

The Digital Therapeutics Revolution

Making healthcare more efficient, personal, and cost-effective

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Credits & contact

Research

KAIA COLBAN Analyst, Emerging Technology
kaia.colban@pitchbook.com

reports@pitchbook.com

Data

ZANE CARMEAN Senior Data Analyst

Design

CAROLINE SUTTIE Junior Graphic Designer

Contents

Overview	1-4
Regulations and approval	5
Business model driven by insurance coverability	5-6
DTx & pharma partnerships key to distribution	6-7
Big tech potential to enter market	7
Opportunities	7-8

Therapeutics represent a broad range of products and services used in the medical treatment and remediation of a diagnosed health problem. Traditional therapeutics consist of a range of treatments including medicines, surgery, and both physical and mental rehabilitation, among others. Traditional therapeutics are part of a very analog process that typically consists of a single course of treatment, often recommended by a doctor, with periodic follow ups to track progress. While this treatment process can be safe and effective, it can also be cumbersome to customize to the specific needs of patients, difficult to gauge success and outcomes in real time, and particularly hard to scale to many patients in a cost-effective way.

Emerging digital therapeutics (DTx) represent a category of products and services that relies on software and data to provide health treatments. DTx can represent entirely new approaches to treatment, as well as supplement existing approaches. In either role, DTx technologies promise to help close the gap with traditional therapeutics by providing data-driven treatments that are scalable, easy to manage, and efficiently monitored and adjusted in real-time, thus providing more patient-centric approaches to healthcare.

As with traditional treatments, DTx are evidence-based, clinically validated, and regulated. However, DTx products rely on data inputs that can help customize treatment while monitoring outcomes in real time. DTx products provide point solutions to prevent, manage, or treat specific medical disorders or diseases, such as PTSD. Existing products may require more development in the areas of user experience and integration with existing provider workflows, but these products have the potential to help empower patients, healthcare providers, and payers with intelligent and accessible tools for addressing a wide range of conditions through high-quality, safe, and effective data-driven interventions.

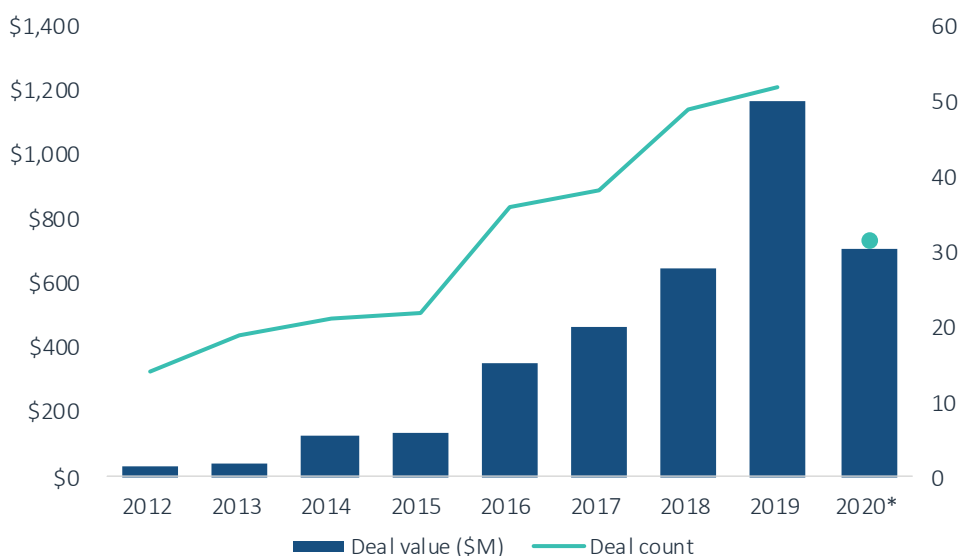
Published on September 14, 2020

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DTx are distinct from pure-play adherence, diagnostic, and telehealth products. However, they may incorporate similar features such as the ability to integrate with mobile health applications, electronic prescribing systems, medical records platforms, and biometric devices. They may also provide complementary diagnostic or adherence interventions and remote intervention delivery. For example, mySugr (which was acquired by Roche in 2017 for \$100.0 million) developed a diabetes management app that provides personalized education and support from experienced, certified diabetes educators to the patient's phone. Using mySugr reduces office visits while providing personalized insights derived from integrated glucose monitors to continually track blood sugar and provide food and medication intake-logging capabilities. Other benefits of DTx include the ability to extend treatment to more patients—particularly those in areas that lack healthcare infrastructure, better alignment of treatment to outcomes, more efficient payment capabilities, and more customized care.

DTx are attracting significant venture capital investment, and we expect the number of companies developing DTx to continue to grow at a rapid pace. Investments in DTx companies have grown from \$134.3 million in 2015 across

DTx VC deal activity



Source: PitchBook | Geography: Global
*As of August 27, 2020

22 deals to \$1.2 billion in 2019 across 52 deals. We have seen \$709.7 million invested across 32 DTx deals as of August 2020.

The global DTx market is currently valued at \$2.1 billion and is expected to reach \$6.9 billion by 2025, growing at a CAGR of 26.7% during the forecast period.¹

1: "Digital Therapeutic (DTx) Market." Markets and Markets, 2020.

Notable VC deals in 2020

COMPANY NAME	CLOSE DATE	DEAL SIZE (\$M)	DEAL TYPE	VC RAISED TO DATE (\$M)
Mindstrong	May 21, 2020	\$100	Series C	\$159.4
Virta Health	January 10, 2020	\$93.1	Series C	\$166.9
Omada	May 18, 2020	\$57	Series D	\$258.1
Mojo Vision	April 29, 2020	\$51	Series B1	\$137.9
Thirty Madison	August 14, 2020	\$47	Series B	\$70.0

Source: PitchBook | Geography: Global
*As of August 27, 2020

Notable VC deals in 2019

COMPANY NAME	CLOSE DATE	DEAL SIZE (\$M)	DEAL TYPE	VC RAISED TO DATE (\$M)
Bright Health	December 16, 2019	\$635	Series D	\$1076.7
Omada	June 26, 2019	\$73	Series D	\$201.1
Pear Therapeutics	January 4, 2019	\$64	Series C	\$139
Mojo Vision	March 19, 2019	\$58	Series B	\$86.9
Talkspace	May 29, 2019	\$50	Series D	\$109.6

Source: PitchBook | Geography: Global
*As of August 27, 2020

Notable VC exits since 2017

COMPANY NAME	CLOSE DATE	TOTAL INVESTED (\$M)	EXIT SIZE (\$M)	POST VALUATION (\$M)	DEAL TYPE
MySugr	June 30, 2017	\$100	\$100	\$100	Merger/ acquisition
Voluntis	May 30, 2018	\$35.6	\$89.7	\$125.3	IPO
Propeller Health	January 6, 2019	\$225	\$225	\$225	Merger/ acquisition
Blue Mesa	January 7, 2020	N/A	N/A	N/A	Buyout/ LBO
Dr. Jud	June 3, 2020	N/A	N/A	N/A	Merger/ acquisition

Source: PitchBook | Geography: Global
*As of August 27, 2020

Digital therapeutics have the potential to:

- Deliver high-quality, evidence-based therapies to underserved and under-diagnosed populations
- Make effective, patient-centered treatments accessible and scalable at relatively low cost
- Support healthcare teams in countries with varying degrees of health-care infrastructure
- Transform how patients and populations manage medical conditions and engage in their own healthcare



Healthcare providers and health systems

- Enable intelligent data-driven care management and clinical decision making
- Provide patients with effective self-managed therapeutics
- Serve a greater number of patients more effectively and at a lower cost
- Receive accurate patient-engagement data, which can be integrated into provider portals, clinical data warehouses, and patient-management platforms



Public and private payers

- Improve clinical and health economic outcomes at population and patient levels
- Decrease medical costs
- Expand therapeutic access and provide treatment options for previously undertreated conditions
- Increase data access to facilitate population health-outcome analysis



Patients and caregivers

- Receive enhanced personalized care and progress updates on goals and outcomes
- Administer therapeutics in a more engaging and convenient way
- Provide and receive care at more convenient times and locations
- Increase access to clinically effective therapeutics

Regulations and approval

While the regulatory pathway for this industry is in its infancy, and a clear set of criteria has yet to be established, DTx must demonstrate they are safe and effective in a manner similar to traditional medicines. Companies creating DTx must invest significant time and money to gain regulatory approval and demonstrate clinical outcomes regarding the specific condition for which the DTx treatment is designed. For example, Sleepio conducted five randomized control trials and published 20 peer-reviewed clinical papers to prove the accuracy of its sleep improvement program.

Currently, products are approved according to their potential risk, with low-risk products requiring less up-front evidence. However, once employed, many DTx products generate data that can help provide clinical evidence. DTx are well-suited to provide real-world evidence as they can continually track and analyze vast data sets at low cost.

Currently, the FDA is working to streamline regulatory processes for DTx. In 2017, the FDA announced the creation of a Digital Health Software Precertification Program, a pilot for approving software-based medical devices. This program enables the FDA to approve the developer of a DTx product instead of each individual software release, quickening product development. Nine companies were selected to participate in the program, which began in 2019. Participants are Apple, Fitbit, Johnson & Johnson, Pear Therapeutics (VC backed), Phosphorus (VC backed), Roche, Samsung, Tidepool (VC backed), and Verily. Pear Therapeutics, the first company to be cleared to develop DTx, aims to integrate software applications with previously approved pharmaceuticals and treatment paradigms to enhance outcomes. Pear's lead product, reSET[®], is an FDA-cleared 12-week prescription-only therapy for substance use disorder (SUD), designed to be used as an adjunct to standard outpatient treatment.

Business model driven by insurance coverability

DTx nearly always follow a model that leverages physicians and hospitals to distribute products via referrals and prescriptions. These products can then attain a drug code and the ability to bill through pharmaceutical claims/spend and drug benefits—although not all DTx products are covered by insurance.

Obtaining insurance coverage for a new therapeutic through traditional health plans is a lengthy and involved process. A key advantage of digital solutions is their relatively low cost compared to traditional face-to-face solutions, as well as their ability to gather usage and outcome data in real time, which makes it easier for traditional insurers to determine coverage levels. However, while these features can help developers demonstrate the value of their DTx, proving measurable and material outcomes over long time periods can be complicated. Many chronic diseases fester for years before requiring costly treatment. For example, in the case of type 2 diabetes, the most expensive procedures, such as amputation, are generally long-term consequences that occur after the disease has worsened for many years. This may disincentivize private health plans from offering preventative therapeutics as individuals in the United States typically change private healthcare insurers every five to ten years. Furthermore, proving

clinical effectiveness could require lengthy longitudinal studies.

We expect DTx products targeting health conditions on which they can have an immediate impact and costs that can be measured and compared against traditional treatments will have an easier route to insurance coverage. For example, Bravrr's wearable diagnostic and digital therapeutic technology provides cognitive training to reduce stress, eliminate fear, and conquer past trauma. The cost of their DTx technology can be directly compared the cost of traditional mental-health-focused therapeutics such as psychiatric drugs and services provided by psychologists and psychiatrists. Even for DTx products covered by insurance, scheduling reimbursements remains a question. One model involves tracking the usage of the DTx product and implementing payment plans based on the level of treatment adherence.

Targeting employer health plans and single-payer systems may be more advantageous for DTx providers. Single-payer systems, such as government programs that provide life-long coverage, are more exposed to longer-term health risks and are hence incentivized to pay for prevention therapies that might mitigate expensive treatments in the future. DTx may also help employers in many novel ways, such as increasing employee morale, decreasing absenteeism, and reducing medical costs. For example, 49% of children with asthma miss school due to the disease, causing parents to miss work. For this reason, employers could benefit from the provision of asthma-management products to help reduce work interruptions. Propeller Health has created a sensor that attaches to an inhaler and integrates with a mobile application that can help patients stick to treatment plans, understand why flare-ups occur, and mitigate their frequency.

DTx & pharma partnerships key to distribution

We believe DTx providers can augment the digital strategies of traditional pharmaceutical companies in many ways. DTx providers have core competencies built around big data and advanced analytics, hardware engineering, human-centered product design, and innovative, flexible business models—skills many biopharma companies lack. In turn, DTx providers can benefit from the larger scale and market access pharmaceutical incumbents can provide.

While some DTx products are used independently, others are combined with a medicinal drug to improve the drug's effect, further incentivizing a partnership approach. This is especially true for DTx products that use data and patient engagement to offer insights into the effectiveness of traditional therapeutics. For example, GlaxoSmithKline partnered with Propeller Health to gain access to device-generated data that would enable them to improve patient care and reduce clinical trial cost and complexity.

While we expect partnerships between pharmaceutical and DTx companies, we do not foresee the former entering the market in a competitive way, at least not in the near term. This is owing to the following reasons:

- Developing DTx requires significant investment and a large appetite for risk in a segment of the market that is outside of the traditional focus of pharmaceutical companies.
- While the pharmaceutical industry is experiencing healthy margins, DTx business models are still uncertain. The pharma industry is likely to wait until clearer revenue and profit models have been developed.
- While drug patents allow 20 years of protection from generic competition, technology and devices can be more easily replicated and commoditized by competitors.
- The R&D, manufacturing, and distribution methods of DTx and pharmaceutical companies are very different. Pharmaceutical companies would need to develop entirely new supply chain competencies to compete.

Big tech potential to enter market

Big tech firms are increasingly making inroads into the healthtech market as their data-gathering, scale, and analytic capabilities enable them to develop distinct healthcare infrastructure. Apple has created many devices, such as the Apple Watch, and platforms/services, such as Health-kit-enabled apps, to help patients monitor their health and communicate with their care team. Amazon has acquired many healthtech startups such as Pillpack, partnered with JP Morgan and Berkshire Hathaway to create Haven Healthcare, and created the ability for their voice-app Alexa to diagnose health problems. We believe these tech firms will continue to pursue the healthtech field and are likely to partner with or acquire DTx startups given the natural synergies, which include digital distribution competencies as well as products.

Opportunities

Focus on the user experience as much as the treatment: Consumers report that experiences with digital therapies tend to fall short of other digital products,² such as traditional mobile apps. This suggests there may be a gap in the market for DTx startups to match treatment capabilities with the user experience. As DTx products are point solutions used only once during a patient's healthcare journey, providers should ensure their products can integrate well with the other data and products used by the patient. A positive user experience is critical to consumer engagement and adherence rates and improves adoption among physicians and payers. Gamification elements have also been shown to improve patient engagement and motivation,³ representing another potential direction for DTx R&D. The FDA approved Alkili's video game-based ADHD DTx, EndeavorRx, in June 2020, making it the first game-based DTx to gain FDA approval as a prescription treatment.

Focus on integration with provider workflows: We expect physicians to be more willing to adopt DTx products that integrate into existing physician workflows. For this reason, startups that pursue a strategy of early engagement with

2: "The Promise of Digital Therapeutics," McKinsey & Company, Austin Hackett et al., March 31, 2020.

3: "Understanding Persuasion Contexts in Health Gamification: A Systematic Analysis of Gamified Health Behavior Change Support Systems Literature," International Journal of Medical Informatics, Tuomas Alahäivälä and Harri Oinas-Kukkonen, December 2016.

hospitals and clinicians may have an edge in the market. Close cooperation with distribution partners can ensure a more seamless integration with clinical management systems such as electronic health records, billing, and other systems.

Evidence-based behavioral or psychological solutions could be a large untapped market: Around 80% of healthcare spend deals with chronic health issues, a very significant proportion of which can be directly or indirectly addressed with cognitive-behavioral therapy. DTx products could present a compelling solution to these health issues, with a potentially large market opportunity given the direct and indirect costs associated with chronic health issues. Cognitive behavioral therapy can be complicated to scale and faces significant capacity constraints. For example, psychiatry requires a high level of patient monitoring. While a therapist cannot be with a patient at all hours of the day, a digital therapeutic can. Mindable developed a DTx product to help patients overcome anxiety. Its application supports the therapy process by combining scientifically proven methods with intuitively designed user experiences based on cognitive-behavioral therapy.