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Pear Bankruptcy Filing Highlights Difficult Challenges Facing Digital Therapeutics

by Tim Casey

Pear Therapeutics filed for Chapter 11 bankruptcy in April and sold its remaining assets in an auction for about $6m. The demise of one the pioneers in the prescription digital therapeutics industry highlights the challenges PDT developers face getting their products reimbursed.

[Editor's Note: *A version of this article by Tim Casey originally appeared in* In Vivo*,* Medtech Insight*'s sister publication, as well as AIS Health's Health Plan Weekly published by Norstella,* Medtech Insight*'s parent company*.]

Prescription digital therapeutics (PDT) companies like *Pear Therapeutics*, *Better Therapeutics* and *Akili Interactive Labs* are facing reimbursement challenges and an investment market that is much less favorable than it was when the companies went public a few years ago.

"It's really important not to abstract from this experience that the market is somehow not healthy," Dan Mendelson, CEO of Morgan Health, the health care investing arm of JPMorgan Chase, said.

"Commercializing a new FDA-approved therapy is really challenging for new devices and it's even more challenging for the more innovative categories like digital therapeutics," he said. "There is a whole array of companies that have raised a huge amount of capital during a period when there was just unbridled optimism

Key Takeaways

- Prescription digital therapeutics (PDTs) companies that went public via SPAC are struggling to stay afloat.
- The companies and the industry trade group primarily attribute PDTs' disappointing uptake to lack of reimbursement and payers' resistance to

and very low interest rates. Some of the valuations got way ahead of the business fundamentals."

In 2017, Pear's reSET digital app to treat patients with substance use disorder became the first US Food and Drug Administration-approved PDT – a software-based therapy to treat medical and behavioral conditions.

innovation.

- Analysts suggest demand for PDTs is not meeting companies' optimistic projections, but there may be a stronger market for PDTs eventually as they prove their cost-effectiveness.

Since then, the FDA has approved more than 40 DPTs, according to Brandon Aylward, director of digital health for RTI International, a nonprofit research institute.

Medicare does not cover PDTs, and many commercial payers and state Medicaid programs have been hesitant to pay for them.

Pear said in October 2022 that about 10 states, a few Blue Cross Blue Shield plans and SelectHealth were the only payers that covered one or more of its FDA-approved products: reSET, reSET-O to treat opioid use disorder and Somryst to treat chronic insomnia. The company generated just $12.7m in revenue last year while incurring a net loss of $75.5m.

Corey McCann, Pear's co-founder and former CEO, acknowledged the reimbursement challenges. "[Payers] have the ability to deny payment for therapies that are clinically necessary, effective, and cost-saving," he wrote in a statement announcing the end of the company on 7 April. "Market conditions over the last two years have challenged many growth-stage companies, including us."

Last month, the company hired MTS Health Partners, an investment bank, to serve as its financial adviser and help "explore strategic alternatives to maximize shareholder value," including selling the company or raising additional capital. A court filing notes that MTS reached out to pharmaceutical manufacturers, health insurers, providers, health technology firms, private equity companies and venture capital firms to gauge their interest and that three parties

Minute Insight: Pear Therapeutics Files For Bankruptcy, Hopes To Find Buyer For PDT Assets

By Reed Miller

07 Apr 2023

A few weeks after announcing that it was exploring its "strategic options," Pear Therapeutics announced that it is filing for bankruptcy and is not filling new prescriptions for its digital therapeutics.

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submitted non-binding offers for Pear.

On 22 May, a *Delaware bankruptcy court* auctioned off Pear's assets for just over $6m to Nox Health Group, Harvest Bio, *Click Therapeutics*, and Welt Corporation.

Nox paid the most, acquiring Pear's Somryst assets for $3.9m. Harvest Bio bought the reSET and PearConnect technologies. Click was the successful bidder for the Pear Platform, and Welt won Pear's migraine assets.

The first sign that Pear's internal projections for growth were overly optimistic appeared when it went public in December 2021 via a merger with a special purpose acquisition company (SPAC). The company had hoped to raise $400m through the SPAC deal, but it only raised $175m.

> *"There is a whole array of companies that have raised a huge amount of capital during a period when there was just unbridled optimism and very low interest rates. Some of the valuations got way ahead of the business fundamentals." – Dan Mendelson*

In January, Pear hired financial firms H.C. Wainwright & Co. and Virtu Americas to help it raise up to $150m through the sale of common stock. But as of the end of March, it had raised just $980,000. The company's stock on NASDAQ started at $10, but never came close to reaching that price again. (Also see "*Is Time Nearly Up For Pear? The PDT Company Could Be Bargain For Acquirer*" - Medtech Insight, 23 Mar, 2023.)

Better Therapeutics – the developer of the BT-001 PDT to help people manage Type 2 diabetes – is another PDT company struggling to stay afloat as a public company. The San Francisco company raised $250m through a SPAC merger in late 2021 and its stock began trading on NASDAQ at $10. Since then, the company's share price has steadily dropped and is now around $0.75.

In late March, Better Therapeutics announced that it was cutting its workforce by 35%, and it secured a $6.5m private placement in April. The company is trying to "extend its runway" until it can launch BT-001. In its 11 May first-quarter 2023 sales and earnings report, the company projected that the US FDA will probably grant BT-001 de novo authorization by the "middle of the year."

Better Therapeutics is also seeking the FDA's breakthrough designation for PDTs for non-alcoholic fatty liver disease and non-alcoholic steatohepatitis. Currently, there are no FDA-approved treatments for NAFLD and NASH, which affect a quarter of Americans, according to the company.

On 11 May, the company recorded a net loss of $9.4m for the first quarter and reported it has $6.1m in cash and cash equivalents, less than half of what it had at the end of 2022.

> *"While not all products or companies will succeed given their own specific circumstances, the need and opportunity for validated digital treatments is as big as it's ever been." – Eddie Martucci*

Akili Interactive Labs went public last year via a SPAC merger, about two years after the US FDA *approved* its EndeavorRx game-based digital therapeutic for children between 8 and 12 years old with attention-deficit/hyperactivity disorder (ADHD). (Also see "*Playing Big: Akili To Be Bought By Chamath Palihapitiya's SPAC In $1Bn Deal*" - Medtech Insight, 26 Jan, 2022.)

But in January, Akili announced it would lay off about 30% of its staff by the end of the first quarter and put programs related to cognitive health, outside of ADHD, on hold to "conserve capital and focus."

In an email to employees, Eddie Martucci, Akili's founder and CEO, *wrote*, "In recent months, the economic environment has dramatically shifted" and that "while EndeavorRx is gaining traction, we still must reduce our spending in response to the new realities of the world around us."

For 2022, Akili generated just $323,000 of product revenue from EndeavorRx, up from $186,000 the previous year. The company lost $8m last year compared with a $61.3m net loss in 2021.

In all, 1,719 prescribers wrote a total of 4,558 prescriptions for EndeavorRx last year, consisting of 3,241 new prescriptions and 1,317 refills. Akili noted that 94% of the prescriptions were self-paid, while just 3% were reimbursed by payers and the remaining 3% were provided for free to patients.

"Innovation is difficult, especially when disrupting the health care industry," Martucci said. "While not all products or companies will succeed given their own specific circumstances, the need and opportunity for validated digital treatments is as big as it's ever been. Health care

providers and patients are increasingly looking for safe and proven treatment options, especially in the area of mental and cognitive health where digital therapeutics shine."

"In pharmaceuticals, there is more than one type of pill. Likewise, in digital therapeutics there are many different technology approaches and target markets," Martucci explained. "Digital therapeutics will continue to find success, and there's no question they'll increasingly become an essential part of [the] standard of care."

> *"My takeaway from this is how the US health care system is not made for innovation." – Andy Molnar*

Industry Seeks Medicare Coverage

Andy Molnar, CEO of the Digital Therapeutics Alliance (DTA) trade group, said that Pear's bankruptcy is disappointing but not surprising given that payers have yet to fully embrace PDTs. (Also see "*Exec Chat: New CEO Of Digital Therapeutics Alliance Says Reimbursement Remains Big Issue*" - Medtech Insight, 28 Jul, 2021.)

"My takeaway from this is how the US health care system is not made for innovation," he said. "The health care system is designed for people to say no….Being a first mover is hard."

"If they had one more year, nobody would be asking this question. But instead, their runway wasn't long enough."

Molnar gave the example of continuous glucose monitors (CGMs) for people with Type 2 diabetes, which payers were hesitant for a long time to cover because CGMs were much more expensive than blood glucose test strips. Payers only recently have begun expanding coverage for CGMs as they see the products' effectiveness and potential to save costs in the long-term.

Molnar hopes payers will begin adopting similar coverage for PDTs, starting with Medicare. As of now, Medicare does not cover PDTs, although a Health Affairs article noted that last year the Centers for Medicare and Medicaid Services implemented a code for "prescription digital behavioral therapy" that covers some of the early PDTs. The authors said that many PDT manufacturers have lobbied CMS to have individual codes for each FDA-approved PDT, although that has not come to fruition.

> *"While I think a large number of physicians are interested in using digital therapeutics, the number of those that actually are is pretty low at this point." – Dan Mendelson*

Last month, Sens. Jeanne Shaheen (D-N.H.) and Shelley Moore Capito (R-W.Va.) introduced the *Access to Prescription Digital Therapeutics Act*, which would compel Medicare to cover PDTs.

"It's always a chicken or egg thing," Molnar said. "But if Medicare were to cover the products and come up with a coding scheme, then everything else could flow a lot easier," and more commercial payers would likely follow suit.

Molnar said the DTA has 105 member companies, each of which is working on multiple products, so he expects the PDT market to expand in the coming years. Managed care leaders agree, according to a survey of 50 health care decision makers that was funded by consulting company Xcenda and presented in October 2022 at the Academy of Managed Care Pharmacy's Nexus annual meeting.

The survey found that 56% of respondents expected there to be more PDTs covered in the next 18 months, while 70% said digital therapeutics would expand beyond mental health, cardiology and diabetes during that same time period.

The DTA's members range from small startups to pharmaceutical companies such as:

- *Boehringer Ingelheim*, which has a partnership with Click Therapeutics to develop PDT for schizophrenia;
- *Otsuka Pharmaceutical*, which launched a clinical trial with Click testing the effectiveness of digital therapeutics in adults with major depressive disorder; and
- Sumitomo Dainippon Pharma, which has partnered with BehaVR, Inc. to develop PDTs for the treatment of social anxiety disorder, generalized anxiety disorder and major depressive disorder.

"We have a huge community of people that are continuing to move these innovations forward," Molnar said. "But without the government really standing behind it, we're stifling the progression of US health care. It's insane."

Physician Adoption Of PDTs Is Lacking

Besides the issue of reimbursement, PDT manufacturers are also seeing slow adoption by health care providers, according to Aylward. He noted that just 22% of providers who responded to a Decimal.health survey last year said they had prescribed a digital therapeutic, although 87% indicated they would be interested in prescribing them in the future.

"While I think a large number of physicians are interested in using digital therapeutics, the number of those that actually are is pretty low at this point," Aylward said. "Some of the challenges are how they fit into the clinical workflow [and] the process they have to go through for reimbursement. And I think there's a lot of education that needs to happen with digital therapeutics compared to if you're prescribing a drug, for example. There's a lot of education, onboarding and then patient engagement to really drive home the adoption of these tools."

Mendelson said provider adoption should come as more payers cover PDTs, although that could take some time. The delay in reimbursement could negatively impact companies that have high expenses and need to show their investors a pathway to profitability.

The Serious Business Of Digital Medical Games

By David Wild

25 Jan 2023

There are fewer than a handful of approved prescription video game digital therapeutics, but gamification in patient care is proving its worth as a novel way of treating a range of conditions, from vision loss to dyslexia and ADHD. Now, the onus is on lawmakers and insurers to create a clear path towards reimbursement.

Read the full article here

"As I look at that [PDT] market, it does not surprise me that reimbursement has been slower than what the entrepreneurs anticipated," Mendelson said. "It also does not surprise me that the payment rates are not what the entrepreneurs want them to be…Without wanting to get into specifics of individual companies, I would say that this is really a matter of applying business fundamentals – what is the revenue, what is the profitability, what is the market uptake – and really judging each of these products through kind of a skeptical lens of how the product is likely to develop in the marketplace. But I do think that over time, they will become much more prevalent."