HEALTHARK

The Rise and Fall of Pear Therapeutics

A Reflection on the Promise & Challenges of Digital Therapeutics

While digital therapeutics hold the potential to revolutionize healthcare, Pear Therapeutics serves as a cautionary tale for the DTx industry, revealing the significant challenges that must be overcome to achieve their full potential

The Global Digital Therapeutics Market was valued at USD 3.84 Bn in 2022, and the global digital therapeutics industry is projected to attain a value of USD 27.5 Bn by 2030 at a CAGR of 27.9% during the forecast period, 2022–2030.

This growth is being driven by a number of factors, including the increasing prevalence of chronic diseases, the growing demand for personalized care, and the rising cost of healthcare. However, what the forecast doesn't clearly account for this current reimbursement, acceptance and profitability of the sector that players are realizing.

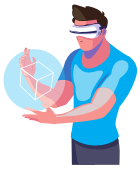
There are a number of different types of DTx products available, including:

Mobile apps

Provides self-management tools for chronic diseases

VR and AR applications

In use to treat a variety of conditions, such as pain, anxiety, & PTSD



Wearable devices

Track patient activity and provide feedback on health behaviors

Digital games

Track patient activity and provide feedback on health behaviors

Some successful DTx that are being used to treat a variety of conditions:

Interactive EndeavorRx for **ADHD**

Diabetes Prevention Program for **type 2 diabetes**

Offers digital therapeutic for **pain relief**

EaseVRx for **pain relief**

As the digital therapeutics industry continues to grow, we can expect to see even more innovative and effective treatments for a variety of conditions

In recent years, partnerships and strong VC funding infusion are emerging across stakeholders

Partnerships strive to integrate digital therapeutics seamlessly into existing healthcare systems and ensure reimbursement for these innovative interventions.

Funding in this sector have collectively raised to $1.1 Bn in H1 2022, accounting for a 20% growth over same period previous year. The US leads DTx funding landscape at $456 Mn within Q1 2022. Early-stage deal share has increased to 60% in the Q1 and Q2 of 2022.

THE TALE OF Pear THERAPEUTICS

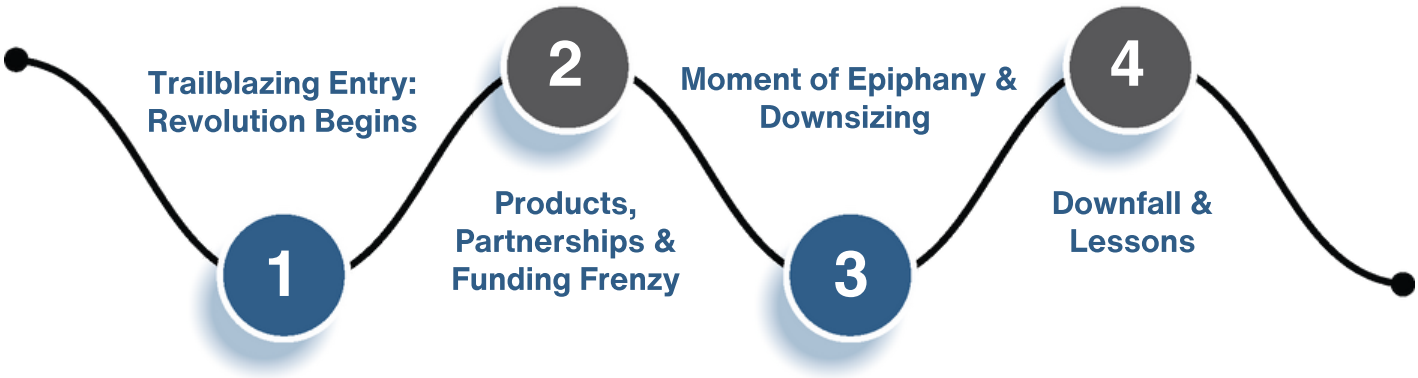
In general, Pear Therapeutics indicated favorable revenue growth, increased patient accessibility, enhanced RWE, and the adoption of cost-saving strategies to enhance financial performance, however, the bankruptcy of Pear Therapeutics is a cautionary tale for the digital health industry.

CEO, Corey McCann

Pear Therapeutics

> *Payors have the ability to deny payment for therapies that are clinically necessary, effective, and cost-saving. In addition, market conditions over the last 2 years have challenged many growth-stage companies, including us*

The story of Pear Therapeutics unfolds in 4 phases:



1 TRAILBLAZING ENTRY: REVOLUTION BEGINS

Pear's FDA-cleared digital therapeutics revolutionized medicine, paving the way for a new era of treatment

Mar 2013

Foundation

Pear Therapeutics entered the market with the aim of revolutionizing medicine through the pioneering development of clinically validated software-based therapeutics

Feb 2016

$20M Equity Financing

The investment allowed Pear to develop and release a range of eFormulations, which encompassed reSET and reSET-O, Pear's digital therapies designed for the treatment of SUD

Sep 2017

Received FDA clearance for reSET

The FDA approved Pear's De Novo request, resulting in the clearance of its SUD program, reSET, as the first-ever digital therapeutic to receive FDA clearance

Jan 2018

Raised $50M financing

Pear secured Series B funding to support the ongoing development and commercialization of its prescription digital therapeutics

2 PRODUCTS, PARTNERSHIPS & FUNDING FRENZY

Pear's innovative products portfolio and partnerships driven commercialization model brought about a paradigm shift in healthcare delivery, transforming how patients receive care

Mar 2018

Inked a development deal with Novartis

Novartis and Pear collaborated to create digital solutions for schizophrenia and multiple sclerosis treatment, enhancing Novartis medications

Apr 2018

Partnered with Sandoz for commercialization

Sandoz and Pear partnered in a go-to-market deal of reSET and reSET-O for drug abuse; Novartis' Sandoz unit took on sales and marketing for reSET and reSET-O

Dec 2018

Received FDA clearance for reSET-O

Pear and Sandoz received market clearance to reSET-O for the treatment of OUD, a prescription-only mobile medical application

Jan 2019

Raised $64M for reSET-O

Completed Series C funding to support the global commercialization of reSET, demonstrate clinical uptake, efficacy and the product's ability to be reimbursed

Oct 2019

Ended partnership with Novartis' Sandoz

Sandoz ended its commercialization experiments; Pear built a standalone commercial infrastructure solely supporting reSET, reSET-O and future PDTs

Mar 2020

FDA authorized 3rd PDT, Somryst

Pear received FDA authorization for **Somryst**, the first prescription digital therapeutic neurobehavioral app aimed at chronic sleeplessness

Sep 2020

First health plan partnered with Pear

Pear began its journey towards reimbursement when PreferredOne partnered to offer coverage for reSET and reSET-O in Minnesota and nationwide across the US

Nov 2020

Launched Somryst via direct-to-patient telehealth model

Pear started providing its app to patients to treat insomnia, similar to the first-line care offered by an in-person specialist

Dec 2020

Completed $80m Series D financing

Pear succeeded to land on a $80 Mn financing through a venture capital round led by SoftBank's Vision Fund 2

Apr 2021

Introduced wearable sensors and activity trackers

Pear collaborated with Empatica and etectRX, and a licensing deal with KeyWise to offer use of wearables and digital biomarkers, digital pill to enhance the medication adherence, and detect changes in mental health via smartphone respectively

Oct 2021

Pear announced its first state Medicaid program

MassHealth extended coverage for Pear's PDTs reSET and reSET-O, targeting SUD and OUD, without the requirement of prior authorization

Dec 2021

Pear Therapeutics went public

Pear Therapeutics went public through a $175 Mn business combination with Thimble Point Acquisition Corp., a SPAC

Apr 2022

Announced first telehealth offering

Pear announced it's first telehealth offering with PursueCare, a telehealth addiction treatment provider with a digital health model for SUD and OUD

3 MOMENT OF EPIPHANY & DOWNSIZING

While engaging in various transactions, Pear soon realized the burden of insufficient reimbursement, high R&D costs, a large workforce, and underperforming sales

Jul 2022

CEO announced first layoff

Pear recognized its escalating personnel-related expenses, insufficient reimbursement for its products, and huge R&D expenses. This resulted in laying off ~25 employees (9%) to save around $28 Mn over the next 18 months.

Nonetheless, the company incurred a charge of $0.9 Mn to cover severance payments and temporary benefits for the affected employees

Aug 2022

Utah-based SelectHealth signed to cover reSET-O

SelectHealth signed for Pear's reSET-O among more than 1 Mn members in Utah, Idaho and Nevada, however Pear faced challenge addressing the regulatory requirements of each state

Sep 2022

Pear faced second layoff

Pear realized its increase in personal-related expenses and laid off ~59 more employees (22%) with an expectation of saving annual cost of ~$10.7 Mn in 2023

Oct 2022

Expanded commercial reimbursement

Pear tried to expand its commercial reimbursement of its products with coverage by Highmark and Excellus, but however, despite these efforts, the coverage obtained was still insufficient

Nov 2022

Evaluated the impact of Somrys on healthcare resource use

Despite presenting an analysis at ISPOR Europe 2022 showing per-patient cost reductions of $8,202 over 24 months, Pear was unable to convince payers and providers to fully accept and adopt their solutions

4 DOWNFALL & LESSONS

Despite an initially successful journey, Pear faced an unfortunate bankruptcy driven by challenges in reimbursement and a decline in financial performance

Mar 2023

Pear withdrew its previous financial forecasts

Pear realized its escalated expenses related to its extensive pipeline, high R&D costs, inadequate reimbursement coverage, and personnel-related expenses, and filed a notice with the US SEC to withdraw its financial forecasts for 2022 and 2023, (estimated revenue of $22 Mn in 2022, a 400% increase from $4.2 Mn in 2021).

Furthermore, the company planned to sell up to $300 Mn worth of stock shares

It then announced their intension of exploring other **strategic alternative** such as acquisition, sale, merger, divestiture of assets, licensing, etc.

Apr 2023

Filed for protection under Chapter 11 of the US Bankruptcy Code

Pear filed to sell assets and laid off more than 90% of its remaining employees However, with the protections afforded by the Bankruptcy Code, Pear intended to continue their marketing efforts to potential purchasers interested in specific assets as well as continuing to seek a sale of the whole business

May 2023

Sold assets at auction after bankruptcy filing

Four different companies agreed to buy the assets of Pear for $6.05 Mn, far short of the $32 Mn debt it carried

Nox Health: Offered the largest bid of $3.9 Mn to acquire the assets related to Somryst

Welt Corp: Offered $50,000 for Pear's migraine-focused program

Harvest Bio: Offered $2.03 Mn for the ISF licenses and patents, assets related to multiple sclerosis, schizophrenia, depression and other pipeline projects and trademarks, its PearConnect commercial platform and the rights to the reSET and reSET-O

Click Therapeutics: Offered $70,000 for the patents for digital therapeutic development, and those related to the company's Invention Science Fund, or ISF

Overall, despite their best efforts, Pear Therapeutics faced a number of challenges that led to its downfall.

It faced low acceptance among potential users and payers, impeding their growth and success. The company relied heavily on third-party pharmacies, further complicating their operations. The company also faced numerous other challenges such as excessive workforce and R&D expenses, and underperforming sales. Moreover, they encountered difficulties in effectively treating substance use and opioid use disorders, further impacting their progress.

Sadly, these cumulative factors took a toll on Pear Therapeutics, destabilizing their financial standing and ultimately leading to their downfall.

WHAT WENT WRONG?

Inadequate coverage and reimbursement

Pear established a HCPCS code, partnered with major payers, and secured some coverage for its DTx (Medicaid, BlueCross BlueShield, SelectHealth). However, Pear's lead products, reSET and reSET-O, primarily found coverage through state Medicaid programs, and was unable to secure reimbursement for its products on high scale. As a result, Pear was unable to generate enough revenue to sustain its operations

High cost of product

Pear's solutions cost an average of $1,300 for 3 months, and made them unaffordable for many patients who were not covered by insurance. Also, the patients covered by Medicaid gets less paid than other payers. The different approaches to Medicaid within each of the 50 states made it even more difficult to provide consistent care to all patients

Low market acceptance among payers and providers

Despite the large amount of investments secured to fund a solid evidence base, Pear was unable to build a strong enough case to achieve reimbursement at scale. In today's economic climate, payers require compelling health economic data, budget impact models, and RWE for large numbers of users to demonstrate the direct benefits of digital therapeutics (DTx) solutions. Additionally, payers need to see evidence that providers are interested in adopting and using DTx solutions

High workforce headcount

Pear incurred net losses of $75.5 Mn and $65.1 Mn for the year ended 2022 and 2021, respectively, representing a period-over-period increase in net loss of $10.3 Mn or 15.9%. This increase in the net loss was primarily due to a $22.7 Mn increase in personnel-related expenses related to increased headcount during the first half of 2022 compared to 2021, and severance costs associated with the 2022 reductions in workforce

High R&D expenses

In 2022, Pear increased its investment in R&D by 30%. The increase of $11.3 Mn was primarily due to an increase of $8.7 Mn of personnel-related costs from higher average headcount and subsequent severance costs in workforce, and $2.1 Mn of impairment of a previously acquired intangible asset. In addition, in the early phases of development, the R&D costs were often devoted to platform and POC studies that were not necessarily allocable to a specific product. This led Pear to lose track of cost at a project level

Underperforming sales

Gaining access to patients and physicians is very expensive. Pear built out direct to consumer (D2C) and HCP sales teams prior to having reimbursement contracts in place. Given Pear's considerable workforce headcount, significant revenue would have needed to be generated to break even

Complete reliance on third party digital pharmacies

Pear relied completely on its limited number of third party digital pharmacies for the fulfillment of prescriptions and did not own or operate any pharmacy, nor were licensed to perform pharmacy fulfillment services. It has no control over the ability to maintain adequate quality control, quality assurance, and qualified personnel. As a result, among 14,000+, and 45,000+ prescriptions that were written for Pear's products in 2021 and 2022, just 51% and 53% respectively of these were actually got filled

Large pipeline before proving commercial viability

Pear build out the pipeline creating over 50 products segregated across discovery, POC, and pivotal stage. However, it built out a pipeline before it had really proven the commercial viability of its first few products

First mover disadvantage

Pear bore a large share of the costs (in both time and $) for blazing some trails that benefit all those who follow. It paid tax by being the one of the first to seek regulatory clearance for a DTx, and were highly dependent on their ability of marketing function to adequately promote, and market DTx among key stakeholders, particularly payers

Challenges while dealing with SUD and OUD

Pear's DTx products have been shown to be effective, but SUD/OUD treatment is still challenging. Given the current market maturity of DTx, these are more likely to succeed in less complex settings where they can be used as a standalone treatment

SOME **LESSONS** THAT CAN BE LEARNED

Dependency on reimbursement for digital innovators

Even if a digital therapeutic (or any other digital innovation) is clinically effective and cost-saving, it will not be successful if it is not reimbursed by payers. This is a major challenge for the DTx industry, as despite the company's achievements, payers have the authority to deny payment for therapies that are clinically necessary, effective, and cost-saving

Awareness of market conditions

The digital health industry is still in its early stages of development, and market conditions can change quickly. Pear Therapeutics was founded in 2013, and it went public in 2021. However, the market for digital therapeutics has not yet matured, and this was a factor in Pear's bankruptcy

Need for regulatory clarity around DTx products

The slow country-by-country market access adds complexity. Unlike general health and wellness apps that can be deployed globally with fewer regulatory consequences, DTx are regulated differently in different countries. This can make it difficult to obtain market access. DTx providers must gain a thorough understanding of each region's requirements and develop adaptable strategies ahead of time, if their business case depends on global expansion

Improvement in data collection

Insufficient data and clinical evidence on the effectiveness of the products make it difficult for the company to make the case for reimbursement and to demonstrate the value of its products to patients. DTx companies need to collect data on the effectiveness of their products in order to build trust with payers and patients

Improvement in digital perception

There is some skepticism around patient adoption of digital therapeutics products. Some patients may try out the technology but lose interest after a few days or weeks. There are also concerns about data privacy. This is a challenge because it can be difficult to get patients to use digital therapeutics, even if they are effective

Improvement in technology literacy

Digital therapeutics are most effective when patients are engaged in their care and some patients may not be comfortable using digital devices or may not have the necessary technology skills. This means making sure that digital therapeutics are easy to use and that patients understand how to use them

Dependence on HCPs & learning to incentivize them

The limited financial incentives and the substantial time investment required to assess DTx options contribute to a lack of motivation among HCPs. It is crucial to think through a viable model to support HCPs to drive adoption and prescription of digital solutions

Pear Therapeutics' bankruptcy serves as a reminder that even the most innovative and impactful companies can face obstacles in the digital health landscape. While their story underscores the challenges faced by growth-stage companies, it should not overshadow the immense potential of digital therapeutics and health towards improving patient health.

The industry continues to evolve, attracting new players and fostering collaborations to improve patient access, overcome reimbursement hurdles, and deliver effective interventions

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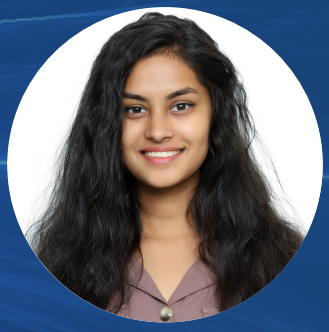

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