MEDTECH INSIGHT
CITELINE COMMERCIAL

25 Jun 2021 | **Interviews**

Exec Chat: Pear Therapeutics' CEO Charts Future For Digital Therapeutics Following SPAC Deal

by Reed Miller

Pear has commercialized FDA-cleared prescription digital therapeutics for substance abuse disorder, opioid use disorder and chronic insomnia and has 14 more in development. CEO Corey McCann explained Pear's vision for how PDTs can transform health care.

Pear Therapeutics, Inc. reached a critical milestone in its plan to pioneer the emerging market for prescription digital therapeutics (PDT).

On 22 June, Pear announced plans to become a publicly traded company via a merger with a special purpose acquisition company (SPAC). Pear will merge with Thimble Point Acquisition Corp., a publicly traded SPAC founded in 2020 by the Pritzker Vlock Family Office in New Haven, CT.

The deal will yield nearly $400m in gross proceeds for Pear, including up to $276m of funds currently held in Thimble Point's trust account and a $125m upsized private investment in public equity (PIPE). The PIPE is "anchored" by Neuberger Berman funds, the Pritzker Vlock Family Office, and a leading integrated delivery network, as well as other "leading investors," according to Pear. Pear's management and other "insiders" will roll over 100% of their equity worth $1.2bn so the total equity value of the deal is about $1.6bn.

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Pear and Thimble Point expect the deal to be completed in the second half of 2021, at which time Pear's shareholders, Thimble Point's shareholders, and the other PIPE investors will hold shares in the combined company, Pear Holdings Corp. The company will be listed on NASDAQ under the ticker symbol PEAR.

The company plans to use the new funds to support its product pipeline and rapidly expand its commercial operations. Pear expects to earn $4m in revenue in 2021, growing to $125m by 2023.

Pear's current management will continue to lead the company, which has offices in Boston, San Francisco and the Research Triangle area of North Carolina.

Building On Early Success

Pear's CEO Corey McCann, a physician-scientist with extensive experience in finance and consulting, founded Pear in 2013 and the company has raised more than $250m in capital from a variety of investors, including Softbank, Temasek, Novartis, 5am Ventures, Jazz Ventures and Arboretum. (Also see "*Pear Therapeutics Plans To Accelerate Reimbursement For Digital Therapeutics With $80M Series D*" - Medtech Insight, 8 Dec, 2020.)

The three PDTs the company has already launched were the first PDTs cleared by the US Food and Drug Administration.

In 2017, the FDA granted *de novo marketing clearance* to Pear's reSET PDT, which delivers cognitive behavioral therapy in conjunction with outpatient therapy to help people recover from substance abuse. In 2018, the FDA *cleared Pear's reSET-O*, a PDT specifically designed to treat opioid use disorder, via 510(k). According to the company, more than 700 clinicians have prescribed treatment with reSET or reSET-O for more than 20,000 prescriptions and the company's health economic research shows these PDTs can save payers about $2,150 per patient.

More than 21 million people in the US suffer from substance addiction, according to the company. The total addressable market for reSET is about $5bn while the addressable market for reSET-O is $1bn.

In 2020, the agency *cleared Pear's Somryst PDT* to deliver cognitive behavioral therapy for chronic insomnia. Somryst was the first product the FDA reviewed through the *Software Precertification*

Pilot Program it launched in 2018 to regulate software more efficiently and consistently. (Also see "*Pear Therapeutics Launches Digital Insomnia Telehealth App*" - Medtech Insight, 18 Nov, 2020.)

About 30 million people in the US suffer from chronic insomnia, so the addressable market for Somryst is worth about $5bn, according to Pear.

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Pear is currently developing 14 more products, including more PDTs for psychiatric and neurologic conditions, as well as products for gastroenterology, cardiology, and oncology indications. During a 22 June conference call with investors, McCann said Pear's platform could eventually support more than 100 PDTs addressing most medical conditions.

The company is also developing remote-sensing technologies to monitor patient's physiology. For example, in April, Pear licensed an artificial intelligence-enabled keystroke detection algorithm from KeyWise to develop digital biomarkers based on smartphone users' interaction with their devices. The company also has a licensing deal with Winterlight Labs for technology that tracks voice-based cognitive health biomarkers.

In an interview with *Medtech Insight*, Pear CEO Corey McCann discussed the company's decision to go public and how it plans to lead the rapidly growing PDT industry.

Q ***Medtech Insight:*** **Why did you choose to take Pear Therapeutics public now and why did you chose the SPAC route with Thimble Point rather than a regular IPO or another option?**

A Corey McCann: We really thought about the opportunity that is before the company as the first in this new space of prescription digital therapeutics. We think there is an opportunity to make this modality pervasive across a whole host of different indications. And with that opportunity comes the need to access capital. So that is really the 'why' of why we're raising [funds right now].

We looked at staying private and traditional IPO scenarios, as we also looked at SPAC scenarios. [But] in order to understand our business – we're one-half tech and one-half life sciences – we're always looking for organizations that can really help us be better at both. And the team at Thimble Point is uniquely suited in that their principals, as well as their board, are all 'hybrid' – they have invested across both [digital] tech and life sciences/biotech.

The more we got to know other SPACs and the more we got to know them, the opportunity for them to come in and help us create a whole new therapeutic category just became too good to pass up.

Q **What makes Pear's platform unique that's allowed you to reach this milestone?**

A McCann: What is different about Pear's approach is the use of software to directly treat disease, opposed to a health and wellness application or opposed to an app to facilitate a telemedicine visit. The latter two spaces existed before, and they'll continue to exist. But this idea of making software as a disease treatment – in some cases to displace drugs, in some cases to work with drugs, and in some cases to treat things that just could not be treated by drugs before – that is entirely new.

And that is what the space has become [with] PDTs or prescription digital therapeutics. We had the first three of those products.

We're really an aggressive 'roll-up' story. We've done about 20 deals with different academic groups and small companies to bring in what are the best-of-breed technologies across a whole host of different disease indications.

What we're doing there is to really unite them all under one shared platform. Much in the same way that clinicians tend to work with one, and only one, electronic medical record platform, we're really trying to be the dedicated platform for PDTs, both from Pear as well as from other companies.

Q **You're working with many different academic 'content partners.' For example, a group at Dartmouth University contribute to the reSET and reSET-O PDTs for substance abuse disorders and researchers at the University of Virginia contribute to the Somryst PDT for insomnia. What do those groups contribute and what do you look for in a content partner?**

A McCann: In the same way that biotech companies tend to in-license novel therapeutic candidates, Pear in-licenses these novel digital therapeutic candidates. In cases like reSET and reSET-O, extensive work had been done at Dartmouth in order to develop the modality and really understand the way in which patients with addiction conditions interact with technology, and then develop some of the clinical data.

Similarly, for the Somryst product – [it is supported by] 29 executed or ongoing clinical studies. There are tremendous bodies of evidence that support the efficacy and the design of each one of these different products.

We're built to in-license products where that is advantageous and also [able] to build them from the ground up where that's advantageous. And we've done both of those.

Q **In your presentation to investors on 22 June, you reported the company has 14 product candidates in the pipeline and expects Pear's platform could eventually support more than 100 PDT products. What are you looking for when identifying a condition or disease that you believe could be addressed by a PDT?**

A McCann: Imagine a two-by-two matrix where we're looking for things with a high probability of technical and clinical success and also a large commercial opportunity and degree of unmet medical need. I think if you really look through that lens, you'll see that mental and behavioral health conditions and addiction conditions really rise to the top of that framework.

We now have what is about half of a comprehensive mental and behavioral health set of solutions. And if you look at our pipeline, the next clustering of assets is in mental

and behavioral health. And that is because we know the clinicians that are in our dashboards regularly.

And there is a tremendous opportunity to [cross-sell] to existing, converted clinicians onto new assets to benefit their existing patient population. That's the genesis behind our development of programs for things like depression, anxiety, bipolar, schizophrenia, and PTSD. And there's an interesting adjacency in chronic neurologic conditions. So, that's the next clustering of [products for] pain, multiple sclerosis, epilepsy, and migraines.

But then this is a space which is much bigger than brain-related conditions. That's [why] we have [started] some earlier-stage discovery work in really big and foundational opportunities like cardiovascular disease and oncology.

Q **So far, you've focused on software that users access through mobile devices. What other types of 'hardware' technology are you looking into to improve remote monitoring and communication?**

A McCann: We we've already done a roll-up of digital biomarkers, starting with different aspects of patient physiology that we can sense using the mobile phone. And so that's where we've done deals with companies that are developing technologies to look at voice, touch-and-tap trajectory, and haptics.

There's a tremendous amount of data that you can get about patient's physiology just from a phone.

There's also a tremendous opportunity for integration with different clinical-grade wearables. And so we've started to do some of those deals. If you start to move outside of brain-related conditions, that's really where you start to move into drug-software combinations, where sensing and digital biomarkers become even more important to impact patient physiology.

Q **Beyond closing this deal to go public, what are your near-term commercial and**

development priorities?

A McCann: I think our pipeline [priority] is relatively obvious, which is that we'll be developing assets to complement our existing ... cluster of mental and behavioral health assets.

On the commercial side, we've been able to demonstrate quite strong rates of prescriber demand and engagement. As we disclosed, we have more than 20,000 prescriptions written across more than 700 clinicians in 30-plus states. And that's driven by a very, very small field force. There's an opportunity to continue to expand that 'prescribership' and do it in the context of increasing market access.

Right now, there are 15 [payor] organizations providing coverage [of Pear PDTs] across about 20 million covered lives. And so expanding both prescribership as well as coverage is what will get us to a rapid revenue ramp area.

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Q **Pear was the first company to earn a clearance through FDA's Software Precertification Pilot Program. As a pioneer in this space, what other regulatory improvements would you like to see?**

A McCann: [The FDA] pretty nicely clarified the 'rules of engagement,' which is that if you want to treat a disease, the only way to do that is through a regulated path. (Also see "*Profile: FDA's Bakul Patel On The Inevitable Future Of Digital Health*" - Medtech Insight, 31 Aug, 2020.)

And even if you want to be, effectively, a wellness product, then, much like with a dietary supplement, you need to disclaim that you don't have clinical data and that

you're not approved to treat a disease. I think that's a step in the right direction in terms of providing clarity for the space.

Q **What reimbursement changes or improvements are necessary to ensure people who can benefit from PDTs will be able to access them?**

A McCann: The big 'mechanistic' issue that we're pushing on right now is our sponsored legislation to develop a new benefit category and a streamlined reimbursement path for PDTs as a class. (Also see "*Expanding Medicare Coverage For Digital Health Technologies Gains Support*" - Medtech Insight, 11 Mar, 2021.)

And if you start to look at particular payors, like fee-for-service Medicare, it's very ambiguous as to what benefit type PDT might fit into. And we see across our payors – some pay for it as a pharmacy benefit, some pay for it as a DME, some pay for it as a medical benefit. We have created benefit-type optionality to work across all of those different payers, but what we do need is some statutory guidance in fee-for-service Medicare. And that's really the next structural issue that the company is set to address.

If you look at our current products – reSET, reSET-O and Somryst – those apply to largely Medicaid populations. We have states like Indiana, Ohio and Kentucky providing access to the product for Medicaid patients. That's an incredibly exciting development for us. We're also working with commercial payors.

The medications that treat chronic insomnia have an [FDA] 'black box warning' for use in the elderly, so there is a tremendous medical value associated with deploying Somryst for chronic insomnia to displace drugs across Medicare patient populations. We're really trying to pioneer this modality. And we're trying to kick open every door we possibly can and develop a whole portfolio of products behind it.

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Q **Q: Is there anything else you want to add about the direction of Pear Therapeutics?**

A McCann: This space is all about the convergence. And I think there are a lot of tailwinds behind what we do. We'll continue to announce positive coverage decisions in tune with making our products standard of care across large patient populations. And then there is a tremendous health economic story here. The platform will be able to pull claims and utilization data for patients utilizing the products in commercial settings.

You'll see us continue to do – for each product – health economic analysis, [investigate how to] extend those time periods, and look at different clinical subpopulations. [And it will not just be] in some sort of a stilted clinical trial setting. We'll do it in real-world patients. And we'll even do it to adjudicate value-based agreements with payers who are skeptical.