STANFORD GRADUATE SCHOOL OF BUSINESS

CASE: SM-369
DATE: 08/22/23

PEAR THERAPEUTICS' FAILURE: PAYING THE TRAILBLAZER TAX

Aidan Tei could not shake the image from his mind. He sat in his favorite armchair, cradling a steaming mug of coffee, the morning sun casting long shadows across his home office. The news of Pear Therapeutics' failure had hit him like a ton of bricks. The digital therapeutics company had once represented the bright future of health care, and now it was in ruins. He couldn't help but feel a sense of personal loss, as he had come close to investing in the company just a few years prior.

He stared out of the window, the city skyline gleaming in the distance, and allowed himself a moment to reflect. Tei had built a successful career as an investor in health care technology, guided by his intuition and a passion for innovation. Digital therapeutics, with its promise to disrupt the health care industry, had captured his imagination like nothing else. He envisioned a world where software-based interventions transformed patient care, making it more personalized and cost-effective than ever before.

But now, in March 2023, the failure of Pear Therapeutics clouded that vision, casting a shadow of doubt over the future of digital therapeutics. Was this a harbinger of doom for the entire industry, or just an isolated incident? As he contemplated the implications for his investment portfolio, Tei knew that he needed answers.

In the days following the news that spring, Tei immersed himself in the world of digital therapeutics, driven by an intense desire to understand the factors leading to Pear Therapeutics' downfall. He realized that to piece together this puzzle, he would need to gain perspectives from various stakeholders—health care providers, payers, regulators, and patients.

James Tai, Ethan Goh, Margaret Wenzlau, Shikha Avancha, and Professor Kevin Schulman prepared this case solely as the basis for class discussion. Stanford GSB cases are not intended to serve as endorsements, sources of primary data, or illustrations of either effective or ineffective handling of an administrative situation. Funding for this case was provided by the Stanford Graduate School of Business.

Tei knew he would ultimately have to confront a question that could define his future as an investor: Could he continue to believe in the transformative power of digital therapeutics, or had the failure of Pear Therapeutics and the harsh realities the company had faced in a rapidly evolving health care landscape shattered that dream forever?

DIGITAL THERAPEUTICS DEFINITION: PILL OR PIXEL?

Investors were excited by a new category, Digital Therapeutics (DTx). DTx were evidence-based, software-driven therapeutic interventions designed to prevent, manage, or treat medical disorders or diseases. Developers envisioned packing the power and hefty reimbursement of a pharmaceutical product into a software product. While this was a new benefit category, there was so much science emerging about the potential benefits of this approach. Instead of going to a pharmacy, patients could download a software app designed to treat their disease. DTx could retain the best of the branded pharmaceutical business model without the development costs and product lead times. Plus, the clinical risk was much more modest—there would be almost no chance of a drug-related toxicity to be uncovered in development. This market was valued at $5 billion in 2022, and expected to grow at an astonishing CAGR of 27 percent through 2030.[1]

The term "digital therapeutics" was first introduced by Dr. S. Cameron Sepah et al. in 2015 as "evidence-based behavioral treatments delivered online,"[2] emphasizing the potential of DTx to increase the accessibility and effectiveness of health care. Further refining the concept, the Digital Therapeutics Alliance (DTA) defined DTx as "evidence-based therapeutic interventions driven by high-quality software programs to treat, manage, or prevent a disease or disorder."[3]

However, this definition was not universally accepted, and interpretations could vary across different countries and research institutions. For instance, the South Korea government defined DTx as "software as a medical device that provides evidence-based therapeutic intervention to patients to prevent, manage, or treat a medical disorder or disease."[4] In contrast, as of 2023 countries like the United States, Germany, the United Kingdom, Japan, Australia, China, and France had yet to provide a government-level definition and generally treated DTx as typical medical devices.

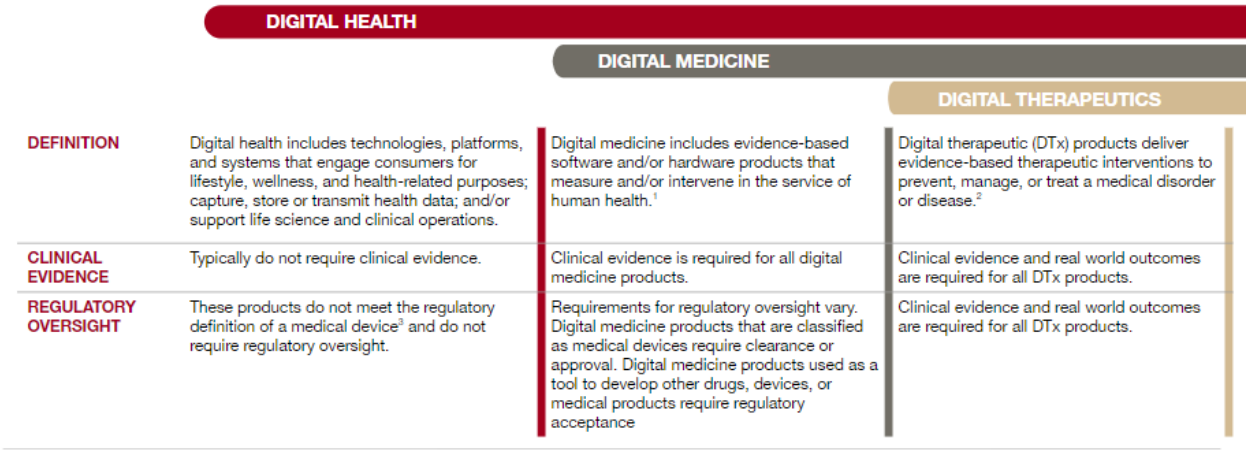
It is important to note that while both DTx and health and wellness apps commonly found on the Apple/Android app stores leveraged technology for health benefits, they differed significantly in their scope, purpose, and regulatory oversight. Health and wellness apps focused primarily on promoting general well-being, facilitating lifestyle changes, and tracking health-related information. From a regulatory perspective, these apps did not make a medical claim about specific clinical benefits. The apps provided useful tools for monitoring physical activity, diet, sleep patterns, and more, but did not typically treat medical conditions.

---

[1] Grandview Research, www.grandviewresearch.com (August 23, 2023).
[2] SC Sepah, L Jiang, AL Peters, "Long-term outcomes of a Web-based diabetes prevention program: 2-year results of a single-arm longitudinal study," *Journal of Medical Internet Research*, 2015;17:e92, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4409647/ (August 23, 2023).
[3] "What is a DTx?" Digital Therapeutics Alliance, https://dtxalliance.org/understanding-dtx/what-is-a-dtx/ (August 23, 2023).
[4] Guideline on Review and Approval of Digital Therapeutics (For Industry), Korean Ministry of Food and Drug Safety, November 4, 2020, https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72624&srchFr (August 23, 2023).

On the other hand, DTx were designed to prevent, manage, or treat specific medical disorders or diseases. From a regulatory perspective, these products were making a specific medical claim and thus were considered regulated medical products. In order to market a product with a medical claim, the company had to provide clinical evidence, usually obtained through rigorous scientific research that possibly included clinical trials.

Product claims matter—is this a digital wellness, diagnostic, or therapeutic product?



Source: Original infographic produced by authors.

DTx came under U.S. Food and Drug Administration (FDA) regulatory purview, similar to other medical products. Under its mandate, FDA was required to establish that medical products sold in the United States were safe and effective. The agency implemented specific guidance for sponsors to ensure that their technologies met FDA standards. Further, the manufacturer's promotion of the product was limited to the "label" or claims approved by the FDA (or cleared through FDA's pre-market 510(k) process). The medical claim and the associated regulatory oversight set DTx apart from general health and wellness apps, ensuring a higher level of trust and accountability in their use for therapeutic interventions.

Prescription digital therapeutics (PDTx) were a subset of digital therapeutics. These were FDA-approved or FDA-cleared clinically validated digital health interventions that added one more step by bringing in a health care provider if a prescription was needed.

Development of DTx Products

Development programs for DTx products required a staged development program designed to develop evidence for FDA's clinical review and for eventual health insurer (payer) negotiations for reimbursement.

DTx development began by identifying an unmet clinical need. Based on this need, DTx companies engineered a solution based on existing clinical evidence or *de novo* clinical discovery. Development proceeded based on the requirements for the FDA regulatory pathway. The solution design phase demanded multidisciplinary collaboration to create a user-centric

product that addressed the clinical need effectively. This approach presented an opportunity for rapid and cost-effective innovation. Akili Interactive's EndeavorRx, a game-based DTx to address attention-deficit hyperactivity disorder (ADHD) in children,[5] emerged from such a process.

Following design, DTx underwent clinical validation. Rather than requiring extensive clinical trials like pharmaceuticals, most countries allowed DTx to gain marketing approval via the medical device regulatory pathway. This typically involved piloting studies (optional) and pivotal clinical trials intended to demonstrate and confirm the safety and efficacy of the treatment. The data analysis phase followed, highlighting another distinctive feature of DTx. Unlike pharmacotherapies, DTx could be updated to improve function or resolve issues based on collected data. This iterative feedback loop ensured DTx remained effective and relevant. The figure below shows a comparison of the benefits of software and pharmaceutical approaches, and how Pear combined the benefits of both:

	SOFTWARE	PHARMACEUTICALS	PDTS (PEAR THERAPEUTICS)
Rapid iteration and enhancement	✓		✓
Real-world data collection	✓		✓
Tested in randomized controlled trials		✓	✓
FDA-authorized safe and effective		✓	✓
Prescribed by clinicians		✓	✓
Reimbursed via product-specific codes		✓	✓

Source: Pear Therapeutics Inc. 10-K filing, for the year ended December 31, 2022, https://www.sec.gov/Archives/edgar/data/1835567/000183556723000018/pear-20221231.htm (August 23, 2023).

The development of DTx also accounted for the potential challenges unique to this field. For instance, user interface/user experience would be critical to adoption and use. Patient access might be limited due to the digital nature of these products and a requirement that users had a smartphone. DTx companies also had to address data security issues related to the storage of clinical data in digital form. Moreover, the success of treatment with DTx required active participation by patients, making patient engagement a key determinant in treatment outcomes.

[5] "Akili Announces FDA Clearance of EndeavorRx™ for Children with ADHD, the First Prescription Treatment Delivered Through a Video Game," Akili press release, June 12, 2020, https://www.akiliinteractive.com/news-collection/akili-announces-endeavortm-attention-treatment-is-now-available-for-children-with-attention-deficit-hyperactivity-disorder-adhd-al3pw (August 23, 2023).

FDA Review Process

DTx were considered regulated medical products, and DTx solutions had to be reviewed by the U.S. Food and Drug Administration. Review by the FDA followed the risk-based review pathways of other medical devices. Most digital therapeutics were evaluated as Class II devices, which meant that they had a moderate to high risk to the patient.[6] From here, DTx manufacturers could either follow the 510(k) pathway, in which they argued that their product was similar enough to a previously reviewed product and could be evaluated for "clearance" by the FDA; or they could follow the De Novo pathway for a novel treatment, which required establishing significant clinical benefit through clinical studies. While the De Novo pathway could take much longer and was more expensive, use of the pathway might be advantageous later when advocating for preferable reimbursement by health insurance companies.

A few special programs allowed some manufacturers to accelerate the review process. The most traditional way to accelerate review was through the breakthrough device designation program. In 2017, the FDA announced the pre-cert program, a pilot program that eased the regulatory requirements for digital health manufacturers with a history of quality product development.[7] Policies under COVID-19 provided a major tailwind for digital therapeutics to gain a regulatory foothold, and many companies took advantage of this; under the Emergency Use Authorization Act, the FDA allowed providers of digital health-powered psychiatric tools to market their products before 510(k) premarket notification filings.

Coverage, Coding, Payment

While pathways to regulatory review were comparatively well established, digital therapeutics manufacturers faced a more ambiguous route to coverage, coding, and payment. The complexity began with the lack of alignment between the FDA and the Centers for Medicare & Medicaid Services (CMS). While the FDA determined safety, receiving FDA clearance or approval did not mean that CMS or other payers would support reimbursement. Unfortunately, this process was not automatic and could take several years, even for breakthrough products.[8] This left a growing number of DTx manufacturers in a tough spot: While their products passed the FDA review, which required significant investment, DTx products faced challenges in gaining reimbursement (and without reimbursement these companies would face cash flow problems).

Emerging digital therapeutics manufacturers faced the challenge of developing a novel pathway for coverage. CMS coverage could be national or regional for Medicare (or Medicaid), while private health insurers could each make their own determination and generally needed to be

---

[6] "What's the Difference Between the FDA Medical Device Classes?" BMP Medical, https://bmpmedical.com/whats-difference-fda-medical-device-classes-2/#:~:text=Class%20II%20medical%20devices%20are,and%20some%20pregnancy%20test%20kits (August 23, 2023).

[7] Evan Sweeney, "FDA unveils precertification pilot program for digital health technology, maps out upcoming guidance," Fierce Healthcare, July 28, 2017, https://www.fiercehealthcare.com/regulatory/fda-unveils-precertification-pilot-for-digital-health-technology (August 23, 2023).

[8] ZA Sexton, JR Perl, HR Saul, AA Trotsyuk, JB Pietzsch, SW Ruggles, MC Nikolov, KA Schulman, J Makower, "Time From Authorization by the US Food and Drug Administration to Medicare Coverage for Novel Technologies," *JAMA Health Forum*, 2023 Aug 4;4(8):e232260, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2807906 (August 23, 2023).

approached individually. CMS was often central to the reimbursement process, as private insurers often waited for CMS's coverage decisions before they provided reimbursement for new therapies. A stand-alone DTx could be covered under drug-like reimbursement, as a medical device, or wrapped in clinician services and billed under more traditional clinical service codes. It was up to the manufacturer to navigate the tradeoffs of preferential reimbursement and pricing with the time required to solidify a path to revenue. Early manufacturers attempted varied routes to coverage, each with their pros and cons:

- Drug-type reimbursement was considered a preferred model for many DTx. It was imagined as a pathway to payment parity with branded pharmaceutical medications. The concept was for each DTx to bill using a uniquely priced national drug code (NDC). This model was not without challenges. The pharmaceutical reimbursement pathway was complex, with pharmaceutical benefit managers (PBMs) and health insurers as intermediaries. PBMs managed branded products through formularies with a rebate model that was separately negotiated by each PBM, and they had been slow to advocate for DTx coverage.

- Many of the initial digital therapeutics addressed mental health and included a cognitive behavioral therapy (CBT) component. Mental health services could be considered as part of a medical health plan, or could be provided through a separate mental health plan with a different set of payer relationships. Lastly, despite FDA approval and efficacy studies, as a novel benefit category, DTx faced higher evidence standards from payers with regards to comparative mental health care effectiveness studies and return on investment analyses.

- Some DTx manufacturers followed a full clinical service model or value-based model where the DTx manufacturer either provided or contracted for the delivery of chronic care management, remote patient monitoring, or remote therapeutic monitoring services. These services had well-established coverage pathways and could offer a billing mechanism to support patients with digital therapeutics, although the reimbursements were not as favorable as for pharmaceuticals. Under this model, the DTx was not a stand-alone technology and required clinician time to review the intervention and manage the patient. One alternative approach to this model was per-member per-month (PMPM) pricing to providers or health plans for access to a DTx or a DTx library.

- Device-like reimbursement would cover DTx via a Healthcare Common Procedure Coding System (HCPCS) code and could be included as part of a patient's medical or durable medical equipment benefit. CMS approved a generic HCPCS billing code for DTx that could be billed as durable medical equipment, an approach that other payers were slowly starting to adopt. This code covered a prescription digital behavioral therapy, FDA-cleared, per course of treatment. This set a precedent for a set price that applied to all CBT-related DTx products using this code. While it opened the door to coverage, it offered little flexibility in pricing between DTx products and, in the end, did not guarantee CMS coverage.

- Lastly, direct-to-consumer reimbursement offered a more immediate path to revenue but carried sticker shock to consumers challenged to pay hundreds of dollars for products they considered similar to other smartphone apps that might be free or low cost.

As of 2023, coverage was minimal but not non-existent for DTx. Despite the various potential pathways to reimbursement, product sponsors still had no guarantee of coverage nor a defined timeline to achieve payment. Much like other therapies, it was up to the sponsors to show a compelling value proposition and unique differentiation behind a therapy: Was it addressing a significant unmet need for patients? How cost-effective was this therapy in comparison to other available therapies? Was there sufficient evidence behind medical claims? Developing a compelling use case and investing in clinical studies or health economic outcomes research were thought to be key steps in attracting payer attention.

PEAR THERAPEUTICS

Pear Therapeutics was founded in 2013 by Corey McCann, Ian McFarland, Stephen Kennedy Smith, and William Greene. McCann's unique background as a physician-scientist with expertise in cellular and molecular neurosciences provided him with a distinct perspective as he embarked on the journey of founding Pear Therapeutics. After his scientific pursuits, McCann ventured into the business realm, working at McKinsey & Company's health care practice in New York before transitioning to the venture capital side. He gained valuable experience at RiverVest Venture Partners and MPM Capital, honing his strategic thinking and investment acumen within the health care sector.

The genesis of Pear Therapeutics was rooted in McCann's quest to identify opportunities to "drugify" cognitive experiences. Specifically, the idea of leveraging software applications to collect data and inform drug dosage, frequency, and timing, while integrating digital therapeutic content, fascinated McCann. This novel approach aimed to create blended products with enhanced efficacy. In a stroke of wordplay brilliance, the name "Pear" emerged, symbolizing the pairing of drugs and software. McCann's personal desire to name a company after a fruit added an element of delight and differentiation to the company, deviating from the traditional naming conventions in the biotech industry. According to one interview, McCann aimed to build the "Genentech of digital therapeutics."[9]

Development and Strategy

Pear Therapeutics pursued a focused and deliberate approach in the development of its digital therapeutics business. From its inception, the company development goal for this new therapeutic class was to demonstrate the software's ability to deliver clinical efficacy on par with prescription medications for patients. The strategic progression involved proving the efficacy of a label, generating value for prescribers and patients, and ultimately institutionalizing the product to secure payer reimbursement.

[9] "Corey McCann, CEO Pear Therapeutics," *Digital Health Today*, March 30, 2021, https://digitalhealthtoday.com/transcripts/corey-mccann-pear-therapeutics/ (August 23, 2023).

The company recognized that the traditional approach to behavior change-based products faced significant difficulties, with clinic-based interventions offering only limited touch-points that were inherently disruptive to patients. Instead, Pear Therapeutics embarked on a patient-centric path, dedicating extensive efforts to understand and collaborate with patients from specific disease populations. This focused approach enabled the development of highly tailored products that drove remarkable rates of engagement and behavior change. Pear Therapeutics aimed to succeed in two key aspects: the specificity of the products, requiring a nuanced understanding of each indication; and the integration of these products into the clinical standard of care. By seeking to embed their products in clinical workflows and foster a symbiotic relationship between clinicians and patients, Pear Therapeutics hoped to achieve enhanced engagement and validation within the medical paradigm.

Pear viewed its products as focused on treating diseases rather than addressing traditional health and wellness conditions. This perspective allowed Pear Therapeutics to leverage telehealth-based business models and PDTx to deliver effective treatment solutions while distinguishing themselves from consumer health and wellness apps as separate verticals.

Pear Therapeutic's Somryst product exemplified the company's approach to delivering digital therapeutics through its remote care platform. Patients suffering from chronic insomnia were targeted by media advertisements, which led to telehealth visits with clinicians who evaluated the patients and prescribed the Somryst product. The prescribed digital therapeutic was then dispensed by Pear Connect, initiating a nine-week treatment period. The product incorporated two therapeutic modalities: algorithmically driven sleep restriction in the initial phase and cognitive behavioral therapy for insomnia (CBTI) content in weeks two to four. The final phase focused on consolidating behavioral changes for long-term efficacy. Notably, the product's impact on insomnia behavior extended far beyond that of traditional pharmacotherapies, as evidenced by significant improvements even 18 months after the nine-week prescription.

In the Pear PDTx model, health care practitioners played a crucial role as prescribers and providers of ongoing support. For instance, Pear Therapeutics' reSET and reSET-O products featured human behavior counselors who engaged with patients on a regular basis. These counselors used the digital platform to review patient progress, provide guidance, and address specific issues related to cravings and triggers. While Pear acknowledged the importance of human interaction in the treatment process, they differentiated their approach by emphasizing software as the curative agent. Corey McCann had envisioned a future where various business models, including prescription digital therapeutics, telemedicine, and virtual pharmacies, would coexist to address the unmet needs in health care. He believed that PDTx would play a critical role in bridging the gaps between traditional telemedicine encounters.

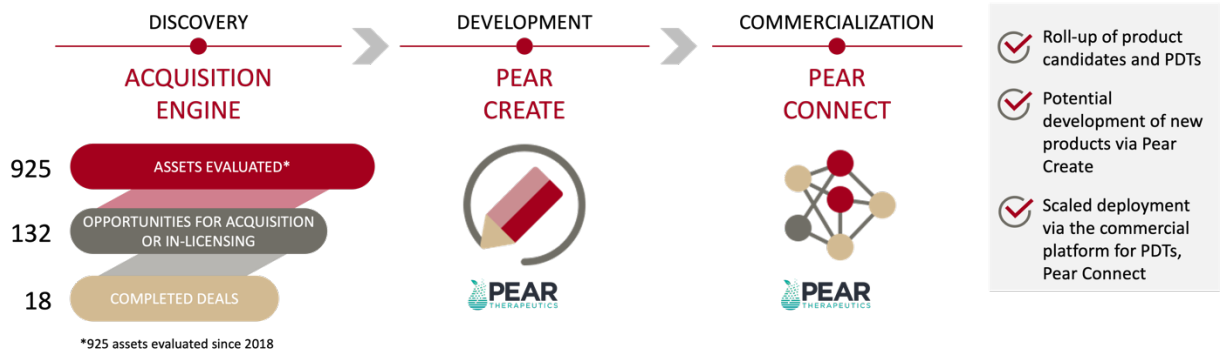
Specifically, McCann was excited about the opportunity for day-to-day engagement with PDTx to allow for real-world demonstration of safety and efficacy in a fully virtual context.[10] Looking ahead, McCann predicted that PDTx products would become the standard of care across multiple indications, supported by robust platforms for dispensing therapies and data collection to support real-world evidence of benefit. Reimbursement for PDTx would involve hybrid benefit categories, with payers recognizing the medical value of these products. McCann considered

[10] Ibid.

value-based agreements (VBAs) to be a significant potential driver and saw PDTx as generating enough data to make VBAs more user-friendly. At the same time, he emphasized the need for a federal benefit type for PDTx, particularly for fee-for-service Medicaid, as a crucial milestone needed for widespread reimbursement and growth of the industry (especially in the substance abuse category).

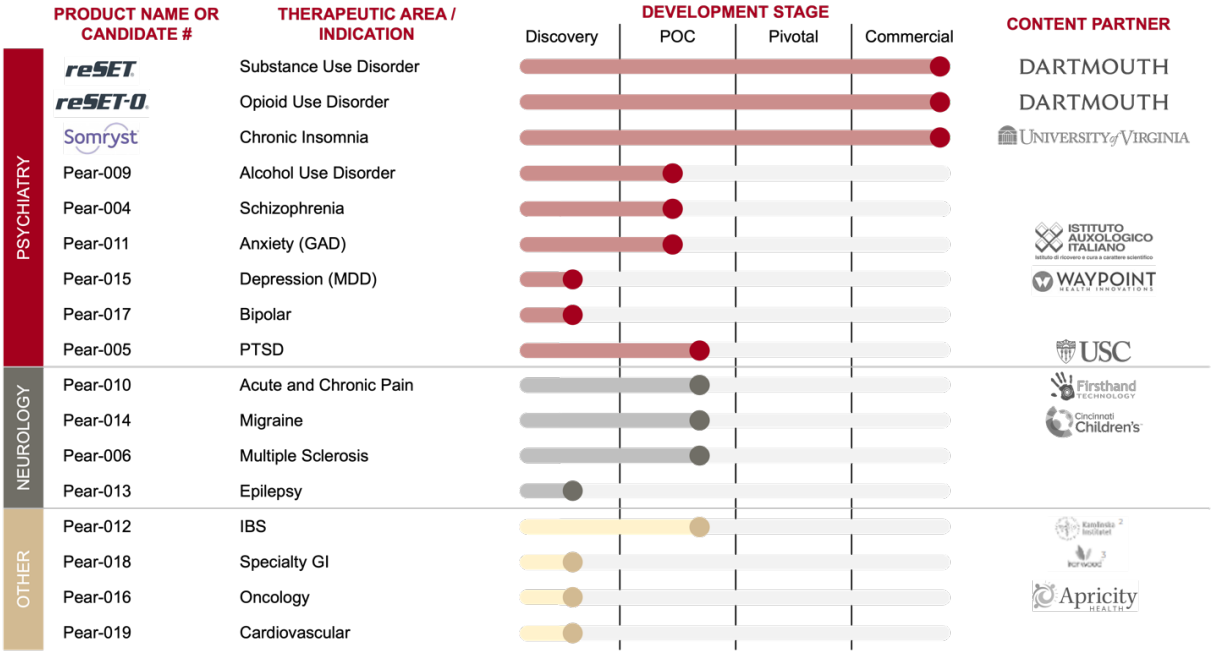
Pear Therapeutics' Pipeline

Pear's DTx engine was designed to fuel product commercialization at scale. Pear wanted to quickly move from a single DTx product to a robust solution portfolio. Pear thought the scale would accelerate a pathway to revenue for the combined portfolio.



Source: Pear Therapeutics 10-K filing, for the fiscal year ending December 31, 2022, https://www.sec.gov/Archives/edgar/data/1835567/000183556723000018/pear-20221231.htm.

The DTx marketplace strategy required a robust pipeline for Pear Therapeutics. In 2022, the development portfolio spanned multiple different clinical indications and had programs at different stages of development, as shown in Pear's SEC filings.



Source: Source: Pear Therapeutics 10-K filing, for the fiscal year ending December 31, 2022, https://www.sec.gov/Archives/edgar/data/1835567/000183556723000018/pear-20221231.htm.

Pear's Commercial Traction

Pear launched its substance use disorder treatment reSET in 2018, and opioid use disorder treatment reSET-O in 2019. Somryst's launch followed a year later in 2020. Yet widespread reimbursement was still lacking. The company supported mechanisms to be reimbursed through several pathways: pharmacy, medical, or self-pay. However, the majority of Pear's revenue came from state Medicaid contracts for reSET and reSET-O. Somryst had even less traction among payers, but was available to consumers for around $899. One option for revenue for Pear was to partner with traditional pharmaceutical companies in co-development and potentially co-marketing and market access development. In 2018, Novartis invested in Pear's series B financing round and started a partnership in treatment products for schizophrenia and multiple sclerosis.[11] Unfortunately, studies revealed these products were not as promising as expected. In January 2021, Novartis published results from a clinical trial of Pear Therapeutics' new digital therapeutic for schizophrenia. The single-blinded 112-person trial found no difference between the Pear app and a placebo app in any outcome measure, including the primary outcome measure of reducing schizophrenia symptoms.[12]

For Pear, balancing continuing investment in development of a robust product portfolio while navigating difficulties in achieving reimbursement and managing investor expectations was rapidly coming to a head in terms of managing cash flow. On July 25, 2022, the company restructured its operations to narrow its near-term business focus and reduce the workforce. On November 14, 2022, Pear announced a second workforce reduction, further reducing headcount by approximately 59 employees. However, the financial challenges continued. For 2022, Pear reported $12.7 million in revenue, but had $48 million in research expenses and $79.6 million in selling, general, and administrative expenses (SG&A)—resulting in an operating loss of $123.4 million.[13] In their 10-K, they reported $43 million in cash, enough for two more quarters of operation.[14] In April 2023, Pear filed for bankruptcy protection, ceased operations, and announced an asset sale of its products.[15]

McCann commented via LinkedIn on the bankruptcy:

> We've shown that our products can save payors money. Most importantly, we've shown that our products can truly help patients and their clinicians. But that isn't enough. Payors have the ability to deny payment for therapies that are clinically

[11] Novartis and Pear Therapeutics to develop digital therapeutics for patients with schizophrenia and multiple sclerosis, Novartis press release, March 1, 2018, https://www.novartis.com/news/media-releases/novartis-and-pear-therapeutics-develop-digital-therapeutics-patients-schizophrenia-and-multiple-sclerosis (August 23, 2023).
[12] Jonah Comstock, "Novartis trial shows no benefits from Pear's schizophrenia app as CEO cites trial irregularities," *Mobihealth News*, January 13, 2021, https://www.mobihealthnews.com/news/novartis-trial-shows-no-benefits-pears-schizophrenia-app-ceo-cites-trial-irregularities (August 23, 2023).
[13] Pear Therapeutics SEC Form 10-K, https://www.sec.gov/Archives/edgar/data/1835567/000183556723000018/pear-20221231.htm (August 23, 2023).
[14] Ibid.
[15] Katie Jennings, "Pear Therapeutics Files For Bankruptcy As CEO Blames Shortfalls On Insurers," *Forbes*, April 7, 2023, https://www.forbes.com/sites/katiejennings/2023/04/07/pear-therapeutics-files-for-bankruptcy-as-ceo-blames-shortfalls-on-insurers/?sh=379cf6d52bd6 (August 23, 2023).

necessary, effective, and cost-saving. In addition, market conditions over the last two years have challenged many growth-stage companies, including us.[16]

Competitive Landscape

Given the large, competitive landscape in DTx, it came as no surprise that companies pursued different commercialization strategies. Although Pear's products were all PDTx, other competitors chose a different path forward. In the following graphic (see p.12) depicting the competitive landscape, chronic disease management and behavioral health emerged as clusters of investment and development within DTx. Leaders such as Pear Therapeutics, Omada, DarioHealth, Akili Interactive, and others begin taking market share. And new pockets of digital therapeutics were starting around oncology and musculoskeletal (MSK) and digestive disorders.

Source: Original infographic produced by authors.

To Prescribe or Not to Prescribe?

Unlike Pear Therapeutics' commercialization strategy, other competitors such as DarioHealth Corp. (NASDAQ: DRIO) developed digital therapeutics for musculoskeletal, metabolic, and behavioral health conditions that did not need a prescription from a provider. Dario developed its Digital Therapeutics as a Service (DTaaS model), and a B2B2C channel.[17] DarioHealth would get a health plan or an employer to cover the benefit, and then Dario reached out directly to the

[16] Corey McCann, statement on LinkedIn, https://www.linkedin.com/feed/update/urn:li:activity:7050137359002038272/
[17] Dario filings, https://dariohealth.investorroom.com/SECFilings (August 23, 2023).

members to bring them on board. In 2022, Dario reported $27.7 in revenue with a net loss of $63.8 million. The company had $49.5 million in cash and securities after a financing round.[18] According to official filings, Dario combined "digital therapeutics, coaching, professional human support and medical devices to drive superior clinical and financial outcomes. We believe that we lead the digital therapeutic market in published outcomes with 38 studies across our suite of solutions, including the first clinical research demonstrating the positive impact of managing multiple chronic conditions with one digital health solution."[19]

On June 7, 2023, Akili Interactive (NASDAQ: AKLI), the developer of EndeavorRx (the first FDA-authorized prescription digital therapeutic video game treatment for pediatric ADHD disorders), announced that the launch of EndeavorOTC. A DTx available through the Apple Store without a prescription for adults 18 years and older, EndeavorOTC incorporated the EndeavorRx technology. The app was free but required in-app purchases ranging from $24.99 to $129.99.[20]

Big Health took the software approach over the pharma route for its insomnia and anxiety therapeutics. Like DarioHealth, the company also sold directly to health plans and employers. Big Health focused on including CBT-based treatments as part of benefits packages for employers.[21] The company was on the digital health formulary for Cigna's subsidiary Evernorth and had partnered with the National Health Service in Scotland.

It is important to note that the competitive landscape for digital therapeutics extended beyond similar digital health start-ups. Traditional health care providers and pharmaceutical companies also played a significant role.

Brick-and-Mortar Service Providers

Traditional brick-and-mortar health care providers—hospitals, clinics, and diagnostic centers—had long been the cornerstone of patient care. These institutions provided face-to-face, personalized care, which could sometimes offer more comprehensive and multidimensional treatment than digital alternatives. They also held existing patient trust and loyalty, which could pose a significant competitive challenge to new, digital entrants. These providers might also subscribe to a "Not Invented Here" philosophy of evaluation of DTx solutions. Finally, providers could also enter the DTx market with their own products and services.

Pharmaceutical Companies

Pharmaceutical companies, with their deep-rooted presence in the health care industry, posed another significant competitive threat. These firms had extensive resources, established distribution channels, and long-standing relationships with health care providers. They also held substantial expertise in navigating complex regulatory landscapes and managing large-scale

[18] Ibid.
[19] Ibid.
[20] EndeavorOTC: Outplay ADHD, Apple Store preview, https://apps.apple.com/us/app/endeavorotc/id6447322997?platform=iphone (August 23, 2023).
[21] "Cognitive behavioral therapy (CBT) in the smartphone age," Big Health, https://www.bighealth.com/lp/cbt-in-the-smartphone-age-report/ (August 23, 2023).

clinical trials. Pharmaceutical companies were clearly interested in exploring the DTx space, either as stand-alone solutions or as complements to existing products. Many pharmaceutical companies had started to invest in or partner with DTx companies, viewing them as a way to enhance existing drug offerings, improve adherence, and generate real-world evidence for their therapies. One of the early entrants in this space, Proteus Digital Health, was envisioned as a lifecycle management strategy for mature pharmaceutical products. However, that effort was not successful.[22]

Indeed, the competitive landscape for DTx was multifaceted, with both traditional and modern players. Navigating this landscape required a nuanced understanding of the opportunities and challenges presented by each potential competitor or collaborator. As the industry continued to evolve, the lines between competition and collaboration would likely blur even further, leading to a more integrated and patient-centered approach to digital health care.

Looking Forward

By the end of 2022, the market was beginning to develop a reimbursement pathway for DTx. Commercial insurers began to develop reimbursement pathways for DTx products.[23] In a bittersweet moment, CMS announced a new pathway forward for DTx reimbursement in March 2023, suggesting there was further interest in the DTx promise by payers.[24]

Aidan Tei took a deeper look at Pear's strategy to determine his next steps. His goal was to determine whether he should anticipate Pear's fate to reflect the future of the DTx sector. He reviewed financial documents (see Exhibits 1 to 4), user experience materials (Exhibit 5), the nuances of Pear's chosen therapeutic, efficacy results (Exhibit 6), and payer utilization management decisions (Exhibit 7).

---

[22] Christine Farr, "Proteus Digital Health, once valued at $1.5 billion, files for Chapter 11 bankruptcy," *CNBC*, June 16, 2020, https://www.cnbc.com/2020/06/15/proteus-digital-health-once-worth-1point5-billion-files-for-chapter-11.html#:~:text=Proteus%20Digital%20Health%20has%20filed,digital%20health%20%E2%80%9Cunicorn%E2%80%9D%20companies (August 23, 2023).

[23] Gabriel Perna, "More Blues agree to pay for prescription digital therapies," Modern Healthcare, November 14, 2022, https://www.modernhealthcare.com/insurance/blue-cross-plans-expand-access-prescription-digital-health-tools (August 23, 2023).

[24] Anuja Vaidya, "CMS Establishes Reimbursement Pathway for Virtual Reality Program," mHealth Intelligence, March 23, 2023, https://mhealthintelligence.com/news/cms-establishes-reimbursement-pathway-for-virtual-reality-program (August 23, 2023).

Exhibit 1
Management Team Discussion from 2022 PEAR 10-K

Financial Highlights

Year-over-year product revenue grew by approximately 178% to $10.4 million from $3.7 million primarily due to an increase in sales of reSET and reSET-O under Access Agreements. Year-over-year collaboration revenue grew by approximately 90% to $0.9 million from $0.5 million primarily due to the development work completed on a Japanese-language digital therapeutic for the treatment of sleep/wake disorders for the Japanese market in collaboration with SoftBank Corp. that was completed in 2022. We also recognized subscription, support, and professional services revenue of $1.4 million for the year ended December 31, 2022, under a new product offering under a pilot offering of a new product by the Medicaid program of a state government.

We incurred net losses of $75.5 million and $65.1 million for the year ended December 31, 2022 and 2021, respectively, representing a period-over-period increase in our net loss of $10.3 million or 15.9%. This increase in the net loss was primarily due to a $22.7 million increase in personnel-related expenses related to increased headcount during the first half of 2022 compared to 2021, and severance costs associated with the July and November 2022 reductions in workforce, partially offset by $8.5 million increase in total revenue period over period and a gain related to the change in fair value of the Public Warrants and the Private Placement Warrants of $6.4 million for the year ended December 31, 2022, compared to a $0.3 million loss for the year ended December 31, 2021. We had an average of 245 full-time employees for the year ended December 31, 2021, and an average of 267 full-time employees for the year ended December 31, 2022. We had a $3.4 million increase in costs related to being a public company period over period, primarily related to our directors' and officers' insurance.

To date, we have funded our operations primarily with proceeds from sales of Legacy Pear's convertible preferred stock, proceeds as a result of the Business Combination, payments received in connection with our revenue contracts and proceeds from borrowings under various credit facilities. We have received gross cash proceeds of $175.3 million as a result of the Business Combination (see Note 3, B*usiness Combination*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K) and gross cash proceeds of $268.2 million from sales of our Legacy Pear's convertible preferred stock; we currently have $30.0 million of debt outstanding under the Perceptive Credit Facility.

Source: Pear Therapeutics Inc. 10-K filing, for the year ended December 31, 2022, https://www.sec.gov/Archives/edgar/data/1835567/000183556723000018/pear-20221231.htm.

Exhibit 2
reSET and reSET-O Economics for 2022

	Q1 2022 Actual	Q2 2022 Actual	Q3 2022 Actual	Full Year 2022 Guidance (Reaffirmed Nov. 14,2022)
Net Revenue	$2.7M	$3.3M	$4.1M	$14M - $16M*
Total Prescriptions[1]	>9,200	>11,000	>11,400	35,000 – 45,000
Fulfillment Rate[2]	57%	56%	60%	50 – 60%
Payment Rate[3]	50%	45%	49%	50 – 65%
Average Selling Price (ASP)[4]	$1,353	$1,323	$1,345	$1,150 - $1,350

Source: Pear Therapeutics Inc. 10-K filing, for the year ended December 31, 2022, https://www.sec.gov/Archives/edgar/data/1835567/000183556723000018/pear-20221231.htm.

Exhibit 3
2022/21 Income Statement

(dollars in thousands, except per share amounts)	Year Ended December 31, 2022	2021
Revenue		
Product revenue	$ 10,417	$ 3,748
Collaboration and license revenue	872	460
Subscription, support, and professional services revenue	1,405	—
Total revenue	12,694	4,208
Cost and operating expenses		
Cost of revenue	8,182	5,233
Research and development	48,311	37,041
Selling, general, and administrative	79,551	67,619
Total cost and operating expenses	136,044	109,893
Loss from operations	**(123,350)**	**(105,685)**
Other income (expense):		
Interest and other (expense) income, net	(3,892)	(4,144)
Change in estimated fair value of earn-out liabilities	45,339	47,038
Change in estimated fair value of warrant liabilities	6,412	(298)
Loss on issuance of Legacy Pear convertible preferred stock	—	(2,053)
Total other income	47,859	40,543
Net loss	**$ (75,491)**	**$ (65,142)**
Unrealized loss on short-term investments	$ (46)	$ (1)
Comprehensive loss	**$ (75,537)**	**$ (65,143)**

Source: Pear Therapeutics Inc. 10-K filing, for the year ended December 31, 2022, https://www.sec.gov/Archives/edgar/data/1835567/000183556723000018/pear-20221231.htm.

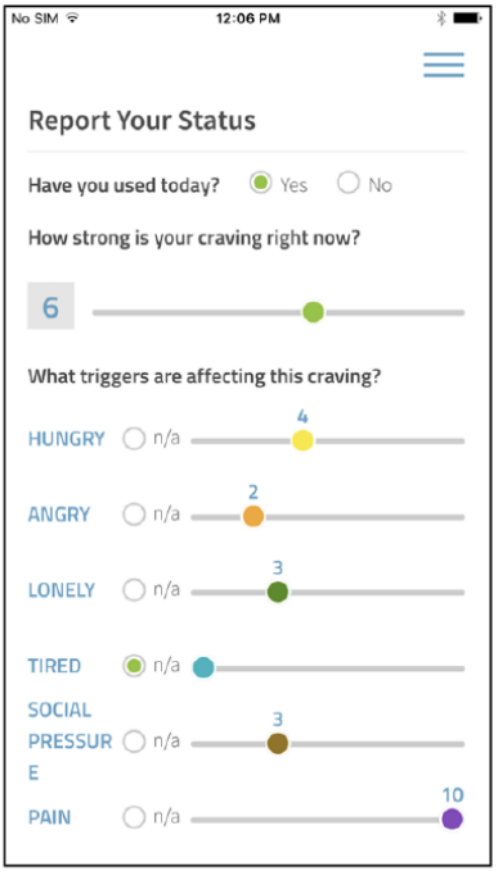
Exhibit 4
2022/21 Income Statement

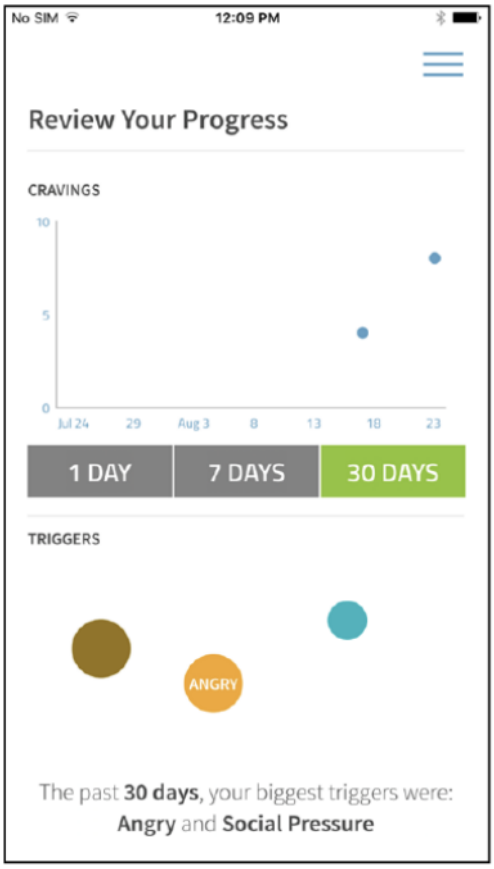
(dollars in thousands, except per share amounts)	December 31, 2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 48,301	$ 169,567
Short-term investments	10,971	5,004
Restricted cash - short-term	69	—
Accounts receivable	6,943	1,794
Prepaid expenses and other current assets	6,675	8,876
Total current assets	72,959	185,241
Property and equipment, net	6,076	6,255
Lease right-of-use assets	8,879	—
Restricted cash - long-term	411	411
Other long-term assets	6,804	5,253
Total assets	**$ 95,129**	**$ 197,160**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,263	$ 1,806
Accrued expenses and other current liabilities	16,464	17,946
Operating lease liabilities - current	1,984	—
Deferred revenues	284	421
Debt	27,447	26,993
Total current liabilities	49,442	47,166
Operating lease liabilities - non-current	8,176	—
Embedded debt derivative	1,245	675
Warrant liabilities	2,116	8,528
Earn-out liabilities	3,024	48,363
Other long-term liabilities	541	1,994
Total liabilities	**64,544**	**106,726**
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2022; and no shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 690,000,000 shares authorized as of December 31, 2022; and 140,454,086 and 137,836,028 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	14	14
Additional paid-in capital	354,092	338,404
Accumulated deficit	(323,474)	(247,983)
Accumulated other comprehensive loss	(47)	(1)
Total stockholders' equity	**30,585**	**90,434**
Total liabilities and stockholders' equity	**$ 95,129**	**$ 197,160**

NET CASH PROVIDED BY/(USED IN) *(in thousands)*:	Year Ended December 31, 2022	2021
Operating activities	$ (113,895)	$ (109,043)
Investing activities	(9,457)	2,883
Financing activities	2,155	164,077
Net (decrease) increase in cash, cash equivalents, and restricted cash	**$ (121,197)**	**$ 57,917**
Cash, cash equivalents and restricted cash—beginning of period	169,978	112,061
Cash, cash equivalents and restricted cash—end of period	**$ 48,781**	**$ 169,978**

Source: Pear Therapeutics Inc. 10-K filing, for the year ended December 31, 2022, https://www.sec.gov/Archives/edgar/data/1835567/000183556723000018/pear-20221231.htm.

Exhibit 5
User Experience Screenshots Included in
De Novo Classification Request for reSET





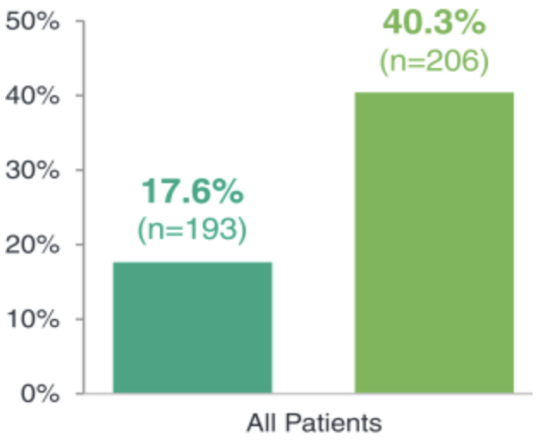
Note: Screenshots submitted to the FDA show the user experience of a patient "Conducting a Functional Analysis" to help them better understand patterns of drug use.

Source: U.S. FDA, De Novo Classification Request for ReSET, https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160018.pdf.

Exhibit 6
Pear Therapeutics RCT and RWE

	Randomized Controlled Trials			Real-World Data		
	Number of Trials	Number of Patients	Duration	Number of Pubs	Number of Patients	Duration
reSET	2* [1-4]	>1,000	12 months	2	>700	6 months
reSET-O	3* [5-12]	>450	12 months	5	>6,900	6, 9, 12 months
Somryst	44† [13-61] (2 FDA pivotals)	>5,000	36 months	3†	>8,000	36 months

reSET Pivotal Clinical Trial. Abstinence in TAU relative to rTAU + PDT.

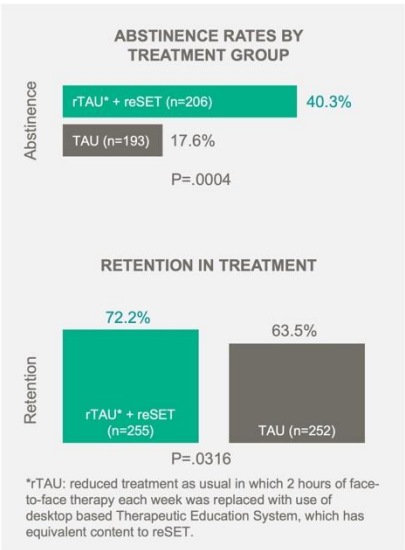


reSET Pivotal Clinical Trial. Abstinence and Retention in TAU relative to rTAU + PDT.

Notes: TAU (treatment was usual), RTAU (reduced treatment as usual), PDT (prescription digital therapeutic).

reSET

HIGHLIGHTS	CLINICAL OUTCOMES SUMMARY FROM 12-WEEK PIVOTAL TRIAL[1]
Abstinence	Among patients whose primary addiction was not opioids, in a secondary analysis, adding reSET to treatment as usual (TAU) more than doubled abstinence rates (40.3% vs 17.6%) during the last 4 weeks of the 12-week trial.
Retention	Among all patients, adding reSET to outpatient therapy improved retention rate compared to TAU (72.2% vs 63.5%) at the end of the 12-week trial.
Safety	Treatment with reSET did not demonstrate a significant difference in unanticipated adverse events compared to TAU.



Source: Pear Therapeutics Inc. 10-K filing, for the year ended December 31, 2022, https://www.sec.gov/Archives/edgar/data/1835567/000183556723000018/pear-20221231.htm.

Exhibit 7
Example of a State Medicaid Utilization Management Review Regarding Pear Therapeutics

In 2020, the Institute for Clinical and Economic Review (ICER) published an evidence report which included published data, to date, evaluating the reSET-O. ICER concluded, "We found no randomized trials, cohort studies or case series that evaluated the DHTs [digital health technologies] reviewed in this report until after the draft report was released. Recently, two uncontrolled studies suggested potential benefits with reSET-O, but there was a high risk of bias for both studies."

Current data is limited to short-term follow-up, and impact on net health outcomes has not been demonstrated. Few of the published studies assess the use of the reSET-O when used outside of a clinic (for example, when downloaded directly to a personal device such as a mobile phone or tablet).

Source: Excerpt from clinical guide for HEALTHY BLUE Managed Medicaid Program, https://provider.healthybluenc.com/dam/medpolicies/healthybluenc/active/guidelines/gl_pw_e000367.html (August 23, 2023).