

Company Spotlight

PEAR THERAPEUTICS TO USE DIGITAL THERAPIES TO IMPROVE PATIENT OUTCOMES

Pear Therapeutics is developing a therapeutic platform that will deliver targeted, clinically validated digital therapeutics to treat a range of brain-related illnesses. The prescription pharmaceutical-software combination products are called *eFormulations*. NeuroInsights spoke with Pear's co-founder and CEO, Corey McCann, who has worked in medical practice, venture capital investment, consulting, as well as an entrepreneur and brings all those experiences into Pear.

The company was formed with the notion that in order to effectively treat many neurological and psychiatric disorders a multimodal approach must be followed. McCann explains, "There are 2 levels for treating the brain: molecules and experience. We are trying to do this via a drug/software combination. It is the only way to impact brain and experience." Pear is developing a cloud-based digital therapeutics delivery platform with integrated assessment tools, analytics, mobile apps, and reporting tools seeking to directly enhance efficacy and outcomes.

Pear is currently focused on treating mental health disorders. Their first therapeutic product, Pear-001, is a clinically-validated interactive behavioral therapy system developed to treat substance abuse disorders combined with buprenorphine. The company in-licensed this asset from Dartmouth College. The therapy has been studied in over 500 patients and has demonstrated that it enhances the efficacy of approved drugs indicated for substance abuse, significantly increasing patient's ability to remain abstinent and reducing required clinician intervention time.

A second program, Pear-002, seeks to provide real-time interventions for schizophrenia patients and create a comprehensive relapse prevention program. This program is also under development in collaboration with Dartmouth College. The smartphone app has been evaluated in patients with severe mental illness, schizophrenia and schizoaffective disorder. In a preliminary efficacy study in thirty schizophrenia patients on antipsychotics, the patients were given access to software and followed for a month. The results demonstrated an 8% reduction in total PANSS in the treatment group. The results also showed that patients were initiating interaction with the software in over 60% of the instances. The company is currently concluding a large multi-site study that enrolled over 400 patients receiving treatment for six months. The readout for this program is expected between late 2016 and early 2017. In addition, Pear is planning additional randomized-controlled trials to begin in 2016. One of the aspects of this app is that it does require a minimum baseline

cognitive functioning, but also delivers a benefit in tackling negative symptoms of schizophrenia.

The third clinical program is focused around generalized anxiety disorder and stems from the Catholic University of Leuven. The digital therapy applies multimodal cognitive, neurobehavioral, relaxation and exposure therapy. Pear has collected efficacy data demonstrating a significant reduction in the primary endpoint of chronic "trait" anxiety by 12% compared to 0.5% in traditional setting.

In addition to these programs, Pear is pursuing development of digital therapies for depression, insomnia, ADHD, PTSD and chronic pain. The company is collaborating with many partners in these efforts including NASA, Catholic University of the Sacred Heart, UCSF, The Hospital for Sick Children, M3 clinician and Cognito.

A differentiating point in Pear's offering is their broad patent portfolio, with nine issued patents and twenty more already filed. Pear has an IP position allowing exclusive access to the drug/software interface. This positions Pear to be a unique partner for pharmaceutical companies seeking label expansions. McCann comments, "We are actively partnering with pharma. The companies may ask, to what extent are these combinations protectable? We can offer that."

The company is planning the next steps to take this therapy to market and has initiated a dialogue with the FDA. The lead program PEAR-001, as it is software, will be submitted via the 510k path in late 2015. McCann shares, "We are very excited about the opportunity to work with the agency and educate about digital therapies. We are taking a step-by-step approach, starting from the simplest filing and working our way up." At this time, they are only pursuing approval for the digital therapies and hence they do not need to engage with the Office of Combination Products. McCann anticipates that type of engagement will come after 2017.

McCann is both optimistic and cautious about the future. He shares: "When you look at CNS, there is interest, but this interest has been mostly in neurology and orphan CNS disorders. That said, if you look at behavioral health, there are few bets in schizophrenia, depression, insomnia, addiction. There are very few new therapies for these conditions, which are the hardest conditions biologically to treat."

Pear secured a seed round led by 5AM Ventures earlier this year and has been working on a Series A bringing in a number of venture investors. McCann shared that they are on path to secure the financing by the end of the year. He anticipates that their inflection point will be FDA approval of Pear-001. 