



INVESTING IN ENTREPRENEURS WHO IMPROVE  
HEALTHCARE

Investment Area of Interest:  
**Digital Therapeutics**

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July 2020

## Introduction to Digital Therapeutics

As smartphones and computers equipped with more powerful processors were developed, almost every industry went through some level of technological transformation, including healthcare. Over the past decade, countless digital health products have been developed to diagnose, treat, manage, and prevent health issues.

Digital therapeutics are a subset of the broader digital health sector. A digital therapeutic leverages technology and evidence-based interventions to prevent, manage and/or treat physical, mental and behavioral conditions. However, the difference between a digital health product and a digital therapeutic is significant. As the digital health ecosystem evolves, it is crucial to understand the differences between various digital health products.

The Digital Therapeutics Alliance distinguishes digital health products from digital medicine & digital therapeutics. Digital health include “technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health related purposes; capture, store, or transmit health data; and/or support life science and clinical operations.”<sup>1</sup> These products do not require clinical evidence and do not require regulatory oversight in the U.S. Examples of digital health products include fitness apps like Fitbit Coach, electronic medical record system technology like CareCloud, and telehealth platforms like Teladoc.

Digital therapeutics are defined as some type of software that “deliver[s] evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.”<sup>1</sup> Clinical evidence is required for a product to be considered a digital therapeutic, and some regulatory oversight is necessary. An example of a digital therapeutic is Propeller Health, which offers a solution meant to help providers and their patients with asthma and COPD manage their condition, and has been shown to increase medication adherence by nearly 60% and reduce inhaler use by nearly 80%.

For the purposes of this report, we will define digital therapeutics companies as companies that have developed or have plans to develop products that meet the digital therapeutic guidelines set out by the Digital Therapeutics Alliance above. While this definition is certainly less rigorous than some potential classifications, it is notable that we are including companies that have plans to develop digital therapeutics in addition to those that have already developed them.

Note that this report will not differentiate between digital therapeutics and prescription digital therapeutics. In general, digital therapeutics are not subject to the clinical rigor and regulatory scrutiny to which prescription digital therapeutics are subject.

## Growth Drivers for Digital Therapeutics

There are two major factors driving the development of digital therapeutics (DTx):

1. The increasing prevalence of chronic disease and mental illness
2. The push for value-based care

A digital therapeutic is, of course, not a physical drug that is consumed by a patient. However, DTx can influence or monitor patient behavior through software. This is why digital therapeutics treat, for the most part, chronic disease (which can require lifestyle or behavioral changes to reduce symptoms) and issues related to mental or behavioral health.

According to the CDC, 6 in 10 adults have at least one chronic disease<sup>3</sup>. Chronic disease is the leading cause of death and disability. Chronic diseases include heart disease and stroke, cancer, diabetes, obesity, arthritis, Alzheimer's, epilepsy, tooth decay, and others. Furthermore, as the population ages, the demand for chronic disease care is expected to grow. Additionally, according to NIMH, almost one in five adults live with a mental illness in the U.S. According to AJMC and the APA, rates of mood disorders and suicide-related outcomes have increased significantly over the last decade among young adults and adolescents.”<sup>4</sup>

It is evident that patient demand for chronic disease care and mental healthcare is increasing. Furthermore, according to SAMHSA, by 2025, the US will have a shortage of more than 15,000 psychiatrists, more than 26,000 mental health counselors, and more than 57,000 psychologists.<sup>5</sup> However, the increasing prevalence of chronic disease and mental illness are significant for other reasons besides demand for care. The type of care and healthcare costs are crucial considerations. Pharmacological interventions are not enough for patients with chronic disease and mental illness. In addition to drugs, these patients need monitoring and other forms of support.

The combination of drug treatment and ongoing care for chronic disease and mental illness increase healthcare expenditures significantly. In fact, according to the CDC, 90% of the nation's \$3.5 trillion in annual health care expenditures are for people with chronic and mental health conditions<sup>6</sup>.

Digital therapeutics provide patients and caregivers with increased access to treatment and enable patients to receive personalized care with fewer scheduling constraints, at a fraction of the cost. Additionally, patients can receive treatment on demand with digital therapeutics. Diseases that is chronic requires treatment that is always available. Payers benefit from the increased exposure that patients receive to treatment options, without having to expand their workforce and with a comparatively reduced cost.

The push for value-based care is another tailwind for the development of digital therapeutics. Healthcare providers benefit through their ability to prescribe digital therapeutics in addition to traditional therapeutics. This allows providers to provide a better quality of therapy and outcomes for their patients. Furthermore, providers are also able to make more data-driven decisions regarding prescribed therapies with the additional data points that digital therapeutics supply.


To summarize, there are significant advantages that digital therapeutics can provide for stakeholders across the healthcare industry. Digital therapeutics provide patients easier and more frequent access to personalized care. Additionally, patients are provided with greater privacy and ability to receive therapy without experiencing societal stigma. In a value-based care environment, healthcare providers can use the data from digital therapeutics to provide better care and achieve better outcomes. Payers benefit from the increased exposure that patients receive to treatment options, without having to expand their workforce. Finally, pharmaceutical companies find that digital therapeutics allow them to gain greater real-world evidence to support patient outcomes and provide them with economic value. Digital therapeutics can also provide pharmaceutical companies with insight into how medicine is consumed by patients, and with additional data on the impact of their treatments.<sup>7</sup>

## Therapeutic Areas

Almost all digital therapeutic services can be categorized as either companion therapies or stand-alone therapies. Companion therapies are designed to supplement traditional clinical therapies, while stand-alone therapies are designed to replace specific traditional clinical therapies. However, digital therapeutics may vary significantly and have a broad range of implementation designs. Examples of digital therapeutics may range from smartphone applications that help patients manage their condition in the form of medication reminders to sensory stimuli delivered through a tablet to manage insomnia or depression.<sup>7</sup>

Today, digital therapeutics address many different areas of medicine, including mental and behavioral health and chronic disease. Within mental and behavioral health, areas include anxiety, depression, autism, substance use disorder, pain, schizophrenia, sleep disorders, and others. Within chronic disease, digital therapeutics can address diabetes, IBS, orthopedic conditions, COPD, asthma, and others.

For the purposes of this report, we categorize digital therapeutics in one or more of the following therapeutic areas: Pain & MSK, Cancer, Digestive, Neurodegenerative, IDD (Intellectual & Developmental Disabilities), Respiratory, Addiction, Sleep, Anxiety & Depression, Diabetes, and Everything Else.

<b>Pain &amp; MSK</b>    	<b>Cancer</b>   	<b>Everything Else</b>  	<b>Respiratory</b>   	<b>Addiction</b>   
<b>Neurodegenerative</b>  	<b>Digestive</b>   	<b>IDDs</b>  	<b>Sleep</b>   	
<b>Diabetes</b>     			<b>Anxiety &amp; Depression</b>      	

Source: GIMBHI ([www.gimbhi.com](http://www.gimbhi.com))

Diabetes, addiction, and anxiety & depression have been particularly popular areas for digital therapeutic developers due to treatment protocols that lend themselves to a digital medium. Digestive health is another example of a quickly growing area for digital health solutions with companies like Vivante Health and Bold Health.

In the pain & MSK category, one startup is Kaia Health, which develops evidence-based treatments for conditions like musculoskeletal pain.

In the cancer category, France-based Voluntis developed Oleena, a software for oncology-related symptoms management and remote patient monitoring. Specifically, Oleena evaluates cancer-related symptom severity based on patient reported data and provides personalized recommendations for self-management of symptoms.

In the digestive category, metaME Health is developing a digital therapeutic product called Regulora, a fully digital behavioral intervention for the treatment of Irritable Bowel Syndrome (IBS).

In the neurodegenerative category, San Diego-based Dthera Sciences is developing digital therapeutics for Alzheimer's.

In the respiratory category, Propeller Health has developed digital therapeutics to treat asthma and COPD. Propeller provides patients with sensors to attach to their inhalers, which, through their software application, helps them more effectively self-manage their condition by better understanding their triggers.

In the sleep category, Big Health developed Sleepio, a digital therapeutic to address poor sleep.

The addiction category contains digital therapeutics for alcohol use disorder, substance use disorder, nicotine addiction, and opioid use disorder. Pear has developed prescription-only digital therapeutics for treatment of patients with substance use disorder and opioid use disorder.

The anxiety & depression category contains therapeutics which treat anxiety, depression, and panic disorders. Palo Alto Health Sciences developed Freespira, a digital treatment for panic attacks. Limbix's product called Spark supports teens with depression and is undergoing clinical trials.

There have been multiple digital therapeutics developed for the treatment of diabetes and related health issues. Welldoc developed Bluestar, which helps manage type 2 diabetes. In the intellectual and development disability category, Akili received FDA authorization for EndeavorRx, a prescription treatment for ADHD. Cognoa is developing digital therapeutics for autism.

We included Proteus, which attempted to develop digital therapeutic to help medication adherence in patients with schizophrenia, bipolar disorders and depression, in the "Everything Else" category, since their solutions could be applied in various therapeutic areas. Recently, Proteus filed for bankruptcy (hence the red-shaded box).

## Regulatory Environment

The FDA's Center for Devices and Radiological Health ("CDRH") regulates all digital health products in the U.S. CDRH launched the Digital Health Innovation Action Plan ("DHIAP"), which establishes the pathways for digital health product approvals. There are two typical pathways for digital therapeutics – the 510(k) pathway and the De Novo pathway.

For devices (meaning hardware or software) that have a predicate device, filing a 510(k) submission is the typical pathway. According to the FDA, "510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is safe and effective by proving substantial equivalence (SE) to a legally marketed device (predicate device)" <sup>8</sup>. To clarify, a predicate device is a device to be used as a point of comparison and that is allowed to be marketed legally. For example, WellDoc's digital therapeutic BlueStar and Pear's reSET followed the 510(k) pathway.

For devices without any predecessors or points of comparison, the De Novo pathway is used. According to the FDA, "The De Novo process provides a pathway to classify novel medical

devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device.”<sup>8</sup> This pathway is certainly more rigorous than 501(k) clearance.

On June 15, 2020, Akili announced that its prescription digital therapeutic to treat ADHD in children, EndeavorRx, was granted clearance by the FDA. According to Akili, “EndeavorRx was reviewed through FDA’s De Novo pathway and its clearance creates a new class of digital therapeutics. EndeavorRx is designed to directly target and activate neural systems through the presentation of sensory stimuli and motor challenges to improve cognitive functioning.”<sup>9</sup>

In addition to these pathways, in 2017 the CDRH launched the Digital Health Software Precertification to establish a regulatory framework for digital health products. This experimental program is intended to make it easier to release or develop digital products through a streamlined review of the software developer’s processes.

In March, Somryst, Pear Therapeutics’ prescription DTx for insomnia, was cleared through the 510(k) pathway, and was the first product to pass through the Software Precertification Pilot. Due to the pandemic and subsequent increase in demand for mental healthcare, in May, the FDA temporarily waived rules for digital health devices intended to facilitate or aid treatment for mental health disorders. The new rule waives the need for a 510(k) submission. A few digital therapeutic developers have taken advantage of this temporary relaxation of regulation. This presents a critical opportunity to digital therapeutics developers. If a developer can use this temporary waiver to deploy a digital therapeutic and demonstrate efficacy and outcomes, the case for formal FDA clearance will be significantly stronger.

Overall, launching the Pre-Cert program and easing regulatory burden on developers in time of crisis evidences the cooperative attitude of the FDA regarding digital health products, at large. These steps encourage innovation, and send an encouraging message to the digital therapeutics industry.

## **Funding for Digital Therapeutics**



From a product standpoint, the development of digital health applications has proliferated over the last decade. In 2017, there were over 325,000 digital health apps available on mobile app stores – a number that has doubled since 2015.<sup>10</sup> The exponential growth in innovation has been met with significant increases in the funding of digital health as well.

## DIGITAL HEALTH FUNDING AND DEAL SIZE

2011-H1 2020

**ROCK  
HEALTH**

TOTAL VENTURE FUNDING

# OF DEALS

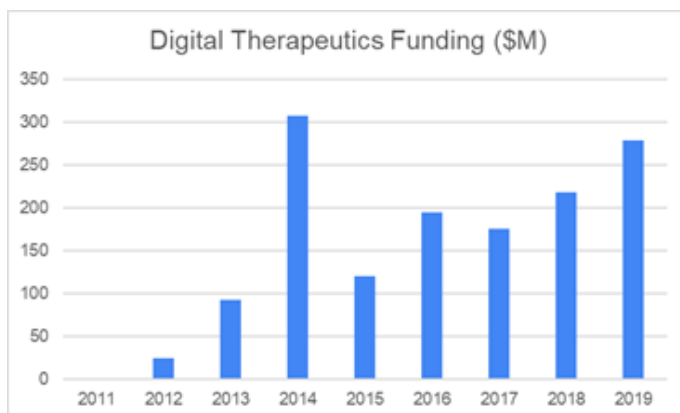


Note: Only includes U.S. deals >\$2M; data through June 30, 2020  
Source: Rock Health Funding Database

Source: Rock Health

In 2011, \$1.1 billion was raised for digital health, with an average deal size of \$12 million. In 2019, \$7.4 billion was raised with an average deal size of almost \$20 million. More specifically, “in 2019, 359 US digital health startups raised \$7.4B from 627 investors”<sup>11</sup>

While digital therapeutics is a specific subset of digital health, from a funding standpoint, the space has grown from a rounding error to an amount demonstrating legitimate investor appetite. We included 43 companies in our classification of digital therapeutics, and funding in 2019 almost reached \$300 million globally. Year-to-date funding volume for 2020 is roughly ~\$175 million, and we project funding to eclipse \$320 million by the end of 2020<sup>12</sup>



Source: GIMBHI ([www.gimbhi.com](http://www.gimbhi.com))

While at face value, \$250 million may not sound like much, it is notable that the number of digital therapeutics investors has skyrocketed over the last decade as well. Investor type has shifted from niche investors like small healthcare VCs to established healthcare titans like health insurance corporate VCs and global pharmaceutical companies.

The fundraising process for a digital therapeutic developer begins with a seed/angel round to fund small studies to prove the therapeutic's impact. Next, if the developer pursues the prescription digital therapeutic route, the company will need to fund FDA clinical trials, usually through raising a Series A round.

"The best teams we see at this stage have designed their early studies with robust controls that are at least analogues to the studies used by more mature FDA applicants."<sup>13</sup> After the Series A, clearance through the De Novo or 510(k) pathway is typically pursued.

## Partnerships with Pharma

Traditional prescription drugs are expensive to develop and expensive to buy. In 2019, the United States spent over \$345 billion on prescription drugs, according to CMS<sup>14</sup>. It is likely digital therapeutics can capture a small fraction of that spend. Generating patient demand for digital therapeutics (assuming a high level of efficacy) would be straightforward, given the relatively cheap cost of digital therapeutics versus a traditional prescription drug.

There's a reason why digital therapeutics would be cheaper as well. According to JAMA, estimates of R&D costs for drug development are between \$200 million and \$2.9 billion, after adjustments for the probability of failure and opportunity costs. And R&D costs seem to keep rising. In 2018, the cost to take a prescription medicine through from development to FDA approval totaled \$2.6 billion according to a study in the Journal of Health Economics.<sup>15</sup> In 2003 this was \$802 million (\$1 billion adjusted for inflation).

The cost of software development is certainly less than developing a traditional prescription medicine. Furthermore, a digital therapeutic developer does not have to spend significant amounts of capital on establishing manufacturing supply chains.

While digital therapeutics will by no means replace traditional prescription drugs, the less capital-intensive nature of DTx development has encouraged a wave of innovation from startups. Furthermore, pharmaceutical firms have been attracted to the prospect of digital therapeutics, and partnerships have been established over the last few years. Some partnership activity is driven by the development of digital therapeutics designed to be used in combination with traditional pharmacological treatment. Digital therapeutics used in combination with traditional treatment can drive better adherence and improve outcomes for patients. Noom's partnership with Novo Nordisk is an example of a partnership resulting from a digital therapeutic designed to be used in combination with a traditional drug.

	Digital Therapeutic	Pharma	Brief Description
<b>Jun-20</b>	Harman	Roche	Partnership to develop autism DTx
<b>Apr-20</b>	Amblyotech	Novartis	Novartis' acquisition of Amblyotech
<b>Mar-20</b>	Voluntis	BMS	Collaboration agreement to create cancer DTx
<b>Dec-19</b>	SidekickHealth	Bayer	Partnership to provide peripheral arterial disease DTx
<b>Nov-19</b>	Welldoc	Astellas	Collaboration and license agreement to develop & commercialize BlueStar in Asia
<b>Oct-19</b>	Pear Therapeutics	Ironwood	Agreement to evaluate DTx for gastrointestinal indications
<b>Oct-19</b>	Omada	Abbott	Partnership to integrate Omada with CGM tech
<b>Oct-19</b>	Noom	Novo Nordisk	Partnership to offer Noom to patients taking Saxenda
<b>Sep-19</b>	DarioHealth	DanceBiopharm	Partnership to integrate inhaler into DarioHealth
<b>Sep-19</b>	One Drop	Bayer	Licensing agreement for Bayer to use One Drop's platform
<b>Sep-19</b>	Happify	Sanofi	Collaboration to develop psychological outcomes for MS patients
<b>Aug-19</b>	Gaia	Orexo	Orexo to have exclusive global commercial rights to GAIA's OUD DTx
<b>Mar-19</b>	Akili	Shionogi	Partnership to develop & commercialize Akili's DTx in Asia
<b>Jan-19</b>	Click Therapeutics	Otsuka	Collaboration to develop & commercialize depression DTx

Under Akili's strategic partnership with Shionogi, Akili received \$20 million with potential payments of up to \$105 million plus royalties. In June, Akili received FDA approval for EndeavorRx.

## **Monetization**

Partnerships between digital therapeutics and pharma are likely to continue, given the benefits for both parties. However, since DTx are not simply digital health apps sold online, it is important to consider the range of monetization opportunities available to DTx developers. The three routes are insurance plan reimbursement, DTC, or enterprise sales.

### **1. Insurance plan reimbursement**

Digital therapeutics can be reimbursed through insurance plans, similarly to any prescription digital therapeutic. Realistically, this route is achievable by prescription digital therapeutics, that have undergone a higher level of regulatory scrutiny. Traditional reimbursement can happen in multiple ways: value-based, fee-for-service, or medical device reimbursement.

With a value-based reimbursement model, digital therapeutics developers would need to demonstrate cost savings for payers. Notoriously, the issue with this model is attributing the cost savings specifically to use of the therapeutic. DTx developers may establish rates for app usage under a fee-for-service model, but this is unlikely without rigorous studies / testing.

Through medical device reimbursement, CPT codes would be established for reimbursement. The software would warrant higher levels of regulatory scrutiny to achieve this.

### **2. Direct-To-Consumer (DTC)**

Of course, insurance plan coverage is coveted by digital therapeutics developers. However, some do choose the route of providing the therapeutic directly to consumers. Before partnerships with EVERANA and Novo Nordisk, Noom provided its weight loss app directly to consumers. Obtaining payer coverage is often a long process, so one benefit of DTC is

realizing revenue sooner. Patients' willingness to pay is crucial to the success of this option. This model can even lead to insurance plan coverage, if significant traction is proven.

The DTC approach may be employed in a hybrid-model with insurance plan coverage. For patients without insurance, a simpler version of the therapeutic could be sold. The differences between the prescription and consumer versions would have to be made clear to patients and payers.

### **3. Enterprise Sales**

Digital therapeutics developers can pursue an enterprise sales strategy as well, as self-insured employers can offer the therapeutic to their employees as a covered benefit. Many digital health companies have pursued self-insured employers as clients as opposed to insurance plans due to quicker sales cycles.

Furthermore, universities, coworking spaces, or other entities that are not self-insured employers may be interested in buying access to the digital therapeutic. Another route is to license the DTx out to a company looking to develop or gain exposure to DTx.

Digital therapeutics all work differently, so it makes sense that different developers will pursue different pathways to monetization. Another sign that the market for digital therapeutic will continue to experience rapid growth is the establishment of digital formularies by some of the largest pharmacy benefit managers.

Express Scripts established a stand-alone digital health formulary in 2019. To be included, digital health products have to be reviewed by doctors and pharmacists to ascertain therapeutic value and safety among other factors. CVS Health also established a service that will help CVS Caremark PBM clients manage digital health products. These moves by Express Scripts and CVS Health will certainly increase access to digital therapeutics and provide visible channels for DTx developers to participate in.

## **Conclusion**

Increase in prevalence of chronic disease and mental illness, healthcare's shift to value-based care, a favorable regulatory environment, robust investor appetite, industry cooperation, and multiple viable monetization strategies all point to the continued growth of the digital therapeutics industry.

Furthermore, these therapeutics are actually helping patients. Sleepio (Big Health's product) demonstrated in a placebo-controlled randomized controlled trial that use of the therapeutic resulted in 76% of users achieving healthy sleep levels. Palo Alto Health Sciences' Freespira demonstrated that 80% of patients had no panic attacks, after using the DTx for 4 weeks. Happify demonstrated a 25% reduction in anxiety and depression symptoms in a randomized controlled trial, as well.

However, as with any emerging technology, there are significant risks in the space. Proteus Digital, a digital therapeutic unicorn that raised over \$500 million, filed for Chapter 11 bankruptcy in June 2020. Proteus made an ingestible sensor for tracking medication adherence. According to MobiHealthNews, Otsuka, the company's pharma partner, said that "delivery of Abilify MyCite – a sensor enabled version of Otsuka's schizophrenia drug that was developed as a result of the companies' collaboration – will not be affected."<sup>16</sup>

2020 has certainly been eventful for digital therapeutics as Akili announced FDA approval of their prescription digital therapeutic, EndeavorRx, for children with ADHD. The therapeutic comes in the form of a video game. In addition, in June, MedRhythms, a digital therapeutic that employs music and sensors to assist with post-stroke walking rehab, received an FDA Breakthrough Device Designation.

As chronic disease and mental illness take a larger toll on the global population, managing the cost of care is expected to become an even higher priority. We are also seeing a sharp rise in digital health tools available to consumers worldwide, and simultaneously, the temporary loosening of regulations by the FDA has sparked a flurry of activity in digital therapeutics. While there have been significant developments in the diabetes segment, we expect growth in other therapeutics areas going forward. Given the positive clinical results of many digital therapeutics coupled with the demonstrated interest from investors, payers, and pharmaceutical companies alike, we expect the digital therapeutics industry will continue to grow substantially on all fronts over the next decade – from company formation and investment to adoption.

## Select Digital Therapeutics Companies\*

## Big Health

Big Health operates a digital healthcare portal used to offer behavioral programs for mental health issues.



The company offers a DTx, Sleepio, to treat patients with poor sleep. Big Health is working on a DTx for worry & anxiety as well.



Sleepio is a six-session sleep improvement program that features CBT techniques. It helps people with even long-term sleep problems fall asleep, stay asleep and feel better during the day.



Big Health raised a \$39M Series B round led by Morningside Group and Gilde Healthcare in June 2020. The company's total funding is \$54.3M.



San Francisco Bay Area, US  
[www.bighealth.com](http://www.bighealth.com)

## Akili

Akili builds clinically-validated cognitive therapeutics, assessments, and diagnostics that look and feel like video games.



EndeavorRx™ is the first-and-only FDA cleared prescription treatment for attention in children with ADHD delivered through a video game.



EndeavorRx is designed to directly target and activate neural systems through the presentation of sensory stimuli and motor challenges to improve cognitive functioning.



Akili raised a \$68M Series C in 2018. The company's total funding is \$140.9M.



Greater Boston Area, US  
[www.akiliinteractive.com](http://www.akiliinteractive.com)





**Click Therapeutics develops and commercializes software as prescription medical treatments for people with unmet medical needs.**



Click is developing DTx across a wide range of therapeutic areas including insomnia, acute coronary syndrome, migraine, overactive bladder, and chronic low back pain.



Clickotine is an app designed to help people stop smoking using input from Magellan Health.



Click raised \$19M of venture funding led by Sanofi Ventures in 2018. The company's total funding is \$27.4M.



Greater New York Area, US  
[www.clicktherapeutics.com](http://www.clicktherapeutics.com)



**DarioHealth is a publicly traded (NASDAQ: DRIO) global digital health company that develops a smart diabetes solution to track, monitor, and analyze patient conditions.**



Dario is engaged in the development and commercialization of technology that provides consumers with laboratory-testing capabilities using smartphones and other mobile devices.



Dario Blood sugar monitor is a mobile, real-time, cloud-based, diabetes management solution based on a multi-featured software application combined with a blood glucose monitoring device.



Dario launched its initial public offering in 2013, at a valuation of \$46.2M. In 2019, the company closed a private placement offering of \$21.3M.



New York, NY & Israel  
[www.mydario.com](http://www.mydario.com)



### **Dthera Sciences**

**(OTCQB: DTHR) is a publicly traded digital therapeutics company focused on the elderly and individuals with neurodegenerative diseases.**



Dthera is developing DTHR-ALZ, a digital therapeutic that digitally delivers reminiscence therapy to Alzheimer's sufferers in a scalable and personalized manner.



DTHR-ALZ is comprised of three key components: 1) tablet for seniors with Alzheimer's disease 2) Facial expression detection 3) AI that optimizes therapeutic content being delivered



Dthera is a publicly traded company. Before it went public, it raised ~\$1.7M in venture funding in 2017.



San Diego, CA  
[www.dthera.com](http://www.dthera.com)



**Happify is a behavior change technology company that drives personal, business and healthcare outcomes through improved emotional health.**



Happify's DTx that have been shown, through randomized clinical trials, to decrease the symptoms of stress, anxiety and depression and improve resilience of users by 25-30%.



Sanofi and Happify are developing a prescription DTx to treat depression and anxiety in patients with multiple sclerosis.



Akili raised \$20.2M of venture funding in 2019. The company's total funding is \$45.7M.



New York, NY  
[www.happify.com](http://www.happify.com)



**Kaia Health is a developer of a digital health platform designed to treat a range of disorders including back pain and COPD.**



Kaia Health is developing DTx for chronic diseases such as low back pain, COPD, osteoarthritis, Parkinson's disease, and others.



One Kaia product is used for self-management of nonspecific low back pain that has persisted for longer than 4 weeks.



Kaia raised \$26M in a Series B round in June 2020. In total, the company has raised \$48M.



Brooklyn, NY  
[www.kaiahealth.com](http://www.kaiahealth.com)



**Limbix is a prescription digital therapeutics platform that provides mental health treatment for young people.**



If Limbix Spark is FDA cleared it will be the first prescription digital therapeutic designed to support adolescents with depression.



Spark is a multi-week cognitive behavioral therapy based program focused on the completion of value-based activities that spark feelings of pleasure or mastery.



In May 2020, Limbix raised \$9M of Series A funding led by GSR Ventures. The company total funding is \$16M.



Palo Alto, CA  
[www.limbix.com](http://www.limbix.com)



**metaMe Health is committed to developing FDA-approved prescription digital therapeutics for the treatment of gastrointestinal conditions.**



Regulora™, is a digital gut-directed hypnosis therapy in late-stage development for the treatment of IBS



Regulora™ is an all-digital implementation of the standardized, fully scripted North Carolina (NC) GDH treatment protocol that provides patients with automated therapy.



In 2019, metaME raised \$3.8M in seed funding led by LionBird.



Chicago, IL  
[www.metamehealth.com](http://www.metamehealth.com)



**Pear Therapeutics is a software-based digital therapeutics platform designed to treat disease and enhance the efficacy of pharmaceuticals.**



Pear has developed DTx for SUD (reSET), OUD (reSET-O), and insomnia (Somryst). Pear also operates Pear Connect, a patient service center for prescription DTx.



reSET is a 90-day Prescription Digital Therapeutic (PDT) for Substance Use Disorder (SUD). Somryst™ is the first and only prescription digital therapeutic indicated to treat chronic insomnia.



Pear raised \$64M of Series C funding in 2019 led by Temasek Holdings. The company total funding is \$134M.



Boston, MA  
[www.peartherapeutics.com](http://www.peartherapeutics.com)



**Voluntis innovates healthcare solutions by embedding connectivity in therapeutics and medical intelligence in software.**



Voluntis develops DTx for diabetes, oncology, and other therapeutics areas.



Insulia® provides basal insulin dose recommendations and coaching messages for people with type 2 diabetes. Oleena, an app, enables self-management of cancer symptoms.



Voluntis IPOd in 2018 on the Euronext Paris (Ticker: VTX).



Paris, France & Cambridge, MA  
[www.dthera.com](http://www.dthera.com)



**Cognoa is developing prescription digital therapeutics to advance the standard of care by enabling earlier and improved treatment of behavioral health conditions**



Cognoa is developing diagnostics and DTx for autism, ADHD, and anxiety.



Cognoa's ASD Therapeutic will help improve social-emotional reciprocity in children diagnosed with autism between the ages 3 and 7 years.



Cognoa raised \$11.6M of venture funding in 2017 led by Morningside Group. The company total funding is \$20.4M.



Palo Alto, CA  
[www.cognoa.com](http://www.cognoa.com)



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Founded in 1996, FCA Venture Partners has a long history of investing in successful healthcare entrepreneurs. We are passionate about building sustainable businesses and providing strategic value to our portfolio companies.

FCA invests \$3-6M in fast growing healthcare companies making processes in the industry faster, better, and more cost effective while improving the quality of care and the patient experience.

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- \* Following content may be from Crunchbase, company websites, or other sources