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The Afterlife Of Pear Therapeutics: Korean DTx Maker Discusses Vision For Salvaged Migraine Assets

by Marion Webb

WELT USA was among four companies that competed at auction for Pear assets following the digital therapeutics trailblazer's Chapter 11 bankruptcy filing in April. WELT also bid on Pear's reSET assets for treating substance use disorder, but was pleased that they went to Pear's former CEO Corey McCann – "a good signal to the industry," says WELT USA head Danny Kim.

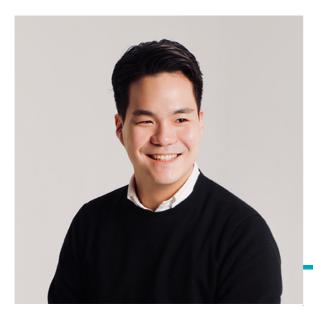
WELT Corp. aims to develop an AI-powered app to predict migraine attacks, leveraging assets plucked from the rubble of Pear Therapeutics, which filed for Chapter 11 bankruptcy in April.

WELT USA was one of four companies – along with Harvest Bio, <u>Click Therapeutics, Inc.</u>, and Nox Health – that partook in a 22 May <u>Delaware bankruptcy court auction</u> of Pear's digital therapeutic (DTx) assets for just over \$6m in total. (Also see "<u>Pear Bankruptcy Filing Highlights Difficult Challenges Facing Digital Therapeutics"</u> - Medtech Insight, 24 May, 2023.)

With offices in Seoul, Korea and Cambridge, MA, WELT uses data and insights collected via its digital biomarkers platform to deliver "personalized, guideline-recommended therapies" to manage, treat, and prevent diseases and disorders. Its pipeline includes DTx products for addressing insomnia, eating disorders, alcohol use disorder, and sarcopenia.

Danny Kim, head of WELT USA, which paid \$50,000 for Pear's migraine assets, sat for an interview with *Medtech Insight* at the inaugural Digital Therapeutics Alliance (DTA) Summit in Washington on 7-9 June. According to Kim, WELT was the second-highest bidder both for Pear's reSET assets for treating substance use disorder and its Somryst insomnia assets. (Also see "*Minute Insight: Pear Therapeutics Files For Bankruptcy, Hopes To Find Buyer For PDT Assets*" - Medtech Insight, 7 Apr, 2023.)

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Source: WELT USA

While WELT didn't take those home, Kim said he was glad to see the reSET assets, among others, scooped up by Harvest Bio, a newly created company managed by Pear's former CEO Corey McCann.

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Kim has a prior connection to Pear, having served a year as corporate development analyst at the DTx trailblazer – which was valued at \$1.6bn in 2021 – before joining WELT USA in 2020. He said Pear's migraine assets are complementary to WELT's DTx program, particularly its work to improve people's sleep.

On 19 April, WELT's WELT-I, a mobile app that administers cognitive behavioral therapy to help people with chronic insomnia sleep better, received marketing clearance from the Korean Ministry of Food and Drug Safety. On its website, WELT notes Korean government research indicating that 15%-20% of Koreans suffer from chronic insomnia, representing a 96% increase in patients over 10 years and a 74% increase in health care cost over four years.

"We already had migraine at the forefront of our mind," Kim said, noting the established link between migraines and poor sleep. According to the American Migraine Foundation, people living with migraine are between two and eight times more likely to experience sleep disorders compared with the general public.

Kim envisions WELT using Pear's migraine assets, including content relating to patient education and cognitive behavioral therapy, along with existing sleep data, to develop a digital therapeutics app that harnesses artificial intelligence to predict migraine attacks and provide

recommendations for next steps, such as going into a dark room or taking medication.

"We wouldn't integrate migraine and sleep one-to-one but there will be components all throughout our pipeline that get integrated into our migraine package," Kim said. "We use [data from] the Apple Watch and Samsung Galaxy Watch and other wearables that goes into our sleep monitoring right now, and that same monitoring tool is also able to measure skin temperature and heart rate variability, and we're trying to find a correlation between that and migraine attacks right now."

It's too early to say whether WELT will create the migraine app from the ground up or build on existing technology, such as the Apple Watch or Samsung Watch, Kim said. But he foresees that the first phase of the migraine DTx development will focus on patient monitoring, with patients recording their migraine symptoms and trigger events, such as stress, weather, sleep, and other passive data.

"Again, we're still in the very early stages of development – we'll have to check back in a few months to tell you what our plan might look like," he said.

As an advisor to the Korean government and a member of DTA's board of directors, Kim, who is fluent in Korean and English, said he is in a unique position to help formulate regulatory guidelines around digital therapeutics as well as reimbursement strategy. While overseeing US operations, he's splitting time between Cambridge and Seoul. (Also see "DTA Standardizes Definition Of Digital Therapeutics" - Medtech Insight, 9 Jun, 2023.)

Pear CEO Harvests Key Assets

Harvest Bio's McCann could not be reached for comment for this story, but according to court filings his new company spent a total of \$2.03m to acquire Pear's assets related to Invention Science Fund licenses, schizophrenia, multiple sclerosis, depression, major depressive disorder, the PearConnect commercial platform, and rights to the reSET program for treating substance use disorder as well as reSET-O for opioid use disorder.

In 2017, Pear's reSET digital app became the first US Food and Drug Administration-approved prescription digital therapeutic, followed by reSET-O in 2018.

"I'm glad it went into [Harvest's] hands, and we didn't further compete," Kim said. "We'll probably engage in a partnership or conversation to bring it [reSET] to the Asian market."

Pear's Somryst PDT to deliver cognitive behavioral therapy for chronic insomnia received FDA clearance in 2020. (Also see "*Exec Chat: Pear Therapeutics' CEO Charts Future For Digital Therapeutics Following SPAC Deal*" - Medtech Insight, 25 Jun, 2021.)

"Somryst we were interested in, because we thought that it would be to save us on the regulatory timeline coming to the US ... We have a product approval in Korea, but not in the US," Kim said.

However, Atlanta-based Nox Health Group walked away with the Somryst assets for \$3.9m.

Insomnia is a common complaint, affecting about 30% of the general population. In 2020, 14.5% of adults had trouble falling asleep most days or every day, according to <u>Centers for Medicare and Medicaid</u> statistics. Insomnia tends to affect more women than men and also is more prevalent among adults who struggle financially.

Nox Health said in a 23 May statement it plans to bring Somryst to a wider audience, starting with its existing Enterprise client base, surrounding Nox's SleepCharge program, and then expand to other opportunities.

"The acquisition of Somryst aligns seamlessly with Nox's mission of promoting science-based solutions that address chronic diseases through sleep care management," said Sigurjon Kristjansson, CEO of Nox Health. He noted that cognitive behavioral therapy for insomnia (CBT-I), which Somryst delivers via mobile app, remains underutilized due to "lack of therapists with adequate CBT-I expertise."

According to Kristjansson, "Somryst offers health care providers a novel treatment delivery modality to enhance the treatment of chronic insomnia for patients who lack access to clinician-delivered CBT-I," and, importantly, the system has been validated in clinical studies.

Gathering evidence to support the efficacy of DTx through a rigorous scientific approach is also a key priority for David Benshoof Klein, CEO of Click Therapeutics. Click, which develops apps for treating migraine, depression, and smoking cessation, paid \$70,000 for patents associated with the Pear Platform for digital therapeutic development.

"These patents will help us to further innovate on this new and emerging treatment option," Klein told *Medtech Insight*. "As a company, we believe in the power of software as medicine to treat disease and are committed to developing the next generation of prescription digital therapeutics with a biotech-like approach."

He added, "We are the only prescription digital therapeutics company with an in-house end-toend discovery lab dedicated to inventing and validating novel mechanisms of action. Additionally, our products go through drug-like clinical validation and regulatory review to ensure a level of rigor that builds trust with providers and patients."

Click Therapeutics has a longstanding partnership with pharma big-leaguer <u>Boehringer Ingelheim</u> <u>GmbH</u> The partners recently launched a randomized pivotal study for treating negative

symptoms of schizophrenia among adult patients. Negative symptoms are defined as those that detract from a person's life.

Without Structural Change, There Will Be More Pears

Pear Therapeutics similarly scored partnerships with prominent pharma companies including Novartis and Sandoz before capital funding dried up, spelling the firm's demise.

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McCann, who stepped down in April, posted on LinkedIn, "We've shown that our products can save payers money," but "payers have the ability to deny payments for therapies that are clinically necessary, effective and cost-saving." He further noted that "market conditions in the last two years have challenged many growth-stage companies, including us."

At the DTA Summit, industry leaders discussed challenges surrounding investment, regulation, reimbursement, clinical guidelines, and patient and physician experiences in using DTx.

A top priority for the industry is advancing the proposed Access To Prescription Digital Therapeutics Act in US Congress. The bill seeks to expand Medicare coverage to software-based medical treatments cleared by the FDA, a key step for putting these types of treatments into the hands of Americans. (Also see "*DTA Standardizes Definition Of Digital Therapeutics*" - Medtech Insight, 9 Jun, 2023.)

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