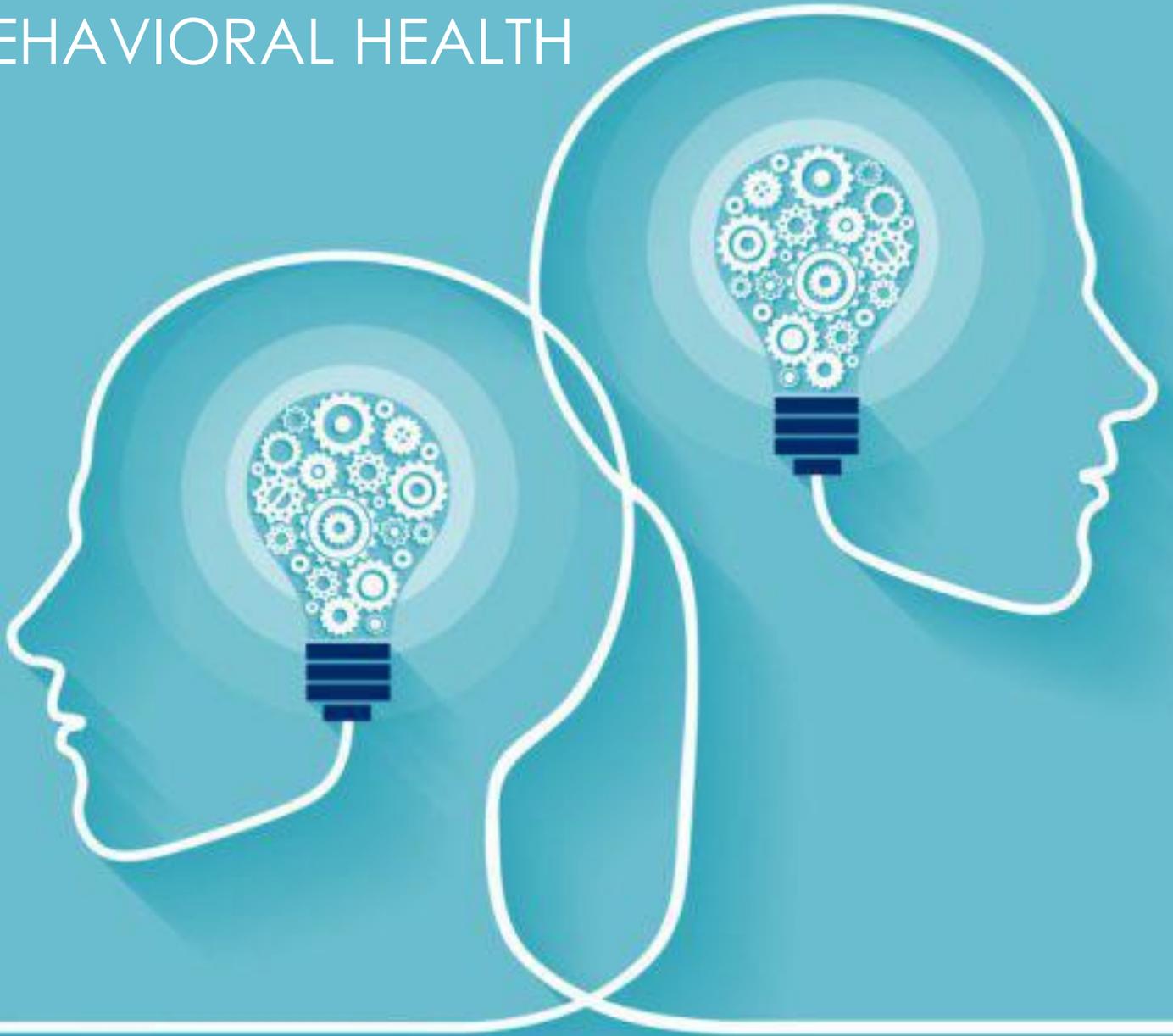


DIGITAL THERAPEUTICS IN PEDIATRIC BEHAVIORAL HEALTH



LAWRENCE, EVANS & CO., LLC

Investment Banking | Healthcare Finance | Consulting

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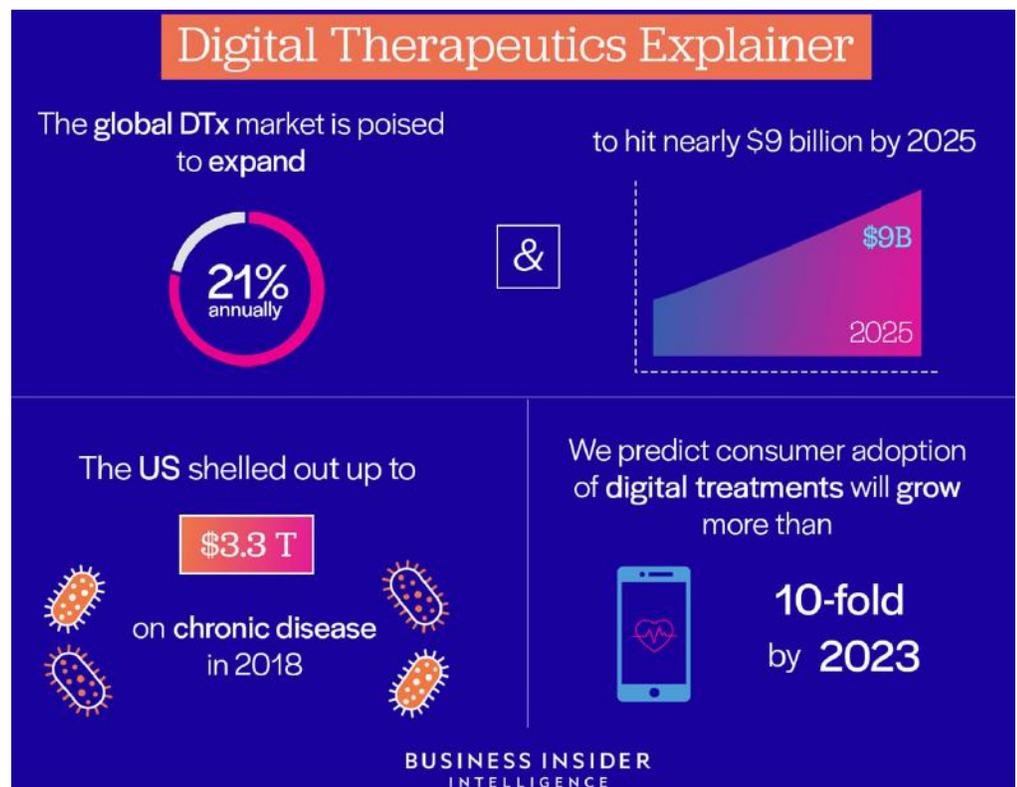
What Are Digital Therapeutics?

In the age of artificial intelligence and advanced, data-driven products, it is no surprise that the medical industry has evolved with the times. Specifically, the sector has seen an exponential increase in technology used to assist in treatment with the ultimate goal of improving patient outcomes. With these developments come many challenges and hurdles for companies looking to enter this ever-changing and highly profitable space.

It is important to realize that what drives this change is the patient. What treatment, medicine, or device will help this person the most and at what cost? The company that answers this question stands to achieve significant revenues and, more importantly, increase everyone's quality of life.

One of these advancements within the budding "health-tech" industry are digital therapeutics. This idea was first established in 2012 and has continually evolved over the last eight years. However, there remains some confusion over what exactly this concept is and how it can be applied to healthcare as a whole. **Digital therapeutics (DTx) use evidence-backed digital instruments and therapies to craft treatment plans and programs that can be used as a substitute or complement to traditional medicine.** These therapeutics typically use a

combination of wearables, medical devices, cognitive behavioral therapy (CBT), artificial intelligence (AI), augmented reality (AR), and virtual reality (VR). Often times treatment can be applied through the use of consumer-facing mobile health apps. With the widespread use of smart phones and other smart devices, application of this novel concept is easier, more accessible, and cheaper than ever before. All of the above can be combined with or used as an alternative to traditional treatment methods.



While digital therapeutics are a part of a broader digital-health landscape, in order to be qualified as one, the product being offered must be backed by evidence, powered by software, and claim to manage, treat, or prevent a disorder or disease. Additionally, they must be approved by regulatory bodies. It is for these reasons that they differ from telemedicine and diagnostics.

What Are Digital Therapeutics? Cont.

In order to better understand this topic, it is important to reemphasize the differences between digital therapeutics and digital health. The latter involves all technologies that interact with patients for health-related purposes. As can be imagined, this is a broad category. Digital therapeutics are independent of this large group and offer evidence supported solutions and interventions driven by software directly to the patient with the goal of managing, treating, or curing a medical ailment.

As chronic illnesses and disorders are becoming more and more commonplace, the price for treatment is continuing to rise. Chronic disorders consume the largest amount of healthcare spending within the United States. In 2018, the US spent \$3.3 trillion on these conditions.

The treatment itself is not the only pricey problem. The current cost of bringing a pharmaceutical to market is as high as \$2.9 billion and rakes in an average return on investment (ROI) of 0%. The combination of lower research and development (R&D) costs, vast distribution channels, and scalability make DTx an eye-catching target for financiers.



As a result of the above, the market for digital therapeutics was created out of necessity. Many DTx applications apply to those suffering from these chronic conditions. Due to these facts, the DTx market is poised to expand 21% to almost \$9 billion in the next five years and tripling in size over the next six years. Additionally, it is estimated that consumer adoption of these products will grow more than 10-fold by 2023.

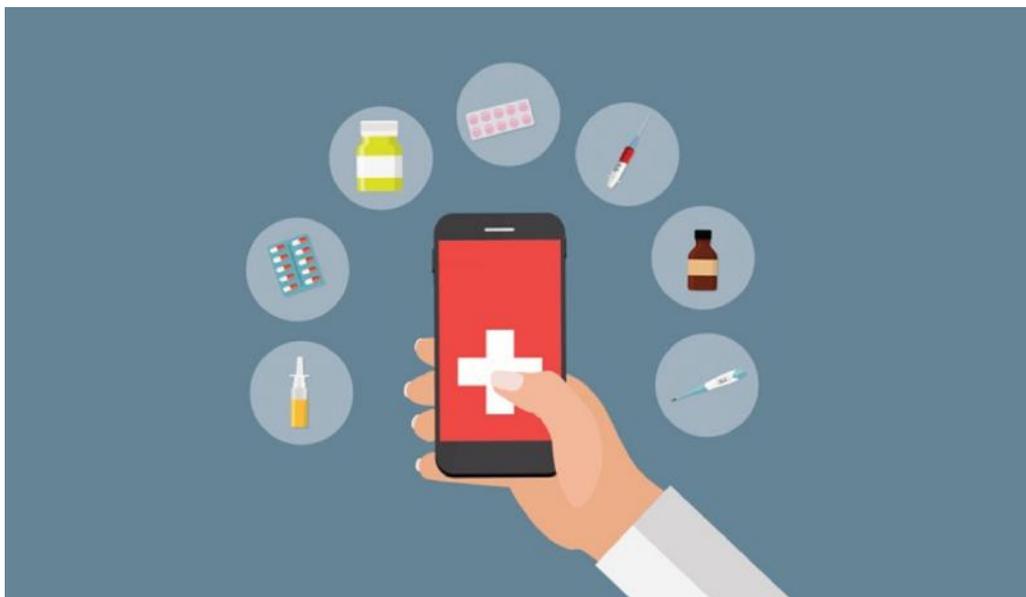
With change on the horizon for the entire healthcare industry, the major participants are starting to take notice. Pharmacy benefit managers (PBMs) are starting to use logs as they would for ingestible medicines, insurance plans are starting to push digital solutions in an effort to cut cash out-flow, and big-pharma is even beginning to partner with select digital therapeutics companies to spur future development.

For example, in a recent article, Business Insider Intelligence advises “Payers should stock portfolios with digital therapeutics to shore up on drug spending, curb their sizable share of chronic disease costs, keep patients healthy, and woo employer contracts.”

These partnerships with DTx vendors can supply med-tech and pharmaceutical companies with enormous amount of real-time data and provide a pathway for future development and customer retention as technology becomes more prevalent.

The Industry

We are currently in the midst of a mental health emergency. In fact, one in every four people will develop at least one behavioral disorder throughout their lifetime. Specifically, one in every five children have a diagnoseable behavioral health condition and under 25% of those children will receive necessary treatment. These conditions, if left untreated or ignored, can cause a lifetime of physical and mental pain for the individual and their families. Not to mention, a burden on finances and the greater healthcare system.



Digital therapeutics have a wide array of applications as it relates to this crisis. They can be used in the treatment/prevention of diabetes, hypertension, psychosis, schizophrenia, substance abuse disorder, and many more. But an area that has seen significant development in recent years is within the pediatric space. Here, DTx is utilized with children suffering from attention

deficit hyperactivity disorder (ADHD), developmental delays (DDs), obsessive compulsive disorder (OCD), nicotine addiction, depression, eating disorders, autism, and anxiety.

This adolescent age group is so critical due to the level of neuroplasticity in the brain. This is the process where the brain is actively changing and developing. It is within this process that there is the greatest chance to positively impact the mind and the individual's behavioral development. Synapses that are used are built into stronger circuits, while others that are left dormant become weak or nonexistent. In these early years, over a million new neural connections are formed every second. These facts, if taken advantage of, can lay the groundwork for a lifetime of mental and behavioral health.

Attention deficit hyperactivity disorder (ADHD)

is a mental disorder that most often occurs in children.



6.4 Million American children ages 4-17 have been diagnosed with ADHD.

Average age of ADHD diagnosis: **7**

Age when symptoms of ADHD typically first appear: **3-6**

6.1% of American children are being treated for ADHD with medication.

42% increase in ADHD diagnoses over the past 8 years

The Industry Cont.

For example, for patients with developmental delays and other behavioral health disorders, the correct digital therapeutic treatment can focus in on this window of neurodevelopment, activate this “neuromodulation,” and offer the child a lifetime of brain connectivity gains. In 2020, the CDC reported that 1 in 54 U.S. children have been diagnosed with an autism spectrum disorder (ASD). Furthermore, recent studies have shown that early diagnosis and subsequent treatment can allow 25% of high-functioning autism patients to move beyond their original diagnosis, and over 75% with autism, in general, to participate in mainstream education, instead of special education classrooms and schools.

While these facts are well documented and profiled, care within this period of neurodevelopment remains a constant struggle. To expand, caretakers who begin to have developmental concerns relating to developmental delays do so around 13 months of age. However, due to the shortage of treatment options and professionals they are forced to delay proper diagnosis until about one to three years old. By then, treatment can be less effective than if conducted upon the realization of DDs.

More specifically, the average age of diagnosis in patients with autism has not changed for 15 years at 4 years, 4 months old, surpassing the early intervention window by years. A reason for this was recently published in a study from



Pediatrics, the most common autism screener test, the M-CHAT, is less effective than previously believed. Furthermore, in another study two out of three children that indicated positive for autism were not referred for follow on treatment. Many pediatricians admittedly report a lack of adequate training, knowledge, and confidence in mental healthcare, which plays a contributing role in the growing shortage of mental health professionals. One remedy to this issue are **Cognoa**'s machine learning algorithms that have been validated to successfully recognize autism in infants as young as 18 months.

These sort of drug, device, and technology manufacturers use four main methods to validate their DTx products; FDA clearance, registered and proven effective clinical trials, observational studies/pilot programs, and retroactive studies.

This is where the Digital Therapeutics Alliance (DTA) comes in. DTA is a global non-profit established in 2017 and has since worked to provide a guide for digital therapeutics companies in their quest for proper regulation and recognition as an evidence-driven medical service that is drastically improving patient outcomes

The Industry Cont.

The benefits are not single sided. DTx has the potential to change the way healthcare is conducted in pediatrics. These devices and products collect patient data that can be used to help the individual make lifestyle modifications, or the doctor intervene to decrease poor outcomes and “big data,” machine learning, and algorithms go even further. They can be adapted to monitor the current condition of the pediatric mental health space. This technological power and the soft skills of the physician in the examination room combine to make everyone involved better off. The ability to track progress will provide even further improved outcomes as doctors can adjust therapies and treatments as needed.

Despite all of this, the sector is still considered nascent, however, it won't remain that way for long. The industry has experienced an average 40% increase in investments each year since 2013, surpassing the \$1 billion mark in 2018. Digital health, as a whole, raised \$7.4 billion last year and even within the current pandemic it is expected to continue its growth trajectory.

Investors are not the only ones looking into DTx. Employers are incentivized to pay for therapies that would reduce their healthcare costs and absenteeism while increasing productivity through employee health, well-being, and retention. One such example is a product offered by **Propeller Health**. This asthma-management therapy uses a sensor attached to an inhaler and a smart phone app which allows those affected to maintain their management plan, as well as, recognize what causes symptoms to flare up. The Centers for Disease Control and Prevention (CDC) report that the leading cause of missed school days for young children (and a main reason parents miss work) is asthma.



Nonetheless, all of this will be voided if the consumer is not willing to pay for it. Most payers will value a treatment if they are given proof that is actually reduces costs, mainly by lowering acute-care utilization, lowering the amount of complications, or replacing expensive in-person visits to the doctor's office. Hence, if a digital therapy can achieve any one, two, or all three of these, there is a greater likelihood of payer acceptance.



Location: 125 Broad St. Boston, MA 02110
Amount Raised to Date: \$119mm
Website: <https://www.akiliinteractive.com>

Akili Interactive is a Boston-based startup tackling the chronic issue of ADHD which plagues 4 million children in the 6 to 11 age group alone. They offer a product that can be used solely or in conjunction with medication or educational programs. What exactly this product is may come as a surprise to many parents. It is a recent FDA cleared prescription video game. The goal is to reduce the child's impulsivity and inattention.

The journey for this technology began in 2019 with clinical trials for the "AKL-T01." The trial concluded in early 2020 and displayed impressive results. After 28 days of use where the game was played five days per week at 30 to 45 minutes at a time, children suffering from ADHD showed major improvements in working memory, inhibition, and attention as measured by performance on the ADHD Impairment Rating Scale (IRS). Another study found that children using the program showed vast improvements compared to peers playing a control game



AKL-T01, now marketed as the **EndeavorRx**, is played on a tablet and uses programming to adjust difficulty levels to the player's ability. This allows the child to remain challenged, stimulated, and un-frustrated. Additionally, as will be discussed in the Regulation section below, the FDA provided new guidance that allowed this new tech to receive fast tracked approval. This decision was announced in early June and as a result, EndeavorRx is now being prescribed to children ages 8 to 12 around the country.

Akili raised \$8.5 million in 2012 from PureTech Ventures, Philippe Cases, and Shire Pharmaceuticals, a \$42.5 Series B in 2016 from PureTech Ventures, Canepa Advanced Healthcare Fund, Merck Ventures, Amgen and Jazz Venture Partners. Most recently, they raised \$68 million in 2018 from Temasek Holdings, Amgen Ventures, Canepa Healthcare, Baillie Gifford, JAZZ Venture Partners, DG Daiwa Ventures, Brooklands Capital Strategies, CLSA, Omidyar Technology Ventures, Fearless Ventures, Merck Ventures, and DG Incubation which puts their post-money valuation at nearly \$200 million.

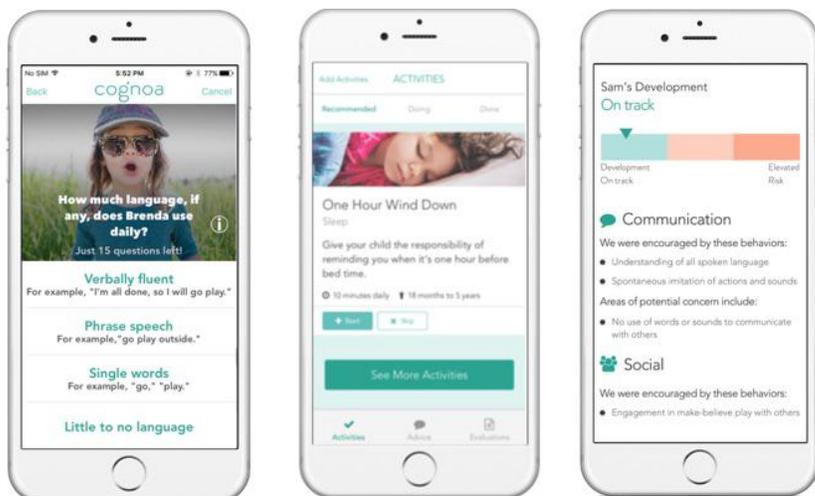
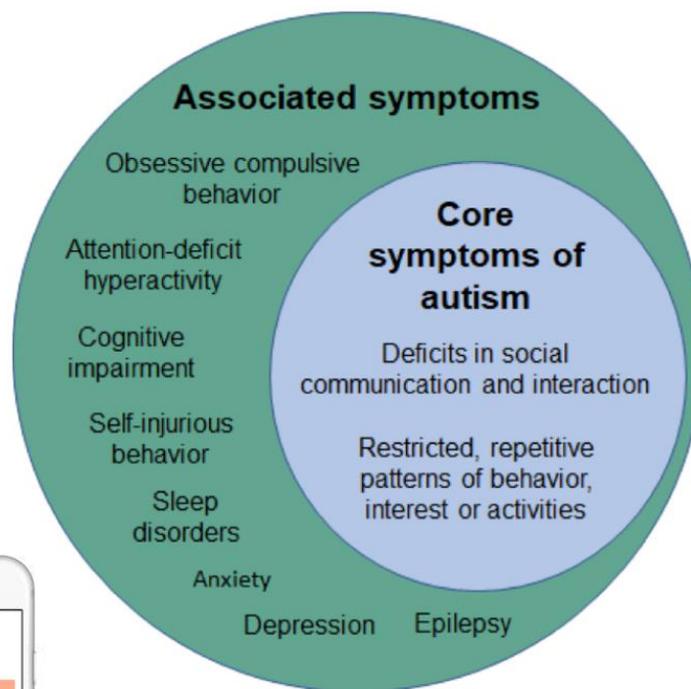


Location: 650 Page Mill Road Palo Alto, CA 94304-1050
Amount Raised to Date: \$63.12mm
Website: <http://www.cognoa.com/>

A company that is addressing the significant gap in autism treatment and care is **Cognoa**. They currently hold two FDA Breakthrough Device Designations due to their potential to provide treatment for a condition in which no other exists. The first device is a diagnostic tool that will help diagnose autism in children in as young as 18 months. This will enable treatment to occur earlier and therefore have a greater effect on the brain's neuroplasticity and the child's future. The second DTx device is a mobile app intended for use among parents and children with autism. The algorithms in this software aim to address the underlying cause of autistic actions in 3 to 8-year olds. It will accomplish this by reaffirming pathways crucial in facial and emotional recognition and increasing social-emotional reciprocity. Through the use of augmented reality, it provides patients with improvement in social responses, facial engagement, emotion recognition, and social initiation

Cognoa has partnered with EVERSANA with the goal of establishing routine prescription, as well as, dispensing and coverage by payors, health plans, and insurers to increase accessibility for those in need.

The California based company has completed 4 rounds of venture funding beginning in 2013 and concluding in 2019; in total raising \$5 million, \$3.82 million, \$11.6 million, and \$42.7 million, respectively. Financers included Morningside Group and an undisclosed investor.

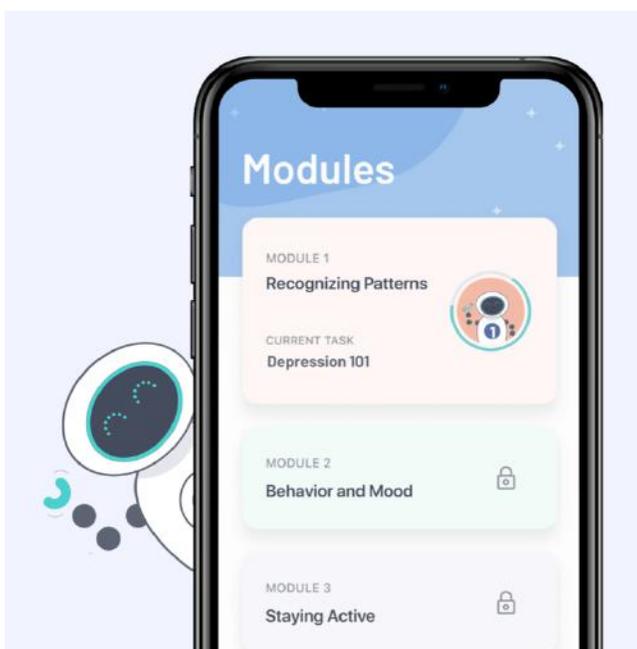
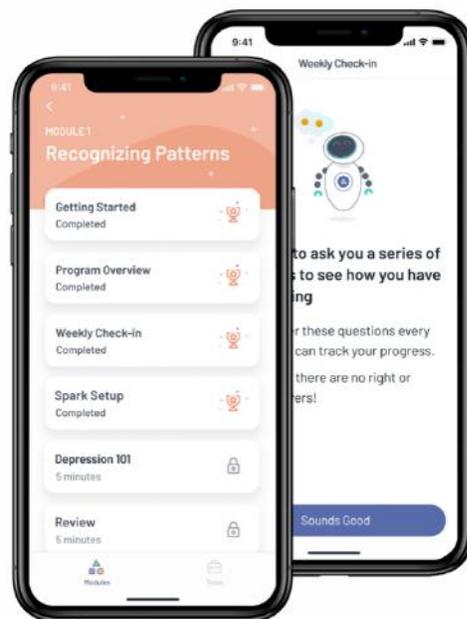




Location: 839 Emerson Street Palo Alto, CA 94301
Amount Raised to Date: \$16mm
Website: <http://www.limbix.com/>

A treatment option for adolescent depression comes from **Limbox** and uses cognitive behavioral therapy (CBT) called Spark. It is a several week program revolving around value-based accomplishments intended to give a feeling of achievement and success. Although the Palo Alto based firm is still in R&D mode, this device will be eligible for FDA approval before February 2021 and received vast amounts of funding and investor interest. After completion of a final clinical trial and FDA approval, it will be marketed to physicians so they can prescribe the treatment to their patients.

Limbox raised a \$9 million Series A from GSR Ventures, Sequoia Capital, Storm Ventures, NextGen Venture Partners, and BIXINK Therapeutics in May of this year and is pursuing an additional \$1.5 million in follow-on monies. These funds will be utilized in the completion its final clinical trial. They are planning to host a Series B in 2021 in order to fund product development and commercialize Spark. They are planning to target their current investors, as well as, other healthcare-oriented venture capital funds.

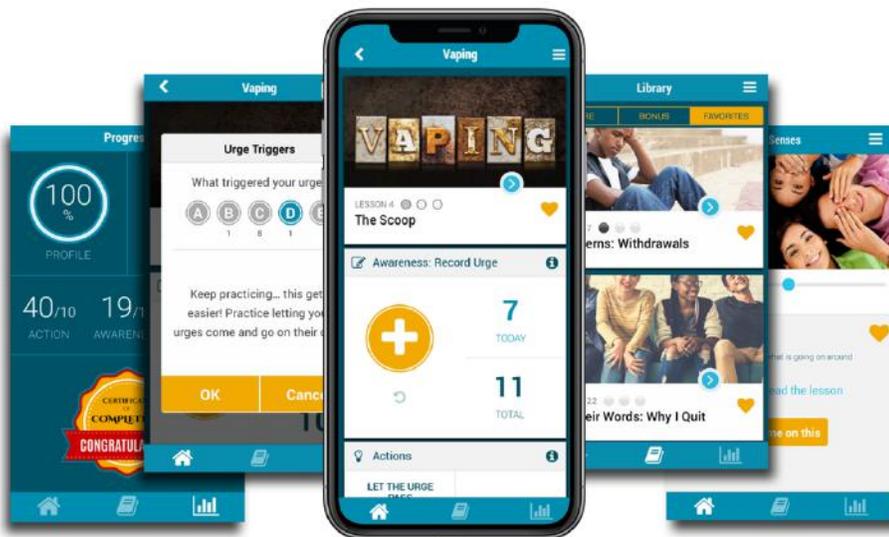


In a meeting with Lawrence, Evans & Co., Ben Lewis, CEO, confirmed that they are hoping to launch their next round of funding in the new year and that the majority of the proceeds will go towards the commercialization of their product. However, he did note that FDA approval is more likely two years away. Additionally, he commented on how other DTx companies have rushed to launch during the pandemic and how Limbox is resisting the urge in order to perfect their product. As it relates to their current R&D phase, Lewis said that "it's nice not to have to worry about bug fixes or customer service and work on making sure those things aren't needed."



Location: 12020 113th Avenue North East Kirkland, WA 98034
Amount Raised to Date: \$1.27mm
Website: <http://www.2morrowinc.com/>

There is another epidemic that has been in the headlines recently and **2Morrow Health** is working to provide a solution with their Vaping Cessation Program. A reported 30% of high schoolers use some sort of nicotine based vaping product. The side effects of this can be a lifetime of dependency, financial strain, chronic health issues, premature death, and a litany of other negative effects.



Like many of the other DTx products, this is an app-based program where the patient creates their personalized, self-paced “quit plan.” The application is designed for teens and provides short daily lessons, text-based messaging, and actionable tips. These text messages will also have the ability to track progress. The goal of this Acceptance and Commitment Therapy (ACT) is to help youths learn ways to cope with urges, cravings, and unhelpful thoughts

while progressing towards their goals. It also offers a non-judgmental and private solution to a sensitive age group. As of now, this product is currently available for states, employers, and health plans.

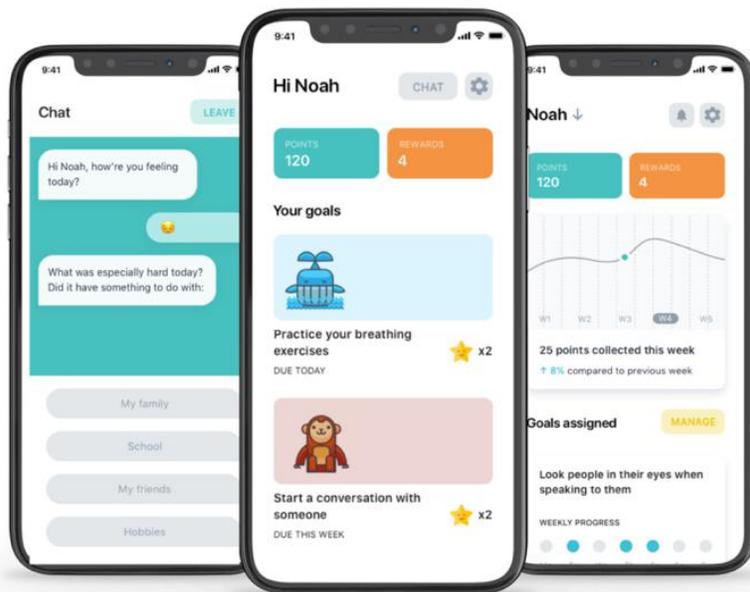
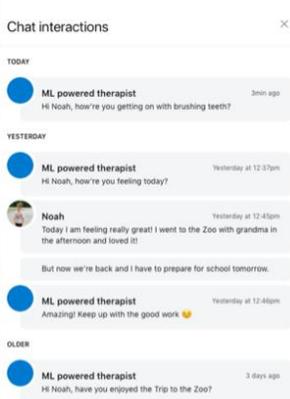
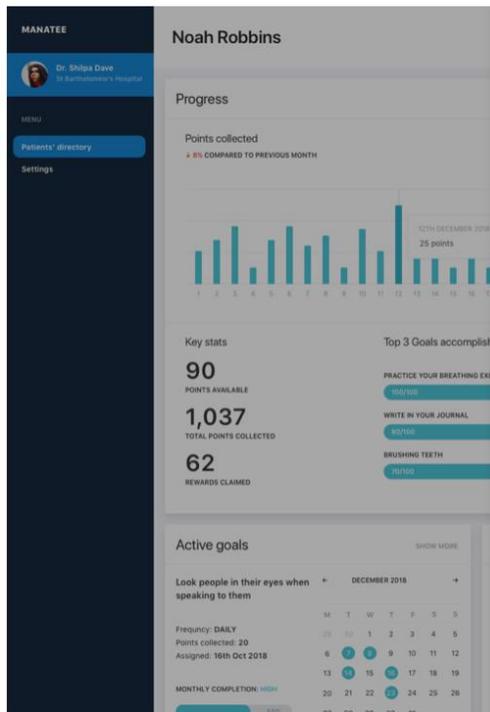
After 2Morrow's most recent funding round, they have raised a total of \$1.27 million from investors such as Big Basin Partners, Cascadia Venture Forum, Portland Seed Fund, The Washington Medical Technology Angel Network, Alliance of Angels, and other undisclosed groups.



Location: 663 South Oneida Way Denver, CO 80224
Amount Raised to Date: \$1.88mm
Website: <http://www.getmanatee.com/>

Another smart phone app that offers therapy services to children is **Manatee**. This can be applied to patients with behavioral disorders or to maintain stable mental health. Instead of going to a therapist or psychologist on a monthly or even weekly basis, the patient can receive therapy integrated into their daily life. The app itself has a parent and patient portal and allows the family to track, remind, and adjust settings in the pursuit of collective treatment goals. Similar to Akili Interactive's EndeavorRx, the software utilizes "gamification" which makes treatment fun of kids. As for providers, the application tracks insights in a clinical dashboard which allows for effective, data driven, value-based care.

So far, Manatee has only conducted a seed round of funding, which raised \$1.74 million from Grand Ventures, Vinaj, SpringTime Ventures, Danish Munir, Luke Leninger, Jonathan Weiner, and The American Family Insurance Institute for Corporate and Social Impact. The deal concluded on July 8, 2020.



Providers

Parents



Location: 200 State Street Boston, MA 02109
Amount Raised to Date: \$139mm
Website: <http://www.peartherapeutics.com/>

One of the major players in the digital therapeutics space is **Pear Therapeutics**. The company offers numerous products that provide solutions to problems such as insomnia and substance abuse. Earlier this year, they announced a partnership with the Cincinnati Children's Hospital Medical Center where they will license their existing cognitive behavioral therapy software to the hospital as a treatment for chronic adolescent migraine patients. The therapy uses this CBT and patient education to produce results, as was evaluated by the medical center in a completed clinical trial.

Additions to the company's platform come from new acquisitions, development, and licensing agreements with Firsthand Technology, the Karolinska Institute in Sweden, Winterlight Labs, and NeuroLex Laboratories.

Pear has completed three rounds of funding (A through C). Their 2019 Series C raised \$64 million from Temasek Holdings, Novartis, Trustbridge Partners, EDBI, 5AM Ventures, Arboretum Ventures, JAZZ Venture Partners, Bridge Builders Collaborative, and Blue Water Life Science Fund. The deal put their post-money valuation at \$494 million. Pear plans to use the funds to commercialize their products, fund their upcoming clinical trials, and acquire new assets. Their Series A and B reigned in \$20 million and \$50 million, respectively.

Pear's Pipeline:

PRODUCT/ CANDIDATE	THERAPEUTIC AREA	DISCOVERY AND TRANSLATION	POC	PIVOTAL	COMMERCIAL	CONTENT PARTNER
reSET	Substance Use Disorder	[Progress bar from Discovery and Translation to Commercial]				DARTMOUTH
reSET-O	Opioid Use Disorder	[Progress bar from Discovery and Translation to Commercial]				DARTMOUTH
Somryst	Chronic Insomnia	[Progress bar from Discovery and Translation to Commercial]				VIRGINIA
PEAR-004*	Schizophrenia	[Progress bar from Discovery and Translation to POC]				
DISCOVERY*	IBS	[Progress bar from Discovery and Translation to POC]				Karolinska* Institutet
DISCOVERY*	Pain	[Progress bar from Discovery and Translation to POC]				Firsthand TECHNOLOGY
DISCOVERY*	PTSD	[Progress bar from Discovery and Translation to POC]				USC
DISCOVERY*	Migraine	[Progress bar from Discovery and Translation to POC]				Cincinnati Children's



Location: 10960 Wilshire Blvd Los Angeles, CA 90024
Amount Raised to Date: \$12.86mm
Website: <http://www.neurosigma.com/>

A product from **NeuroSigma, Inc.** is not a smart phone application, but a medical device called the **Monarch eTNS** and is the first non-drug treatment for ADHD to be approved by the FDA. Another unique feature of this device is that it works while the patient is asleep. It uses external Trigeminal Nerve Stimulation (TNS) in the form of a patch applied to the child's forehead before going to sleep. Throughout the night, it will stimulate the brain's trigeminal nerve which is the largest cranial nerve and is responsible for transmitting sensations from the nervous system and brain areas involved in mood disorders, epilepsy, and attention span. In fact, TNS is approved for treatment of mood disorders and epilepsy in both Canada and Europe. The nerve is also believed to be a pathway to the inner brain and other areas that are not easily affected by neurostimulation.



A recent study conducted by UCLA tested the Monarch eTNS in a double-blind, placebo-controlled trial. The study yielded compelling evidence that, compared to the placebo, children suffering from ADHD showed major reductions in impulsivity, hyperactivity, and inattention (measured by clinician-administered ADHD rating scales) after four weeks of use.



The device is intended for use among children ages 7 to 12 and is not to be used in conjunction with medication. Additionally, it is by prescription only and should be used under direct supervision of a caregiver. The device starts at \$980 and includes everything required for a month of use. Follow-on refills of electric patches are sold in packages of 7 and costs \$70 per unit.

NeuroSigma has raised \$12.86mm to date, primarily in the form of convertible debt and grants.



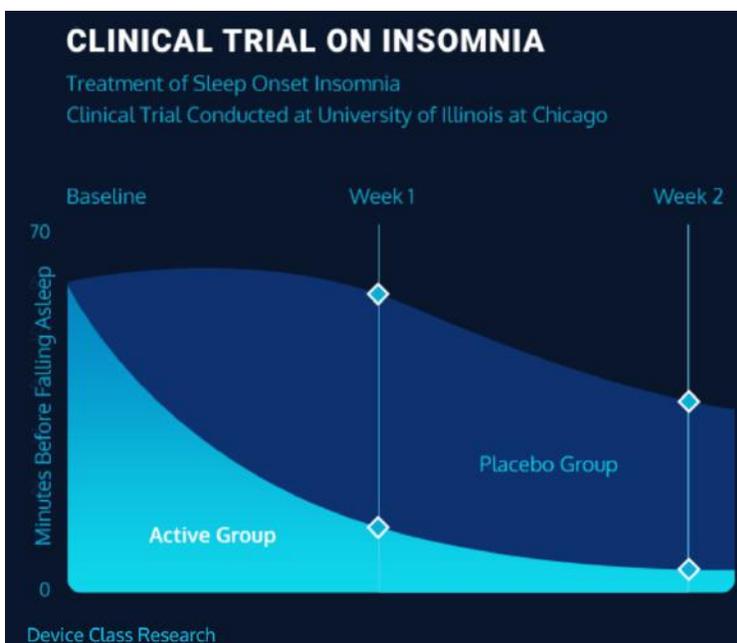
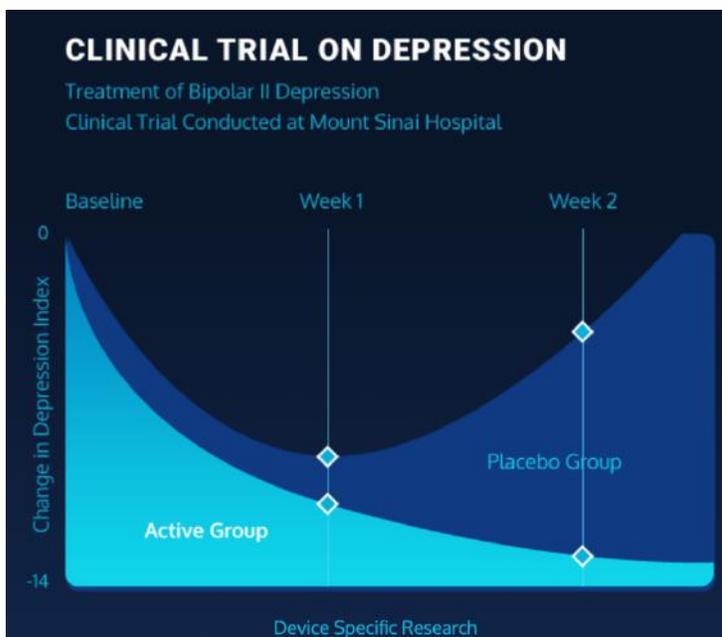
Location: 515 Madison Avenue New York, NY 10022
Amount Raised to Date: \$1.06mm
Website: <https://www.fisherwallace.com>

The Fisher Wallace Stimulator is a self-administered neurostimulation product that, similarly to the Monarch eTNS, is attached to the forehead and sends waves of electricity through the brain. As of now, this device is not cleared to treat ADHD, but is FDA approved to combat mood disorders, anxiety, and insomnia. These disorders often occur with ADHD and have been known to make certain symptoms worse. It accomplishes this treatment by releasing serotonin and reducing cortisol levels (if the amount of cortisol in the brain remains high for long periods of time it can trigger multiple negative physical and mental effects). Fisher Wallace Labs reports a 75 to 80% success rate among patients in their clinical trials.



Unlike the device from NeuroSigma, the Fisher Wallace Stimulator is meant to be used for 20 minutes a day for the first month and then on an as needed basis. These patients must receive authorization from a licensed medical professional.

The company has not completed any funding rounds and has sourced most of its capital from crowd and angel funding with their most recent influx of cash occurring in March of 2020.



Treatment in a Pandemic

The past few months have changed nearly everything about our daily life and healthcare is no different. We now choose to access healthcare in ways we never could have imagined 20, or even 10 years ago. Maybe the only good thing about the lockdown occurring in 2020 is that we are still able to access crucial care that in years past would have caused us to risk our health in order to receive or would have altogether been impossible.

In a way, the pandemic could be seen as a positive as it relates to the progression of technology in medicine. The use of telehealth services has exploded in recent months and for obvious reasons. Patients are now able to consult physicians via the internet or telephone. This keeps everyone safe from potential sickness. Telemedicine now covers everything from dentist visits to orthopedic appointments.

Those in the digital therapeutics space will have the chance to benefit in more ways than one. For the most part, their products do not require a large number of in-person visits, but also, the pandemic and subsequent lockdown has taken a toll on millions of people's mental health which is a major treatment focus for DTx products.

Adult's mental health is not the only victim in these turbulent times, children also suffer from the effects of a lack of social interaction and limited time outside. For an age group that is sensitive to begin with, this can have enormous adverse effects. The number one leading cause of death in English children ages 5 to 19 is suicide, which is the second leading cause of death in young people worldwide. Specifically, in young people aged 5 to 19, 1 in 8 have at least one mental disorder. Mental health professionals have taken notice and are expecting a large increase in the need for adolescent mental health services in the coming months. Some professionals are even asking for children to be exempt from the stay-at-home guidelines and should even be allowed to attend school.



The Food and Drug Administration has also taken notice and action to help those suffering from these lockdown measures. Briefly, the FDA announced an expedited approval process for certain medical services as a result of the

pandemic. This recent action has allowed for payors to be more inclined to reimburse DTx treatment as these products begin to prove themselves as substitutes for expensive (and dangerous) in-person treatments and medications. These FDA actions will be thoroughly discussed in the following section.

Treatment in a Pandemic Cont.

COVID-19 has also acted as a catalyst for potential partnerships with digital therapeutic companies and digital pharmacies. In the past, these services have been offered separately, but now as consumer demand has risen it is clear that the patients prefer an integrated system. One such partnership occurred recently between **Express Scripts** and Propeller Health. The PBM picks DTx companies to add to its formulary based on clinical effectiveness and usability. **CVS** also recently began a digital health formulary. As COVID fuels these frequent mergers, the higher the likelihood of payor DTx acceptance, reimbursement, and placement alongside traditional products and devices.

Another example of the pandemic progressing the use of digital therapies came on July 14, 2020. One of the country's largest digitally enabled mental healthcare providers, **Integrated Behavioral Health, Inc.**, launched a digital healthcare centered incubator and consortium called **Dysruption**. IBH's incubator program was crafted with the goal of quickly prototyping, evaluating, and launching novice evidence-backed technologies that will improve quality and accessibility of mental healthcare. Dysruption will act as a gathering place for scientists, providers, and entrepreneurs in the pursuit of exploration and deployment of quality patient care during the COVID-19 health crisis.



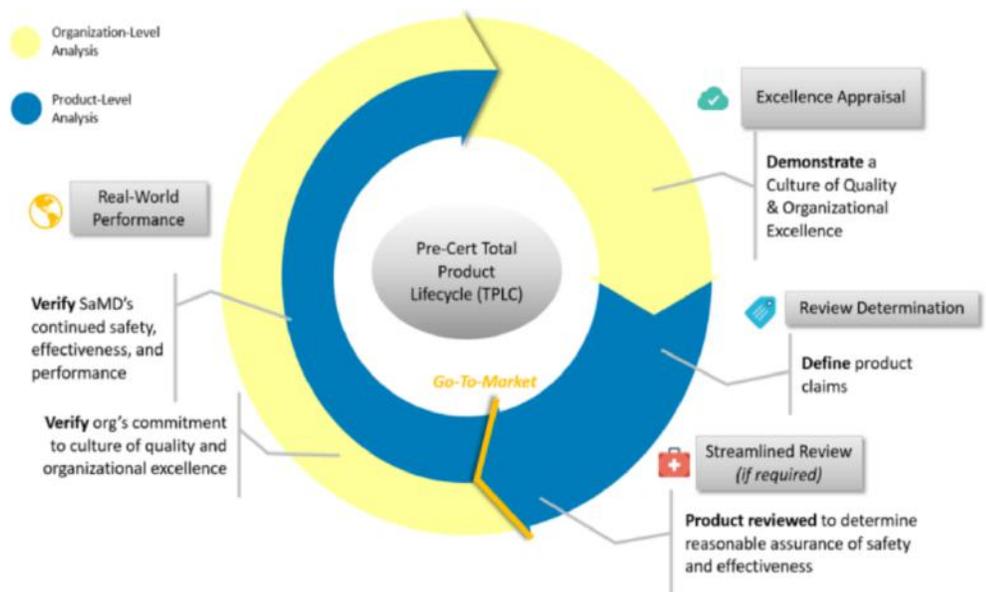
Shaping the future of behavioral healthcare using **artificial intelligence (AI)** and **machine learning** to improve quality and outcomes of talk therapy counseling sessions.



Regulation and payor reimbursement are two of the remaining hurdles for the digital therapeutics industry. Payers can be hesitant to support DTx because success rates can be hard to prove, and regulation is difficult because it is hard to limit something that can adapt on a daily basis. Some of the questions regulatory agencies seek to answer include: What would act as a placebo in a DTx clinical trial? How can DTx generics be created? How far must regulation go – does it need to regulate the operating system or smart device? Would internet connection providers require guidelines? How often should software be reviewed due to its constantly adapting nature as algorithms change with machine learning and AI? These questions and many more fuel the debate among the DTx and regulatory communities.

The Pre-Certification Program

Recent events have forced the hand of government agencies. The timeline begins in 2017 when the Food and Drug Administration announced their first “Pre-Certification Program.” This pilot phase only pertained to biopharmaceutical and medical device companies, until 2019 when it was announced that a similar Pre-Cert Program was being launched for digital health software companies. This program “will help inform the development of a future regulatory model that will provide more streamlined and efficient regulatory oversight of software-based medical devices developed by manufacturers who have demonstrated a robust culture of quality and organizational excellence, and who are committed to monitoring real-world performance of their products once they reach the U.S. market,” the agency explained.



Total Product Lifecycle Approach of the Software Precertification Program

The goal of these programs is to offer a streamlined option for health software companies. Just after the announcement the FDA noted, “Because software products can be adapted to respond to glitches, adverse events, and other safety concerns quickly, the FDA is working to establish a regulatory framework that is equally responsive when issues arise to help ensure consumers continue to have access to safe and effective products.”

The FDA showed understanding in that it would be unworkable to run each software product through the traditional channels of approval. A way they are working to improve efficiency is by simply approving the developer. This allows for rapid product development instead of a never-ending approval cycle.



The FDA still maintains strict guidelines on companies in the Pre-Cert Program. Products still must undergo and display software verification, as well as, validation and hazard analysis. Additionally, they must meet the agency's requirements for cybersecurity and include proper labeling alerting the patient that they must contact their medical professional before use.

COVID-19

In March of 2020, everything changed, and the nation went into lockdown. While devastating for the economy and the moral of the American people, it did provide an opportunity for digital therapeutic companies and telemedicine, in general.



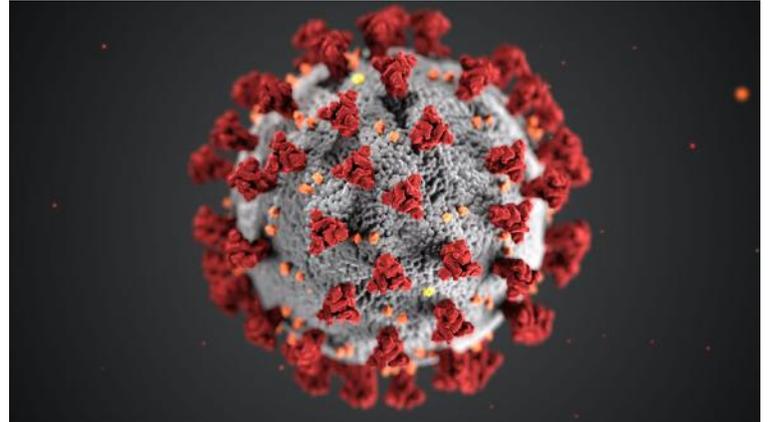
Specifically, on March 18th, Vice President Pence, head of the White House Coronavirus Task Force, announced that healthcare providers would now be able to practice across state lines which allowed tele-med companies greater access to physicians. Also, CMS recently raised reimbursement rates for telehealth treatments. These facts point to a greater tele-med use among healthcare providers.

The DEA also took action that week and provided new guidance on an existing act which allowed physicians to prescribe narcotics without an in-person visit. This alone could allow for digital pharmacies to make major gains in the coming months

It is evident that the tele-health sector is benefiting from the current situation and digital therapeutics is no different. The FDA announced that they will, for the duration of the pandemic, lower major barriers in the approval process for low risk technologies that provide relief to those suffering from psychiatric disorders including autism, post-traumatic stress

disorder (PTSD), ADHD, anxiety, insomnia, and depression. Specifically, the agency made adjustments to their clinical evidence standards, the necessity for 510(k) submissions, and registration and listing requirements. The FDA was sure to note that this policy will not increase risk for existing, validated products and will require that all products follow their cybersecurity guidelines.

The agency also released a label guide to help patients better understand these devices that now flood the market. This guide is directed towards the developers of the products and will allow for complete transparency between producer, provider, and patient. Specifically, it is recommended that the label includes each of the following: a statement recommending that the patient consults their physician before use, directions on what to do in the event of



a medical emergency, a vivid description of use, a list of any functions that are not officially FDA-cleared, a description of the therapeutic method and summary of clinical testing, instructions on when to consult a physician and what to do if symptoms are not improving, and even diagrams displaying proper use of the device.

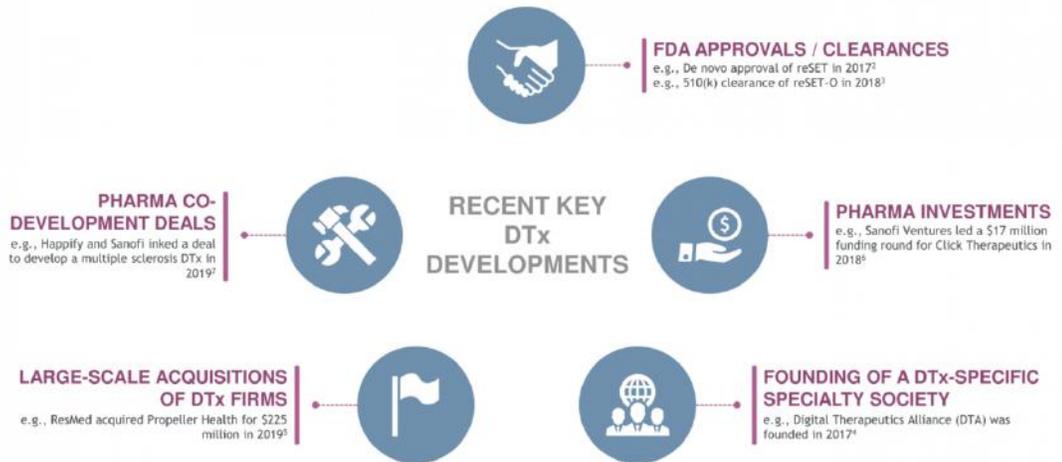
An example of a device that took advantage of this adjusted approval pipeline was the EndeavorRx from Akili Interactive. Because of its low to moderate risk profile, it qualified for the program. Another aspect of this new approval process is the allowance for similar products to easily follow in the footsteps of devices that have gone before. For example, the EndeavorRx approval created a new classification that allows devices with the same intended use to easily obtain marketing authorization from the FDA.

A lot of things about our country's current climate remain uncertain. This adjusted approval process is intended to last only for the duration of the pandemic. Of course, no one knows how long that could be and what the state of healthcare will look like after. However, one thing is almost certain, if the FDA reverts back to their traditional method of approval for DTx products, the makers of these life improving devices will be extremely well positioned to submit their therapies for approval.

These facts could lead to enormous changes in the field of digital therapeutics and, more importantly, the role they can play in the improvement of millions of people's lives.

Payer Reimbursement

While in recent months and years the DTx industry has clearly expanded and gained popularity in consumer, provider, and regulatory communities, it still remains underutilized when compared to the positive impact it could potentially have. This is largely due to the lack of payer reimbursement that stems from a lack of education. This fact remains the final major hurdle for digital therapeutics



companies and the industry as a whole. While it is almost certain to reach widespread acceptance in the coming years, the question remains, how does the industry get to that point and how long will it take? This question was summarized over and over at the annual DTx West Conference in Silicon Valley in February, but was posed more generally

as “Can we achieve replicable reimbursement?”

The antiquated processes and mandates of traditional payers have created a major challenge for DTx startups as they attempt to begin the commercialization process. These processes certainly miss the complete value add opportunities digital therapeutics offer. As a result, these companies are forced to adapt to a less beneficial, more accepted business model. This poses the secondary question of should the DTx industry continue to pursue payer reimbursement or resort to a direct-to-consumer (DTC) method? Furthermore, as digital therapeutics is a new way of administering healthcare, could there be a new way of receiving payment for this life-improving care (i.e., value-based health care and risk-sharing)? With the now abundant use of “FinTech,” this is a question to entertain and possibly a topic for another report.

The current payment models and methods for payment remain disjointed. This is primarily because of the various techniques and applications offered by the digital therapeutics industry. Some experts in the budding sector maintain that those involved should be open to a shifting, adapting payment platform that alters as innovation arises and technology progresses. While others maintain that the goal is to determine a universal payment program that promotes patient access. The questions that fuel these debates include: What if traditional methods of reimbursement fail to fully capture the value of DTx? What if the optimal method varies by product, product version, and/or customer? Industry leaders believe that their path is clear. A Decision Resources Group study has revealed the answer. Of the 22% of U.S adults who are interested in using digital therapeutics to treat, manage, or prevent health conditions/disorders, 20% say they would like to pay for it as they would for any traditional medication and another 20% expect that their insurance will over their DTx treatment. Other digital health brands have tried this form of commercialization and have displayed these percentages in a lack of revenue and a lack of use. It is far too easy to download an app from the App Store, use it for a week, and leave it to collect dust on your home screen. This makes it clear that payer acceptance is the only way forward.



Payer Reimbursement Cont.



Industry trailblazers are beginning to voice their opinions and next moves as they continue to brainstorm ways to influence wider acceptance. Brent Vaughan, CEO of Cognoa, says that the goal for payers is balancing cost reduction and quality care and that larger payers will engage those digital therapeutics that are able to present efficient pharmacoeconomic data. Yasodhara Paruchuru, VP at **Happify Health**, which has recently partnered with the American Heart Association, Sanofi and Cigna, stated the obvious in that DTx needs “sustainable reimbursement,” but went further by noting that these products will certainly deliver cost savings and efficacy and that payers are fueled by company models that promote adherence and efficacy, while lowering costs. These facts make future acceptance inevitable.

POTENTIAL PAYMENT MODELS FOR DTx

	Payer Pays			Institution Pays	Patient Pays	Innovative Payment Models
	Medical Benefit	Pharmacy Benefit	Direct Investment			
Definition	<ul style="list-style-type: none"> • Payers reimburse physicians for procedures and medical products • Typically assigned CPT/HCPCS for billing purposes 	<ul style="list-style-type: none"> • Payers reimburse pharmacies for the distribution of self-administered medical products • Typically assigned NDC for billing purposes 	<ul style="list-style-type: none"> • Payers, employer groups, institutions (health systems, hospitals, physician offices) may absorb the costs of medical products to save downstream costs (e.g., a product that boosts compliance to avoid readmissions and readmission penalties) 		<ul style="list-style-type: none"> • Patients pay for medical products directly (direct-to-consumer/retail) 	<ul style="list-style-type: none"> • Value-based health care contracts (e.g., risk-sharing agreements)
Manufacturer Considerations	<ul style="list-style-type: none"> • Payer coverage will determine access to medical products and evidence of clinical and/or economic benefit will be needed to support coverage 		<ul style="list-style-type: none"> • There is no need for manufacturers' to apply for CPT/HCPCS/NDC codes; however, the cost of medical products must be aligned with payers' /institutions' budgeting process 		<ul style="list-style-type: none"> • There is no need for manufacturers to apply for CPT/HCPCS/NDC codes; however, the cost of the medical products must be aligned with patients' willingness-to-pay 	<ul style="list-style-type: none"> • Depending on the terms of agreement, manufacturers may not be paid unless success metrics (clinical or economic) are met (e.g., X amount of cost-savings)
Stakeholder Implications	<ul style="list-style-type: none"> • Patient: may be responsible for cost-sharing (e.g., copay) • Physician: need to bill payers and are at financial risk should payers decide to not cover the product 	<ul style="list-style-type: none"> • Patient: may be responsible for cost-sharing (e.g., copay) • Physician: no need to bill payers and are therefore not at financial risk 	<ul style="list-style-type: none"> • Patient: not responsible for cost-sharing (e.g., copay) • Physician: no need to bill payers and are therefore not at financial risk 		<ul style="list-style-type: none"> • Physician: no need to bill payers and are therefore not at financial risk • Payer: no need to reimburse providers or pharmacies 	<ul style="list-style-type: none"> • Other Party: at less financial risk for paying without demonstrated results

CPT = Level I HCPCS codes (procedures); physicians are reimbursed for their time spent performing services, which can include the cost of using medical products
 HCPCS = Level II HCPCS codes (procedures and products that are not included in CPT codes (e.g., drugs, surgical supplies, etc.)); physicians are reimbursed for medical products only
 NDC = Identification codes for drugs





Payer Reimbursement Cont.

Other leaders, such as Alex Waldron from Pear Therapeutics, pushes peers to embrace payment models based on low distribution costs. He also said that data is the product and that those in the industry must highlight the economic impact of quality patient outcomes.

An alternate approach comes from Megan Coder from the Digital Therapeutics Alliance who believes that CMS should create a new category. Specifically, she said that as of now those on Medicare do not have DTx covered and that the industry is laboring to establish that “this evidence-based type of medicine is legitimate and should be covered as long as we maintain security and patient safety. DTx data shows outcomes as well as provides insights for appropriate treatments.”

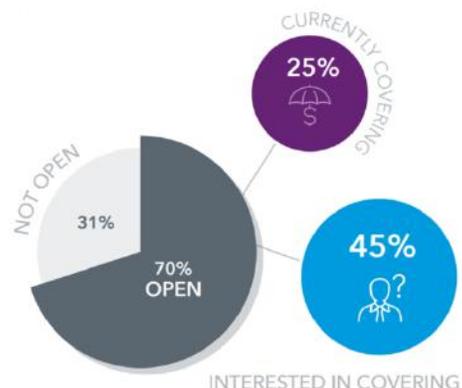
Coder makes an important point, those on Medicare and Medicaid are being deprived of the life-altering options DTx can provide. For example, there are 37 million children on Medicaid health insurance, 9 million of whom are in the Children’s Health Insurance Program (CHIP). Furthermore, 11.2 million of these adolescents have special health care needs. As of this writing, all of these individuals do not have access to payer subsidized digital therapeutic treatments. **Below is a breakout by state of total children in Medicaid and CHIP:**

State	Total Children on Medicaid & CHIP	State	Total Children on Medicaid & CHIP
Alabama	665,956	Montana	110,434
Alaska	98,473	Nebraska	163,831
Arizona	NA	Nevada	300,950
Arkansas	367,766	New Hampshire	90,642
California	4,758,270	New Jersey	810,651
Colorado	565,613	New Mexico	332,532
Connecticut	334,354	New York	2,408,010
Delaware	105,862	North Carolina	1,199,369
DC	NA	North Dakota	44,044
Florida	2,454,210	Ohio	1,184,214
Georgia	1,293,844	Oklahoma	530,880
Hawaii	141,912	Oregon	420,389
Idaho	178,988	Pennsylvania	1,404,702
Illinois	1,353,607	Rhode Island	116,915
Indiana	817,825	South Carolina	640,353
Iowa	338,941	South Dakota	78,575
Kansas	270,855	Tennessee	824,094
Kentucky	599,686	Texas	3,358,735
Louisiana	727,484	Utah	188,466
Maine	104,844	Vermont	61,564
Maryland	622,300	Virginia	762,391
Massachusetts	670,412	Washington	820,036
Michigan	949,631	West Virginia	212,950
Minnesota	532,897	Wisconsin	511,820
Mississippi	408,752	Wyoming	37,593
Missouri	552,584		

Payer Reimbursement Cont.

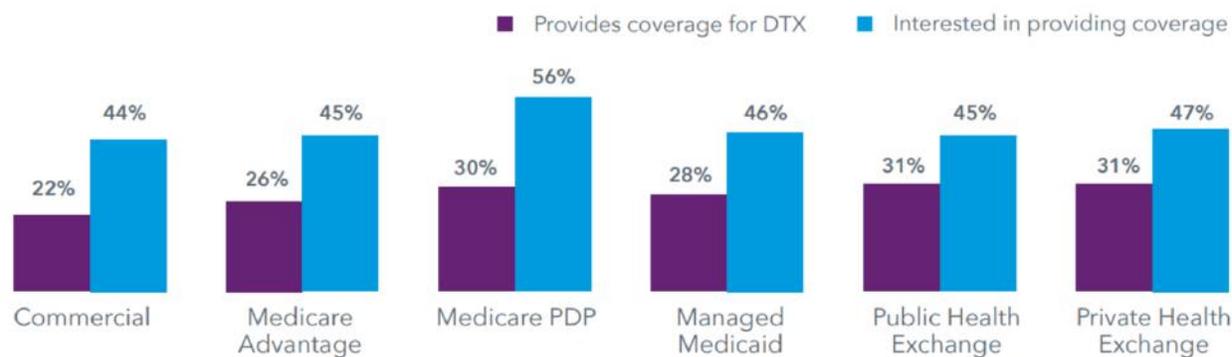
All of these actions and comments are starting to have an effect. Decision Resources Group has surveyed 157 Pharmacy and Therapeutics (P&T) committee members and found that almost 50% agree that “Digital therapeutics are the future of healthcare.” Among these healthcare professionals, who make formulary decisions in hospital systems (IDNs, MCOs, and PBMs), 1 out of 4 said that their organization already provides coverage and 45% showed extreme interest in providing coverage in the future.

Decision Resources Group went further and found that receptiveness from these formulary decision makers could boost physician interest in digital therapeutics even further. In the United States, 44% of doctors surveyed showed interest in prescribing medical applications to patients and among doctors who are P&T members, that number grows to 52%.



Among all U.S. P&T committee members
Source: Multichannel Payer Marketing 2020

Openness to digital therapeutics (DTx) coverage by health plans offered:



Among all U.S. P&T committee members in IDN+s, MCOs, and PBMs
Source: Multichannel Payer Marketing 2020

Payer Reimbursement Cont.

The recent partnerships between large PBMs, pharmaceutical companies, and DTx firms also help advance the payer reimbursement timeline. Another Decision Resources Group study conducted in the latter half of 2019 showed major shifts in the payer landscape. This was mainly driven by the decision of two major PBM's (comprising of 53% of the market share) to facilitate DTx into their U.S. health plans.

As these powerful partnerships, CEO comments, and PBM acceptance continue to become more and more frequent, support from all those involved in the healthcare space will undoubtedly follow to include, and maybe most crucially, the payers



CVS Caremark unveiled a platform enabling payers to formalize and streamline the process for DTx reimbursement and distribution, allowing health plan clients to access negotiated pricing, verify member eligibility, and navigate the payments process.



Express Scripts announced that DTx solutions would be added to its digital health "formulary." The categorization of DTx into coverage tiers, much like traditional medicines, aims to protect health plans from higher costs while providing better access to these novel solutions.

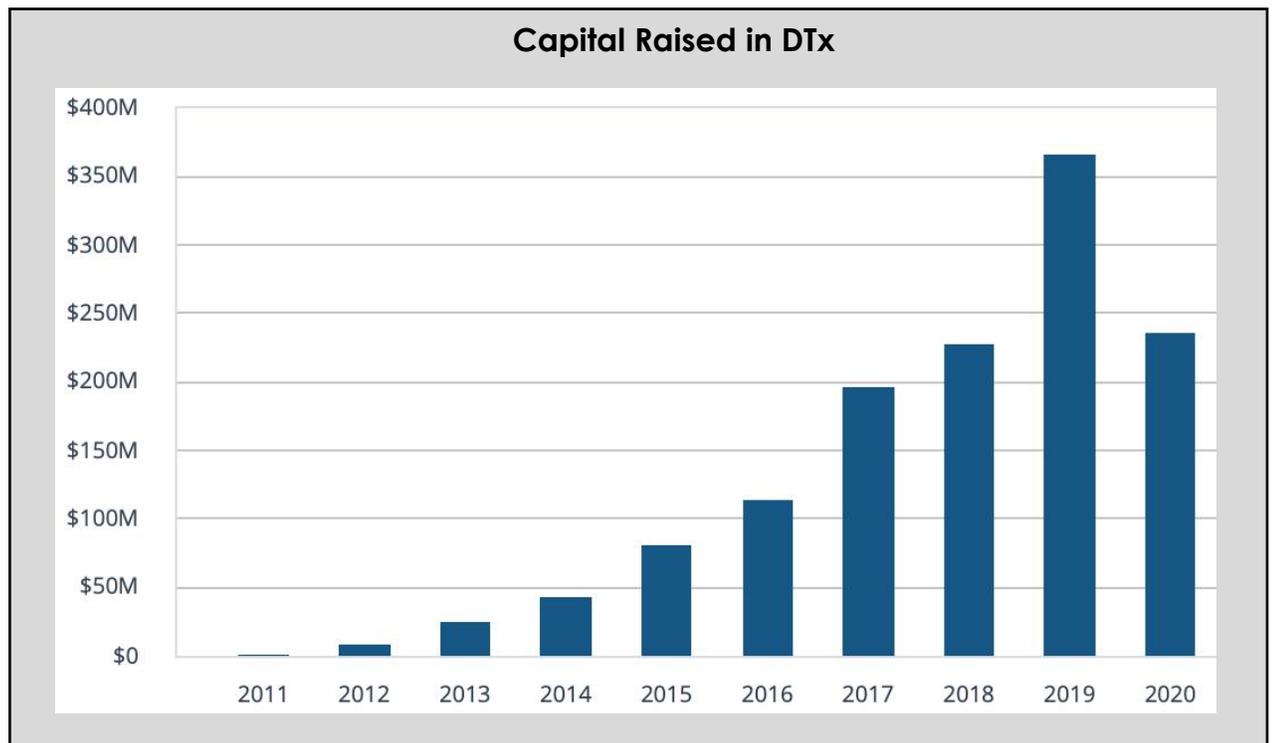
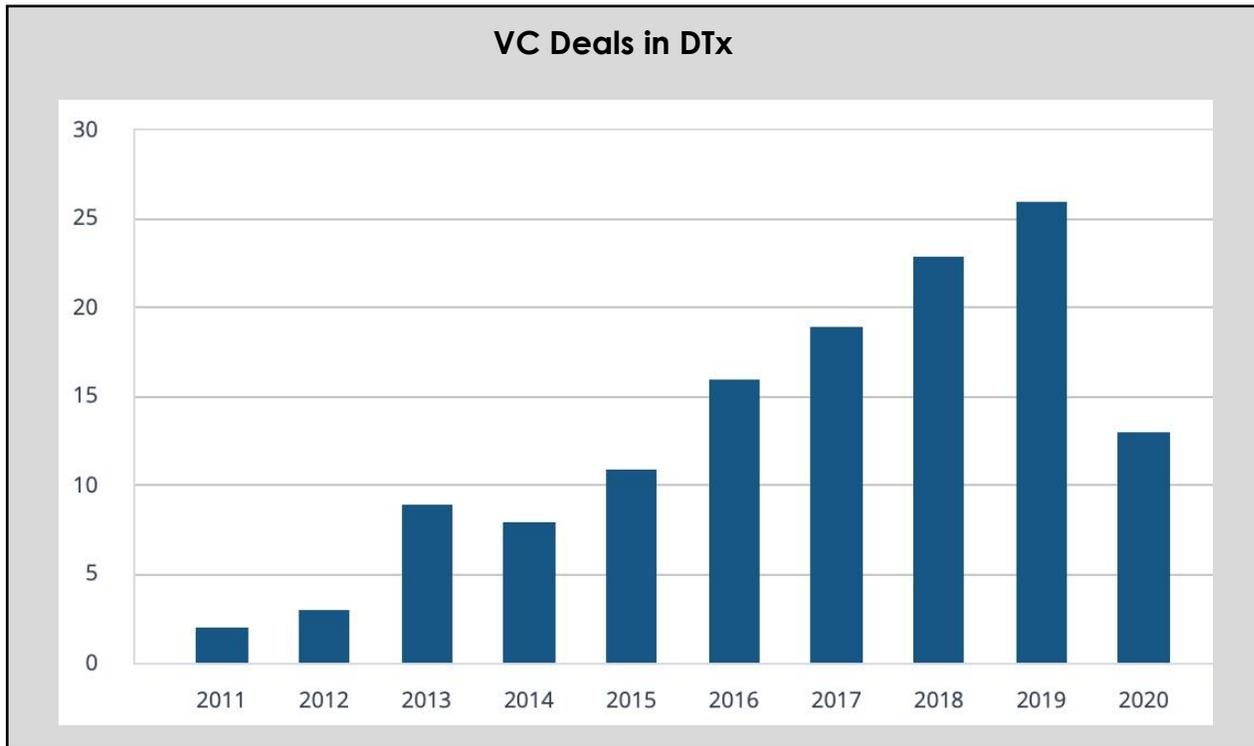


In addition, Blue Cross Blue Shield, Medicaid, Highmark Health and Competitive Health added digital solutions to their benefits lists. Notably, Medicaid and Highmark have expanded coverage for tools beyond traditional therapeutic area indications (e.g., mental health or diabetes) to include novel digital tools for precision prenatal/postpartum care and cardiac rehab respectively. Findings from DRG's Multichannel Payer Marketing study revealed that P&T committee members who have voted for, or advised on, new prescription medications or indications related to cardiovascular disorders are more interested in providing coverage for DTx compared to those voting/advising on other therapeutic areas.

Source: decisionresourcesgroup.com



Investment Activity in DTx



Accessed July 2020 from PitchBook Data, Inc.

Investment Activity in DTx Cont.

Major Investors into DTx



JAZZ Venture Partners

Deal Count
9

Last Deal Date
30-Jun-2020



Plug and Play Tech Cent...

Deal Count
6

Last Deal Date
08-Jul-2020



Aspect Ventures

Deal Count
5

Last Deal Date
28-May-2020



US Venture Partners

Deal Count
5

Last Deal Date
30-Jun-2020



Connecticut Innovations

Deal Count
4

Last Deal Date
01-Jul-2020



Andreessen Horowitz

Deal Count
4

Last Deal Date
13-Jul-2020

Top Capital Raising Companies in DTx



Click Therapeutics

Total Raised
\$322.46M

Last Deal Type
Corporate



Omada

Total Raised
\$257.50M

Last Deal Type
Later Stage VC



Mindstrong

Total Raised
\$159.85M

Last Deal Type
Series C



Pear Therapeutics

Total Raised
\$139.00M

Last Deal Type
Series C



Akili Interactive

Total Raised
\$119.00M

Last Deal Type
Series C



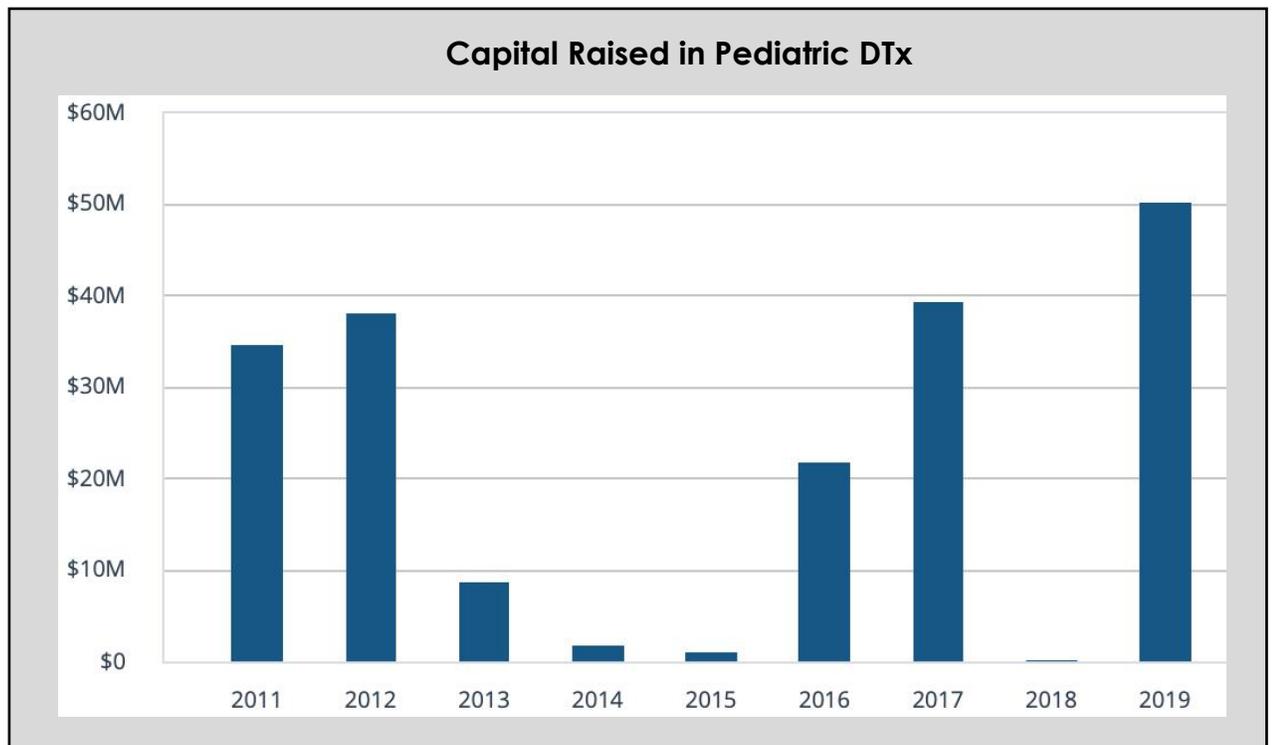
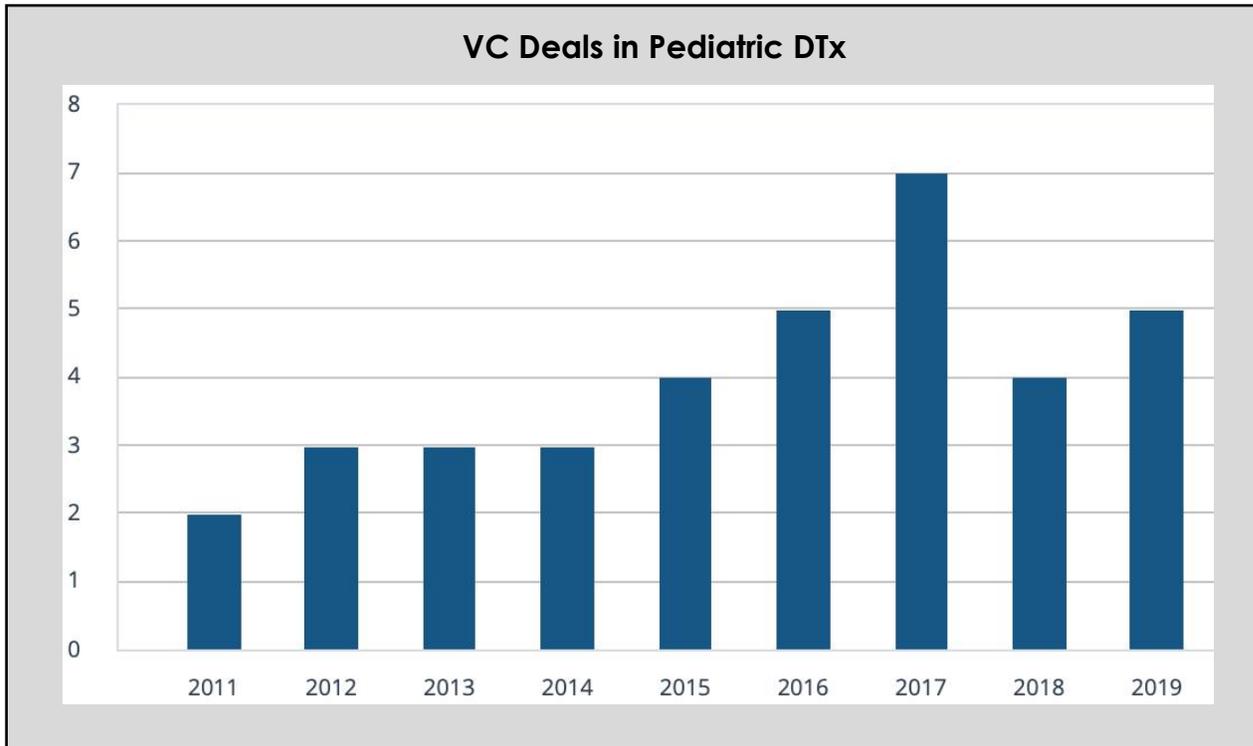
Vida Health

Total Raised
\$83.00M

Last Deal Type
Later Stage VC

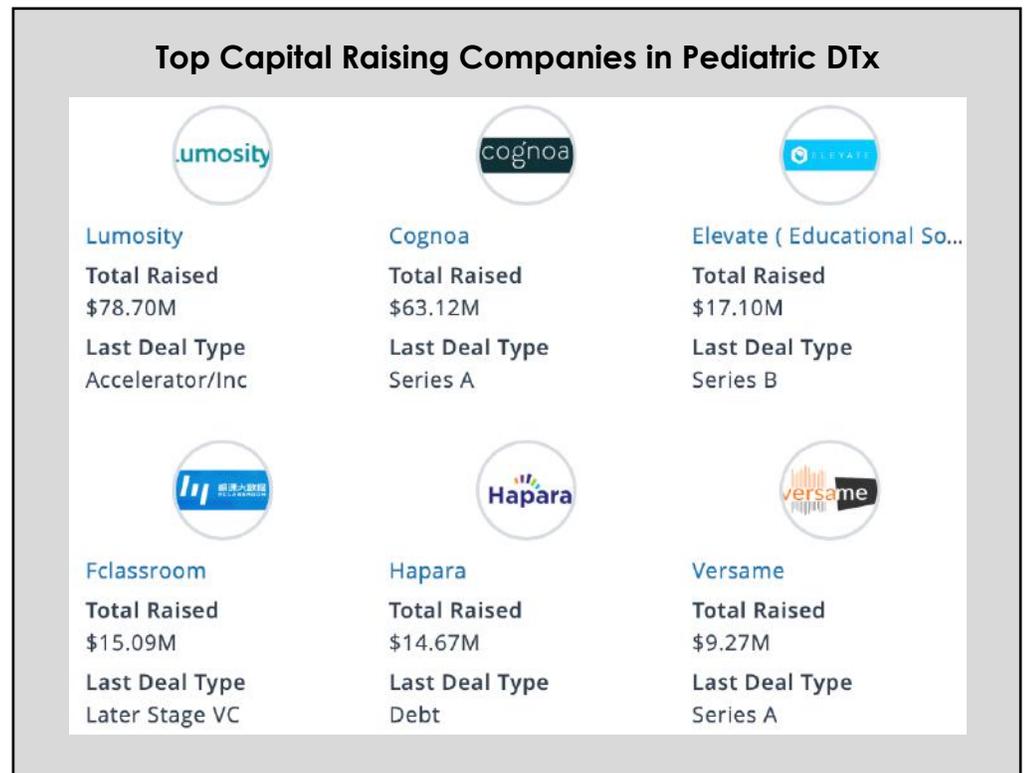
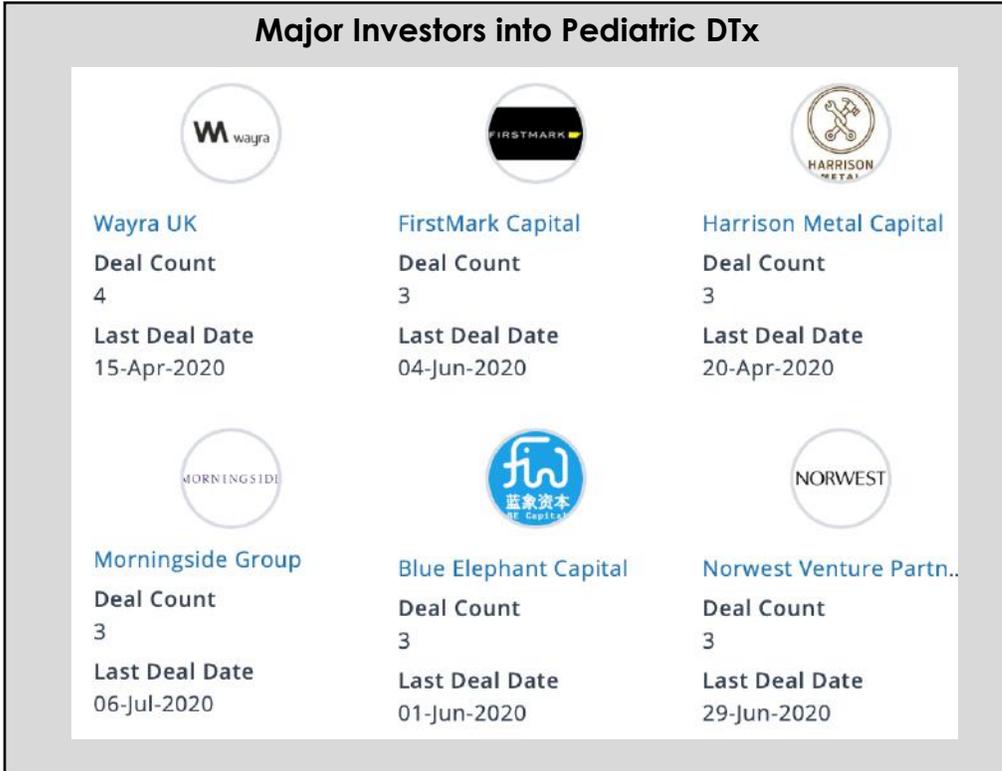


Investment Activity in Pediatric DTx





Investment Activity in Pediatric DTx Cont.





VC Transactions in Digital Therapeutics

#	Company Name	\$ Amount	Investors	Deal Date	Type	Description
1	Embr	7.6	Bose Ventures, DigiTx Partners, Garage+, Intel Capital, MADMEC	9/19	Early Stage VC	Developer of wearable thermostats intended to change skin temperature according to comfort.
2	Mindstrong	100.0	8VC, ARCH Venture Partners, Berggruen Holdings, Bezos Expeditions	5/20	Later Stage VC	Developer of a digital therapeutic platform intended to address personal, societal, and economic problems.
3	Kiio	0.3	Andy North, DaneVest Capital, Joshua Martin, Mark Bakken	11/17	Later Stage VC	Provider of digital therapeutic solutions for musculoskeletal care intended to serve health insurance companies and large self-funded employers for use in their populations.
4	Better Therapeutics	21.8	Undisclosed	10/17	Early Stage VC	Developer of prescription software designed for treating cardiometabolic diseases.
5	Blue Note Therapeutics	10.0	JAZZ Venture Partners	1/18	Seed Round	Operator of a digital therapeutics company intended to discover, develop, and commercialize software-based medicines targeting serious diseases.
6	Cara Care	7.0	Asabys Partners, Atlantic Labs, B.I.F., Ey Ventures	6/19	Early Stage VC	Developer of a virtual health advising application designed to help people with chronic digestive disorders.
7	CaredFor	1.0	Jumpstart Health Investors	8/19	Seed Round	Developer of a community engagement platform designed to keep alumnus and families connected to each others.
8	Click Therapeutics	305.0	Hikma Ventures, Otsuka Pharmaceutical, Sanofi Ventures, Supernode Ventures	1/19	Corporate	Developer of a software as prescription medical treatments intended to offer digital therapeutics solutions.
9	Closed Loop Medicine	3.9	BGF, Cambridge Angels, Innovate UK, IQ Capital Partners, Longwall Ventures	2/20	Early Stage VC	Developer of an integrated healthcare technology intended to improve patient outcomes and health system performance.
10	DEARhealth	6.8	Health Innovations, Kairos Ventures, Philips Health Technology Venture Fund, Vesalius Biocapital Partners	7/19	Later Stage VC	Developer of an AI-powered platform intended to significantly improve the health outcomes and experience of chronically ill patients.



VC Transactions in Digital Therapeutics Cont.

#	Company Name	\$ Amount	Investors	Deal Date	Type	Description
11	GlucoseZone	0.5	Connecticut Innovations, Kendall Hochman	10/19	Seed Round	Provider of digital therapeutic products and services designed to meet the exercise requirement for diabetes self-management.
12	Healium (StoryUp Studios)	1.3	Centennial Investors, LaunchKC, Nancy Gion, Nueterra Capital, Panther Financial Group, Women in XR	9/19	Early Stage VC	Creator of an interactive, immersive media channel for the self-management of anxiety, sleep, addiction, and burnout.
13	Huma	25.0	Dale Ventures, DigitalHealth.London Accelerator, Healthbox, Intel Capital	11/19	Later Stage VC	Developer of a mobile platform designed to improve every facet of digital health.
14	Joint Academy	7.0	Alfven & Didrikson, Dendera Venture, Incos Invest, LU Innovation, StartUp Health, Sweet Capital, Walking Ventures	9/18	Early Stage VC	Provider of a digital health platform created to connect osteoarthritis patients with physiotherapists to provide them with individual care and recommend exercises.
15	Mahana Therapeutics	12.0	JAZZ Venture Partners, Lux Capital Management	1/20	Seed Round	Developer of digital therapeutics designed to help patients suffering from gastrointestinal conditions.
16	Medocity	1.4	Undisclosed	3/18	Angel (individual)	Provider of a virtual coordinated care platform designed to provide organizations with digital solutions to improve outcomes and reduce healthcare costs between visits.
17	Medrhythms	1.5	Bose Ventures, Harvard Innovation Launch Lab, Werth Family Investment Associates	8/19	Early Stage VC	Operator of a digital therapeutics company intended to build evidence-based neurologic interventions to measure and improve walking.
18	metaMe Health	3.9	Hemi Ventures, LionBird, Matter, Service Provider Capital	7/19	Seed Round	Developer of an online platform intended to provide non-drug treatment to patients suffering from gastrointestinal disorders.
19	Naluri	1.1	3 T Venture Capital, 500 Startups, BioMark, Cradle Fund, Duopharma Biotech Berhad, Global Founders Capital, RHL Ventures, StartX, TH Capital	4/20	Early Stage VC	Provider of a healthcare platform designed to connect employees or policy-holders with health psychologists.
20	nQ Medical	2.7	DigiTx Partners, Esplanade Healthtech Ventures, Lunsford Capital	2/20	Early Stage VC	Developer of neurological disease detection platform designed to substantially change the way disease is managed for neuromotor and neurocognitive disorders.



VC Transactions in Digital Therapeutics Cont.

#	Company Name	\$ Amount	Investors	Deal Date	Type	Description
21	NuvoAir	3.0	Industrifonden, Spiltan	4/19	Early Stage VC	Developer of digital therapeutics intended to make respiratory diseases measurable and more treatable.
22	Omada	57.0	Aberdare Ventures, California Health Care Foundation, Cigna, Cigna Ventures, Civilization Ventures, and others	5/20	Later Stage VC	Provider of a digital care platform designed to help inspire and engage people in lifelong health, one step at a time.
23	Polyfins	0.2	Undisclosed	5/18	Early Stage VC	Developer of a digital therapeutic application designed to help patients manage, reduce flareups and improve quality of living.
24	Progentec Diagnostics	5.0	Burns & Stowers Investments, i2E, Mayo Clinic, Mayo Clinic Ventures, NMC Healthcare	1/20	Later Stage VC	Operator of a therapeutics company intended to improve access and health outcomes for patients in therapeutic areas with a high level of unmet need.
25	Reliefband	4.8	Delaware Crossing Investor Group, JVC Investment Partners, PathoCapital	6/20	Early Stage VC	Developer of a digital therapeutic device designed to help in the treatment of nausea and vomiting.
26	Self Care Catalysts	5.0	JLABS, Prosoft Development, Springboard Enterprises	2/18	Later Stage VC	Provider of a cloud-based digital therapeutics, patient informatics, intelligence and self-care platform intended to bring health storylines to patients.
27	SilverCloud Health	16.0	ACT Venture Capital, B Capital Group, Dublin Business Innovation Centre, Enterprise Equity Venture Capital, and others	4/20	Later Stage VC	Developer of behavioral health platform intended to improve mental wellness.
28	Solera (Healthcare Ecosystem)	42.0	Adams Street Partners, Blue Cross and Blue Shield of Alabama, and others	5/19	Later Stage VC	Provider of an integrated benefit network intended to connect patients, payers and physicians with community organizations and digital therapeutics providers.
29	Susmed	8.0	Beyond Next Ventures, Dai-Ichi Life Insurance, Sony Innovation Fund, X-Hub Tokyo	6/18	Early Stage VC	Provider of digital therapeutics designed to revolutionize the treatment of insomnia.
30	Swing Therapeutics	9.8	JAZZ Venture Partners	1/19	Seed Round	Developer of novel prescription digital therapeutics intended to empower people to live joyful and vibrant lives.
31	Vida Health	25.0	Ally Bridge Group, AME Cloud Ventures, Aspect Ventures, Canvas Ventures, and others	4/20	Later Stage VC	Developer of a mobile health coaching application designed to eradicate chronic disease and transform lives through better health.
32	Welkin Health	17.5	Altos Ventures, Asset Management Ventures	5/19	Later Stage VC	Developer of a platform designed to provide patient relationship management solutions.



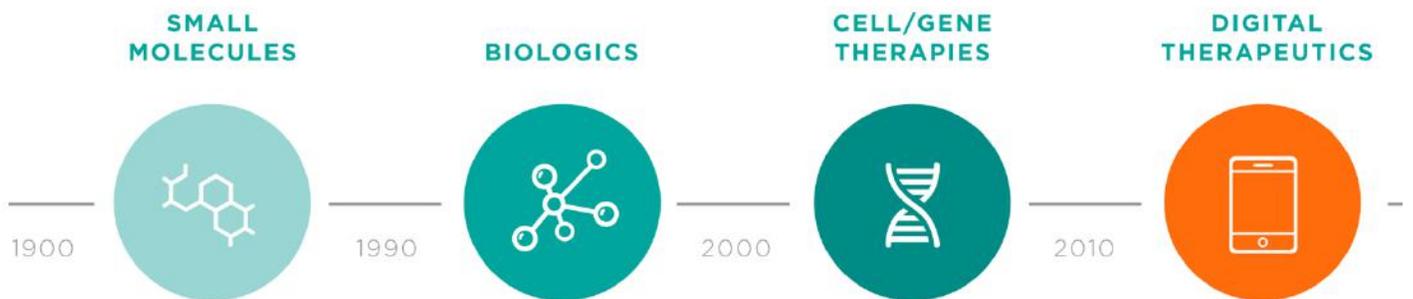
Transactions in Pediatric Digital Therapeutics

#	Company Name	\$ Amount	Investors	Deal Date	Type	Description
1	Akili Interactive	68.0	Amgen, Amgen Ventures, Brooklands Capital Strategies, CLSA, DG Daiwa Ventures, DG Ventures, and others	8/18	Later Stage VC	Developer of digital treatments for cognitive dysfunction with direct therapeutic activity. The company is developing a broad pipeline of programs built on its platform to treat cognitive deficiency, enabling doctors and healthcare providers to improve symptoms associated with medical conditions across neurology and psychiatry, via an action video game,.
2	Atentiv	1.5	Ernest Pomerantz, North Shore InnoVentures, Pierpoint Capital, StoneWater Capital	12/18	Debt - General	Developer of digital learning applications designed to offer primary care therapy and delivery of behavioral health for executive dysfunctions. The company's digital learning applications offer tools that use an individual's unique cognitive signature of brain wave activity to measure, train and manage multiple cognitive function development, enabling children to significantly improve attention and impulse control.
3	Cognoa	42.7	Morningside Group	10/19	Later Stage VC	Developer of a platform designed to improve lifelong outcomes for children. The company's proprietary machine-learning platform provides for a continuum of care from identification and diagnostic aid to digital therapeutics to advance the standard of care by enabling earlier and improved treatment of behavioral health conditions, enabling parents to improve lifelong outcomes for children.
4	Dopavision	1.4	Boehringer Ingelheim Venture Fund, Flying Health, German Government, Ralf Meister	6/19	Seed Round	Developer of digital therapeutic technology designed to slow down myopia progression in children and adolescents. The company's technology delivers light stimulation to specific photosensitive cells on the retina which in turn modulate dopamine, a neurotransmitter that is important for the regulation of eye growth, enabling health professionals to treat myopia with a clinically validated therapy.
5	Limbix	9.0	Anorak Ventures, BIXINK Therapeutics, DN Capital, GSR Ventures, JAZZ Venture Partners, and others	5/20	Early Stage VC	Developer of prescription digital therapeutics platform intended to improve healthcare with virtual reality. The company's platform adheres to strict compliance with FDA quality management standards and also is put through rigorous research trials and in certain cases is paired with existing pharmacological treatments, as well as uses virtual reality to administer VR exposure therapy, assign CBT assessments or exercises and track patient progress, enabling patients to overcome anxiety, phobia and obsessive-compulsive disorder easily.
6	Pear Therapeutics	Undis.	5AM Ventures, Arboretum Ventures, Blue Water Life Science Fund, Bridge Builders Collaborative, EDBI, and others	7/20	Mezzanine	Developer of a software-based digital therapeutics platform designed to treat disease and enhance the efficacy of pharmaceuticals. The company's platform combines novel digital interventions with drugs to enhance efficacy well beyond anything that is commercially available or in clinical development, enabling clients to get better outcomes for patients, smarter engagement and tracking tools for clinicians and cost-effective services for payors.

While our daily lives remain shrouded in uncertainty and fear, there is one aspect that we know will be forever changed. The healthcare industry, which has been beaten and bruised during the worldwide pandemic, has undergone momentous adaptations that will have long-lasting effects on the future.

Digital therapeutics and the activation of widely used telemedicine have been on the front lines of this change. Most healthcare professionals have reached a general consensus. Eventually this pandemic will end, but tele-health is here to stay. As the months go by, payers, patients, and providers will grow more and more comfortable with the idea of treatment through technology which will only allow for greater industry growth. This growth will inevitably lead to further regulatory approval and acceptance, while further technological innovation will advance this sector even further. As can be seen through the first half of 2020, all of these factors seem to feed off of each other.

As a result, the entrepreneurs, developers, insurance companies, and healthcare providers that choose to accept digital therapeutics sooner rather than later will find themselves on the top of a de novo industry with the potential for near-infinite growth in the years to come.





Lawrence, Evans & Co., LLC. is a boutique healthcare financial advisory and investment banking firm comprised of senior level professionals who provide lead advisory services to private companies, lenders, and other parties-in-interest that are executing financial and strategic transactions. Founded in 2003, the firm provides a wide array of services such as finance and capital raising, mergers and acquisitions, management consultancy services, turnaround management and restructuring, and real estate finance and development. The firm caters to the healthcare providers and service companies (senior housing, hospital, physician services, dental, dermatology, ophthalmology, physical therapy, behavioral health, RCM, HCIT, Population Health, etc.). Transactions are typically under \$250 million or \$10 million EBITDA.

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- Orderly Liquidations
- Chief Restructuring Officer (CRO)
- Bankruptcy Planning / 363 Sales
- Receivership / Trustee

Represented Healthcare Transactions:

 HealthCell <small>Discover. Simplify. Perform.</small> ACQUIRED MULTI SPECIALTY MEDICAL BILLING COMPANY ACTED AS ADVISOR	 MedWorx GROWTH CAPITAL RAISE Grenville <small>STRATEGIC ROYALTY CORP.</small> ACTED AS ADVISOR	 MINGLE <small>ANALYTICS</small> GROWTH CAPITAL RAISE ACTED AS ADVISOR AND INVESTOR	 GLOBALNET SOLUTIONS <small>Public School</small> ACQUIRED BY MTBC <small>A Unique Healthcare IT Company</small> ACTED AS ADVISOR
 RANAC <small>Optimizing Performance & Profit For Healthcare Professionals</small> ACQUIRED BY A STRATEGIC BUYER ACTED AS ADVISOR	MEDICAL BILLING AND TECHNOLOGY COMPANY \$8,000,000 ACQUIRED BY A STRATEGIC BUYER ACTED AS ADVISOR	MULTI SPECIALTY MEDICAL BILLING COMPANY MIDWEST ACQUIRED BY A STRATEGIC BUYER ACTED AS ADVISOR	 ICE <small>redefining Health Care</small> DENTAL PRACTICE MANAGEMENT AND EDUCATION SOFTWARE ACTED AS ADVISOR

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