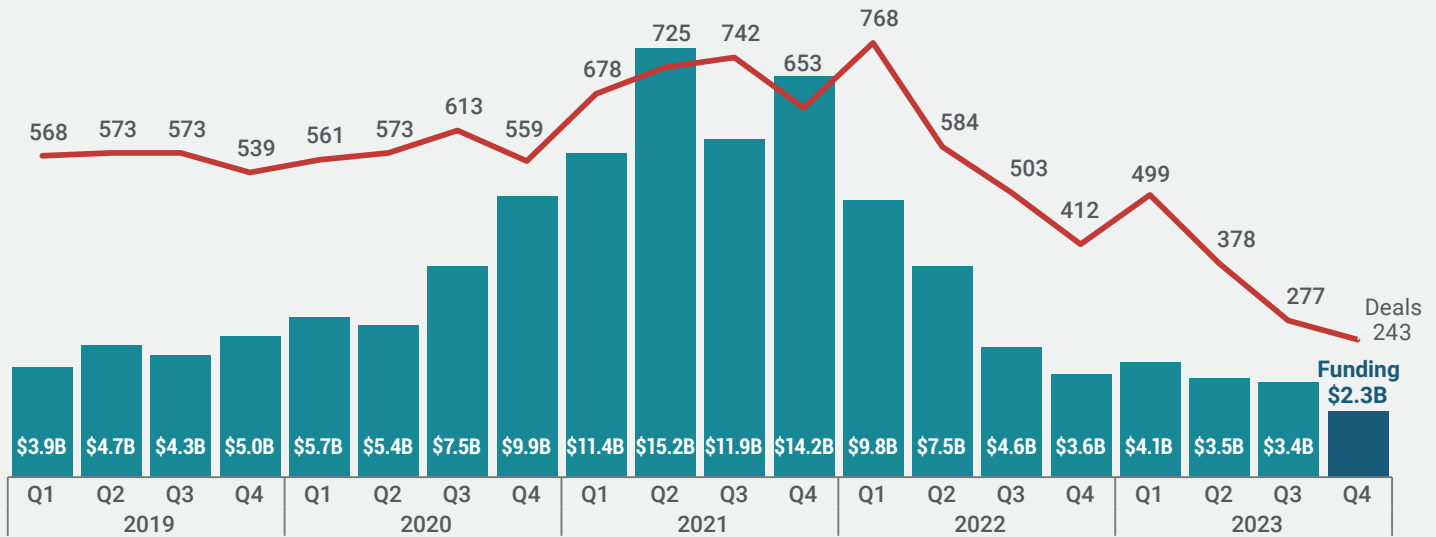
Overall, Norris sees 2023 as a transition year, with a return to a more normal, but also more stringent, funding environment going forward, comprised primarily of legacy healthcare funds

and corporate VCs, who are refocusing on the fundamentals and taking a more “methodical” approach with fewer deals and “smaller check sizes.”

“Tourist” Fallout: The Bloom Is Off the Rose

When the bubble burst in 2022, digital health company valuations “really got crushed,” notes Karl Hess. Many of the

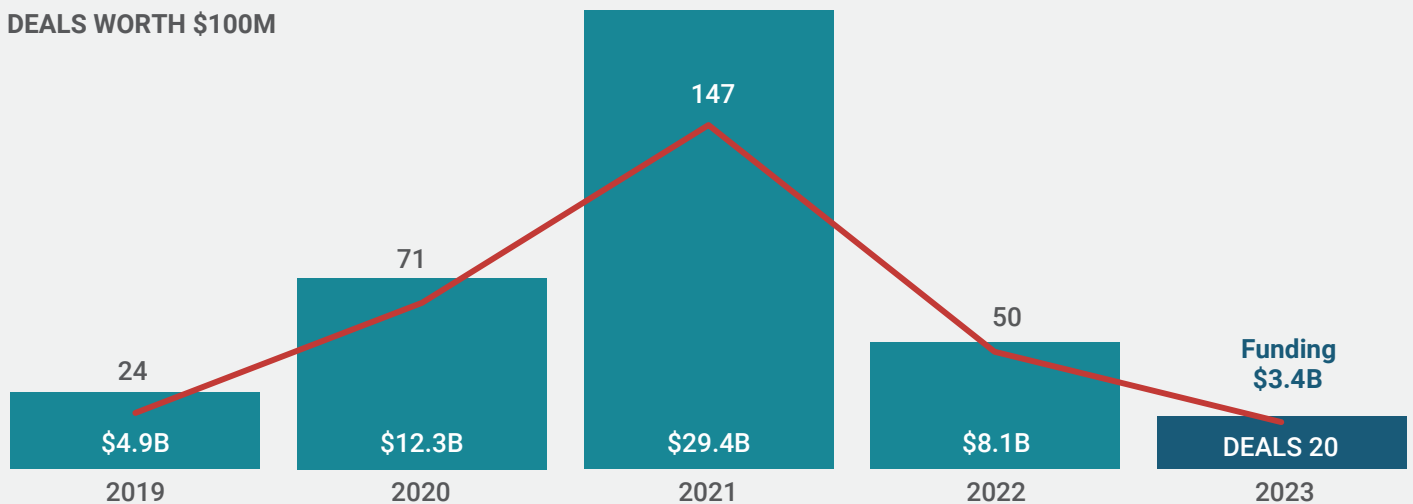
Figure 2
Global Digital Health Quarterly Funding & Deal Volume, 2019-2023



CBINSIGHTS

Figure 3
Global Digital Health Mega-Rounds, 2019-2023

DEALS WORTH \$100M



CBINSIGHTS

drivers of growth during the surge of 2020 and 2021, including relaxed regulatory and reimbursement policies the US put in place during the pandemic, had disappeared, he explains, and “once that happened, those companies that had gone public in 2021-2022 were really kind of unfairly judged in terms of their value.” That’s still impacting the market to a degree, he adds. “Even some companies with good metrics in terms of valuation drivers are unfavorably perceived in the public markets. There’s still that disconnect; and that has had a trickle-down effect that continues to impact investing in this space.”

The rush of money that came in during the height of the pandemic was made possible in large part by what Janke Dittmer calls “tourist” investors—tech investors, generalists, and family offices, by and large—who entered the healthcare field for the first time during the pandemic and often lacked a thorough understanding of the healthcare market’s intricacies.

These tourist investors were excited about the opportunity to apply technology to the huge healthcare space, but were anticipating unrealistic returns, notes Paul Grand. “Medical device investors are trained to expect low exit multiples—for example, five to 10x would be a solid return—and they set appropriate valuations with those multiples in mind,” he explains. “But tech investors are used to 100 to 1,000x returns, and that just doesn’t happen often in healthcare. They accepted high early-stage valuations in digital health, and with reality now sinking in, the bloom is off the rose in terms of company valuations.”

The market downturn in early 2022, when company valuations—for digital health in particular—got hammered and potential return multiples evaporated, prompted most of these tourist investors to pull back or leave healthcare altogether. And that’s a good thing, notes Dittmer, because “the valuations they supported were not sustainable.”

But they also left something of a mess in their wake. “Far too many digital health companies were funded,” Dittmer states, “with the majority representing point solutions that are not scalable. And with end-users now moving away from point solutions toward broader platform capabilities, there are many companies out there with sub-scale point solutions that have “little hope to secure funding and cash-out dates rapidly approaching.”

“In terms of investment activity and dollars, we are significantly down in the rolling average from the ‘21/’22 peak,” notes Dittmer. However, the numbers are a bit misleading due to the uptick in insider rounds. “We are seeing a large number of insider-led rounds, often combined with venture debt—unpriced bridge financings—a large portion of which are not reflected in the overall funding numbers, as they tend not to be announced,” he explains. This also impacts valuations, he points out, because

insider rounds typically are not priced, “and those that are priced “put forth complex structures with super liquidation preferences/participation features that allow them to keep inflated valuations intact and avoid write-downs. So, although valuations are also way down from the 2021 peak, this is not fully reflected in the available numbers.”

And with venture funds putting so much of their resources into supporting their existing portfolios, the bar is now higher for new investments, putting pressure on early-stage deals in particular. “The available capital is going toward later-stage deals,” Dittmer explains, “leaving a large gap in the market for sub-scale digital health companies looking for funding.”

“A lot of companies are financially strapped right now and haven’t been able to successfully cross the chasm from early-stage growth to later funding stages,” concurs Hess. “Many really just waited too long to act when the downturn began and essentially ran out of runway,” he adds. “Some didn’t even have the wherewithal to have a fire sale and just evaporated overnight. We’re working with a couple of clients [right now] that are kind of struggling to keep the lights on while determining strategic options.”

Telemedicine/telehealth companies, in particular, are having real difficulties growing, he notes. “They’re looking for new revenue, new strategic opportunities. They’re not sure quite what those are, but they have kind of reached a plateau in terms of their growth and market penetration.”

But it’s a tough environment for a variety of digital health players, Hess says. “If you don’t have the money to really build a channel and you spend a lot on customer acquisition, then you might be in trouble at this juncture. You might be forced to explore strategic partnerships or potential acquisition to survive.”

Hess believes that many investors are holding back and waiting for things to improve. He hopes things will pick up in the second half of this year if interest rates come down, which affects financing and the ability to go public. But companies may have difficulty meeting investors’ now more stringent qualifications. “I know there are a lot of investors who want to invest, but they’re just not finding companies that meet their criteria because the bar has been raised. Companies that traditionally might have qualified for a Series A investment are now looking at more seed-stage investors, and Series A companies typically need to have revenues and be close to profitability, or maybe even profitable and growing rapidly. And there aren’t that many start-ups that fit that description these days.”

Those that have figured out reimbursement and their customer acquisition costs, and have been able to reduce the latter

significantly, are the best positioned, Hess says, as are companies that are growing rapidly and are profitable, or nearly so. Companies need to have a clear, stable business model in terms of who pays for what, he notes, and it helps to establish an ongoing relationship with a payor and/or provider.

Unfortunately, there are a lot of others that aren't so well positioned and were funded during the height "without a real plan for how to spend those proceeds," Hess continues. A good deal of that money went into customer acquisition, which he says was unfortunate. "It was growth at all costs, but that changed almost overnight, and some were not able to adjust to that."

As a result, it's been kind of a "wild ride" for start-ups, Hess says. "If a company finds a niche and an unmet need in the market, and there are many, success depends on how niche they are. And at some point, the company may become too niche to survive on its own."

Both Hess and Dittmer expect to see more consolidation in this space going forward and potentially even roll-ups of these point solutions as companies unable to secure new funding reach the end of their cash runway.

"Valuations are still coming down to a degree," Hess notes; "that hasn't stabilized yet." And strategics are starting to take notice. "A lot of the strategics are taking advantage of these decreased valuations and have been very busy at least evaluating opportunities" to add to their portfolios, he asserts. "So I think there will be some M&A there, at least in the first half of this year. I don't see venture funding going up in the first half, but I am hoping that things improve this year and going into 2025 and we see some sort of return to normalcy."

Strategics may help as far as exits are concerned, but it could be too late for some digital health companies teetering on the brink. Notes Dittmer, "Companies that bet on the wrong business model and those sub-scale point solutions that cannot secure an

What Digital Health Investors Want

Gilde Healthcare, based in the Netherlands, is one of Europe's most active investors in medical devices and healthtech. Digital health-related products and services—defined as any solution with a digital component in the product or business model, including combinations of digital devices, pharma, diagnostics, and services—make up about one-third of Gilde's global investments, according to Janke Dittmer, general partner and head of European healthtech investments for Gilde, and the firm intends to maintain that level of investment. "Our motto at Gilde is better healthcare at lower cost, and digitization and automation are great levers to improve efficiency, reach healthcare's triple aim to improve patient care, and address issues of escalating costs and barriers to access," he says. (See "Gilde's Transatlantic Approach to MedTech Investing," *MedTech Strategist*, July 25, 2023.)

According to Dittmer, Gilde (along with most investors today) is looking to invest in digital health start-ups that meet a specific list of criteria. These include companies that have solutions targeting major patient unmet needs as well as pain points in the industry (e.g., resource shortages, administrative burdens, lower-cost care settings, reducing readmissions, and increasing patient adherence), have a clear path toward profitability that's within reach of the current financing round, and have at least two established customer channels/segments.

Technologies of particular interest to Gilde at the moment include nonclinical AI, such as workflow automation and clinical documentation, or any AI-based solution that can reduce the administrative burden on clinicians and drive more efficiency; specialty virtual care (e.g., kidney care, behavioral health, cardiovascular, GI);

asynchronous care models, including those targeting chronic disease management; and convergence plays, such as software doing the job of a medical device, diagnostic, or therapeutic or combinations such as digital-enabled devices and software-enabled drug development.

On the flip side, Gilde is cautious when it comes to digital health companies with an offering only suitable for providers as the paying customer. "We want to see a track record of selling through payors, pharma, or some other channel, and in Europe, we want to see business model validation in different healthcare systems," notes Dittmer. Many investors also are setting arbitrary recurring revenue thresholds for companies seeking to move to a later stage, he adds. For Gilde, that magic threshold is \$10 million, although it's probably closer to \$15-20 million for companies in the US, he says.

exit, run out of insider capital, and can't get traction with new investors will fail or get scooped up by competitors."

The situation is particularly "tricky" because of the proliferation of insider rounds, Norris points out. "The rubber is really going to hit the road on those rounds this year," he says, "because typically those insider rounds provide less than 12 months of cash. And these are all cash-burning companies that are not in a position to hit profitability. If they can't find a new investor after that insider round, that's where we're going to start to see a lot of consolidation, mergers, or even selling IP for pennies on the dollar."

Conversely, companies most likely to survive under these difficult conditions, Dittmer contends, are those that recognized changes in the market early on and were able to move back to a much more capital efficient organizational structure. "If companies can reduce headcount, likely impacting future growth rates for an extended time period, and reach cash-flow break even, they can go into maintenance mode and survive until the funding environment is more attractive," he says.

"In addition, consolidators with management teams capable of absorbing and integrating other sub-scale point solutions, and recognizing cost synergies, will also have a high probability of survival in this market," notes Dittmer. "Generally speaking, companies that have found a business model that allows them to get paid fairly and an operational model that scales will be the winners in digital health."

But even companies that are fairly well positioned could find it harder to get funding in today's climate. As Norris points out, most of the VCs still active in healthtech are traditional investors who are very knowledgeable about healthcare and are looking for technologies they think are most interesting. "At some valuation, those companies will get funded, but those investors are going to be pickier."

According to Norris, the top 15% of companies under the "healthtech" umbrella will "still find an up round and a lot of investors around the table wanting to join." The next tier—maybe the next 30-40%—should be able to find a new investor, he says, but could be facing a flat round or valuation reset. "It's the bottom 40% that is the real danger zone for me," Norris states. "Those are the companies where maybe half or more are going to have to do something that is company-changing in their financing—either consolidation, a complete valuation reset, or an asset sale."

The Upside: Digital Is Here to Stay

The situation may be precarious for some companies, but it's definitely not all bad news, asserts Paul Grand. He acknowledges that things are tough for digital health start-ups right now, with valuations down and an inevitable reset

in that sector. However, he insists "there's no sense of doom and gloom." In fact, interest in digital health remains strong among all stakeholders, including investors and healthcare organizations. "Everyone's interested in digital health; demand is not going away."

But he admits the sector still has some work to do. The primary problem, says Grand, is a business model disconnect. "People haven't figured out the business model [in digital health] for how they're going to get paid and how their technology will be reimbursed. That is still evolving and has been limited; payment and reimbursement haven't kept up with innovation. The companies that have figured this out and have reimbursement are doing great and those that haven't aren't. And a lot of companies fail before they figure that out, he says. "There could be a great, promising digital health innovation for helping people, but if it's not prescribed and not reimbursed, ultimately, it's going to fail."

Unfortunately, the rash of investment that occurred during the pandemic did the digital health industry no favors in this regard, according to Grand. "Many of the new investors came from the software industry and were often not familiar with the medical field. They say things like 'Software is going to eat everything' and they come in with their preconceived understanding of 'Give it away for free and then we'll make it up later.' But as they're experimenting with business models, some of them are going to destroy it for everyone else."

Those companies expecting consumers to pay for their healthcare are not doing well, he asserts. "But companies with enough clinical and economic data to show they can save the system money and improve outcomes are going to get adoption and coverage." In addition, many of the companies coming out on top right now are more enterprise in nature, he adds; they're nonclinical and unregulated and don't need reimbursement.

The bottom line is that digital health companies must have a solid business model, and they must be focused on how they will get paid from the very beginning, says Grand. "You can't figure that out later." Companies should partner with payors to figure that out, he adds, rather than going it alone and trying to disrupt the system. "Healthcare does not want to be disrupted," he asserts. "Doctors and payors and hospitals don't want to be disrupted. That's the wrong approach. They want someone to come in and partner with them, work with them. They need to be there from the beginning. That's the only way these things will succeed."

As for the current investment environment, Grand says recent high-profile failures of companies such as Pear, Babylon, and Olive, and the loss of value in the stock market overall (some healthcare companies have lost 80-90% of their stock value), are causing some investors pause. Those events are "very scary,"

he says. "People expect companies to fail, that's normal. But the ones that are supposed to be darlings shouldn't be failing."


Still, Grand insists that digital health investment is not going away. "There's been a ton of money raised by venture funds in the last several years, so there's a lot of capital to deploy," he says. And even though some investors have paused new investments and are focused on their existing portfolios, "there's still a lot of investment going on." Good companies are still getting funded, Grand says, although he concedes it may take longer, valuations may be lower, and who's funding them might be changing (with some companies turning to sovereign wealth funds or groups of doctors, for example). "There's money, and they're still sizeable rounds."

That said, Grand acknowledges 2024 could be a year of reckoning for some. "The value of some of the companies that grew so fast during the pandemic has just been destroyed. So, there's definitely a reckoning there. And there's a bit of a reckoning elsewhere in digital health as well because we're seeing big companies go under. So, for a lot of companies that have been around a while and haven't yet proven themselves or figured out their business model, this is a year of reckoning."

Many of those companies "will run out of funding and people will pick them up for cheap," he continues. "Unless a company

does a complete recap, those companies on the brink will go out of business. But I still predict, at the same time, there will be a lot of funding. Because people have money, and they want to put it to work. There are some very smart and experienced healthcare investors who are starting digital health funds, so it can be done. You just need to understand the markets and how they work and understand which things to target—the ones that have reimbursement and coverage or a clear path to that."

Although Grand is certain digital health will make it through this transitional period, he is concerned that some good companies may be lost along the way. "I worry that a lot of companies won't get funded because people are afraid. And that's going to stop them from investing in things that really can make a difference for patients."

Despite those fears, the overriding sense among those we spoke with seems to be one of cautious optimism. "As in previous bubbles," notes Dittmer, "the opportunity for digital health is there, and winners will emerge from the present market correction." One thing's for sure, he adds: "The degree of digitization and automation in healthcare has to increase to bring costs under control and improve patient care at the same time." 

Posted on MyStrategist.com March 21, 2024



**YOUR PARTNER IN
MARKET ACCESS AND REIMBURSEMENT**

 **Strategic Reimbursement Services**

 **Clinical Trial Reimbursement Programs**

 **Credentialed Advisory Council**

 **Payer Engagement**

 **Patient Access Platform Solutions Hotlines & Patient Access Programs**

PRIA  **Accelerating Healthcare Innovation**

www.PRIAHealthcare.com