

## Company Spotlight

### **PEAR THERAPEUTICS ADVANCES THE FIRST REGULATED DIGITAL THERAPIES FOR ADDICTION**

**Pear Therapeutics** has grown significantly over the past year and now boasts forty employees split between the Boston, MA office and the San Francisco, CA location. NeuroInsights caught up with Dr. Corey McCann, founder and CEO, to learn about Pear's progress developing digital therapeutics.

Leading Pear's pipeline are two digital therapies: *reSET* and *reSET-O*, both addressing addiction disorders. The mobile digital therapy *reSET* is designed to address substance use disorder (SUD) related to opiates, stimulants, cannabis, cocaine and alcohol. The product provides patients with a set of rewards around abstinent behaviors and completion of *reSET* modules, ranging from managing cravings to life skills. The app leverages the "Community Reinforcement Approach," arguably the most clinical validated form of behavioral therapy for addiction conditions. Patients utilize the app several times each week and their use is tracked by the physician in charge of their care. McCann explains, "The clinician dashboard helps the physician understand real-world abstinence, concept proficiency and/or lack of proficiency." Also based on the use of the modules, face to face time can be efficiently targeted to problem areas.

*reSET* has been studied in six randomized clinical trials and in over 1500 patients. The pivotal study enrolled 507 patients across ten centers in the US and was designed and executed in the same manner as a traditional drug trial. Patients were randomized to receive either control face-to-face therapy only or *reSET* with a reduced amount of face-to-face therapy for a period of twelve weeks. The control arm of the study received intensive outpatient therapy by highly trained therapists. In terms of outcome measures, abstinence was assessed via urine analysis. McCann shares, "What keeps us very excited is the fact patients who received *reSET* had roughly doubled rates of abstinence as compared to patients that received only face-to-face therapy, and for refractory patients *reSET* was just about several fold more efficacious than best-of-breed face-to-face therapy."

In addition, patients that were randomized to *reSET* also showed statistically significant enhancement of program retention compared to the control arm. McCann elaborates, "It is paradoxical -patients receiving *reSET* reported higher degrees of satisfaction and had a higher degree of connection to the providers when they used the digital therapy. It may be due to the immediacy factor, as the patient is able to access the digital therapy at times when the provider is not available. Standardization is another element as the Community

Reinforcement Approach is challenging to master by providers and *reSET* provided a consistent level of quality. Finally, accessibility plays a role. Patients in the digital therapy were able to access it more readily than patients in the traditional face-to-face approach." Armed with these strong findings, Pear has been engaged in securing regulatory approvals for *reSET* in the upcoming months, which would make it the first FDA-approved patient-facing digital therapy for an addiction condition.

Following close behind, Pear is developing a product that will address opiate dependence. This product combines pharmacotherapy with the digital intervention. McCann explains, "In order to properly address opiate dependence, you really need to have pharmacotherapy on board to curb cravings." *reSET-O* is similar to *reSET* but it in addition it incorporates specific modules that are geared to pharmacotherapy as these address compliance and adherence. Pear plans to pursue a label indication for opiate dependence for *reSET-O* when used concomitantly with methadone or buprenorphine. Top line results from three different trials looking at the difference between pharmacotherapy plus face-to-face therapy or pharmacotherapy plus *reSET-O* have demonstrated results similar to those obtained with *reSET* in other addictive disorders. Pear is currently in discussions with the FDA as they are looking to finalize analysis of these data. They are also in conversations with a number of drug manufacturers that market drugs for opioid dependence.

Pear's other programs focusing on schizophrenia, post-traumatic stress disorder (PTSD) and anxiety also moving forward. The *Thrive* product for schizophrenia is currently in trials with top line results expected in 2017. The other programs, *reCALL* for PTSD and *reVIVE* for anxiety, will soon follow suit, and should be in clinical studies in 2017.

McCann sees a great deal of progress in the dialogue around regulated digital therapies. The agency is looking to educate the industry on their constraints and limitations, while industry is hoping to transmit the value of these novel approaches. McCann shares, "I have been personally impressed by the way the FDA is thinking about this and by their responsiveness." Pear has strived to build a relationship with the agency, and to understand which and why novel therapeutic modalities are being regulated. He comments, "It seems that if you want to treat a disease or diagnose a disease, if you are going to work in a high-risk patient population where severe adverse events are possible, or if you are intimately tethered to a medical device or drug, that will get you regulated. There are companies that are making clever arguments as to why they should not be regulated, but if you want to do any of those things and speak to them as explicit claims, you'll likely be regulated."

When thinking ahead about the product positioning and pricing, there are several other hurdles to overcome. McCann highlights, "When you take a digital therapy and turn it into a

medical device, you become eligible for reimbursement codes, streamlining transactions with payers. We are also advancing conversations with CMS to secure a new drug code for *reSET* in addition, which would allow us to address the Medicaid market, the biggest patient population for this indication.” In terms of pricing, Pear’s strategy will be based on the amount of medical value that their product creates. They have a team doing all the health economic work that would be typical for any traditional pharmaceutical and will incorporate the knowledge gained through these efforts into their pricing discussions.

In January, Pear closed a \$20 million Series A financing led by 5AM Ventures, JAZZ Venture Partners and Arboretum Ventures. Looking forward Pear is focused on de-risking digital therapeutics from a regulatory standpoint, and after approval is secured for *reSET*, additional financing will be sought to support the next set of programs. 

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