

Better Therapeutics banks on data and partnerships



[Elizabeth Cairns](#)



But difficulties around reimbursement, selling and market value could make it hard for the app maker to live up to its name.

Prescription app developers have had a tough time this year, with Pear Therapeutics cutting both staff levels and guidance, and Teladoc [taking a \\$6.6bn writedown](#) on its acquisition of the health management app maker Livongo.

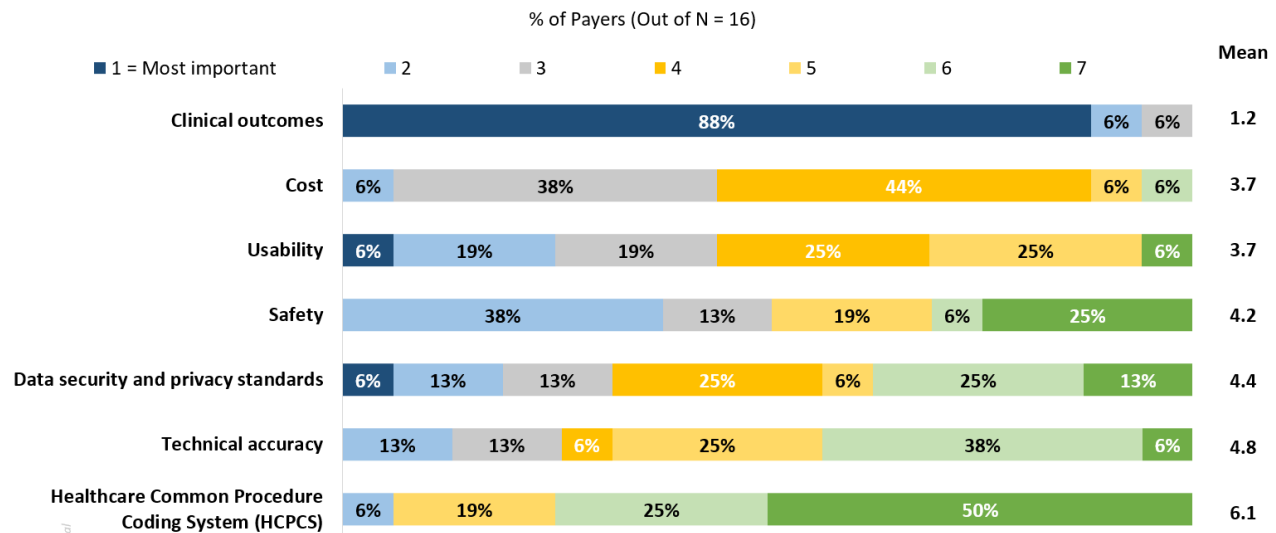
Better Therapeutics is putting its faith in clinical data to help it avoid similar difficulties. Long-term results from the pivotal trial of the cognitive behavioural therapy app BT-001 put this on track to become the first such product approved for the treatment of type 2 diabetes. But, like its peers, Better faces difficulties: since going public via a Spac in October it has lost more than 80% of its value.

Apps that allow diabetes patients to manage their condition are [already pretty common](#), but tend not to have regulatory oversight. Better is hoping to distinguish its offering from those on the market by getting FDA approval and reimbursement – and that means getting data.

Naturally the FDA will want to see clinical data; perhaps it is more surprising that payers also regard these as crucial when deciding whether to reimburse a prescription digital therapeutic, as apps like Better's are known. Among 16 health insurance companies recently surveyed by [MMIT](#), 14 regarded clinical outcomes data on these apps as the most important factor in the payment decision, ahead of cost, safety, technical accuracy and other attributes.

Payers largely agree that the most important attribute in the review of a new PDT is clinical outcomes

Ranking of Importance of Attributes in Evaluation of Prescription Digital Therapeutics



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Please rank the following attributes in order of importance when evaluating a prescription digital therapeutics product.
Rank 1 = most important, Rank 2 = second most and so on

N = 16 Payers
Survey Field Dates: 3/18/2022 - 3/25/2022

Source: MMIT.

Better says [its study](#) is the world’s first randomised controlled trial for a prescription digital therapeutic in type 2 diabetes. The app is designed to help patients exercise, plan healthy meals and manage stress, for example.

The trial hit its primary 90-day endpoint in May, with patients using the app on top of standard therapy having a statistically significant improvement in blood sugar levels over the control group, which was on standard treatment only.

But Better decided to wait for 180-day data before going to the FDA. These showed further decreases in blood glucose among app users, with average absolute A1c reduction improving from 0.3% at day 90 to 0.4% at day 180, and the difference between the groups remained significant even as more control group patients increased their diabetes medications.

On top of this, the new cut revealed something usually seen with drugs, not software.

“As we’re analysing the data, we’re seeing a very clear dose response,” Mark Berman, Better Therapeutics’ chief medical officer, tells *Evaluate Vantage*. In short, the patients who used the app more had larger falls in their blood sugar.

Whether the FDA will be impressed by this – Better intends to file for a de novo clearance this quarter – is unknown. But the agency is likely to look with favour on the safety data from the trial.

“The safety implications are likely fundamentally different from what you see with a traditional drug, where you try to push the dose as high as you can to get into the therapeutic window, and you tolerate side effects,” says Frank Karbe, Better’s chief executive.

With BT-001, Mr Karbe says, you can increase the “dose” without a corresponding increase in risk – indeed, patients in the treatment group in the pivotal study had significantly fewer adverse and serious adverse events compared with the control group.

Challenges

While clinical data ought to smooth the path to approval, reimbursement for prescription digital therapeutics remains iffy. Only a quarter of payers surveyed by MMIT said that they were willing to cover these apps, with the others respondents rating digital therapeutics as a low-to-moderate priority.

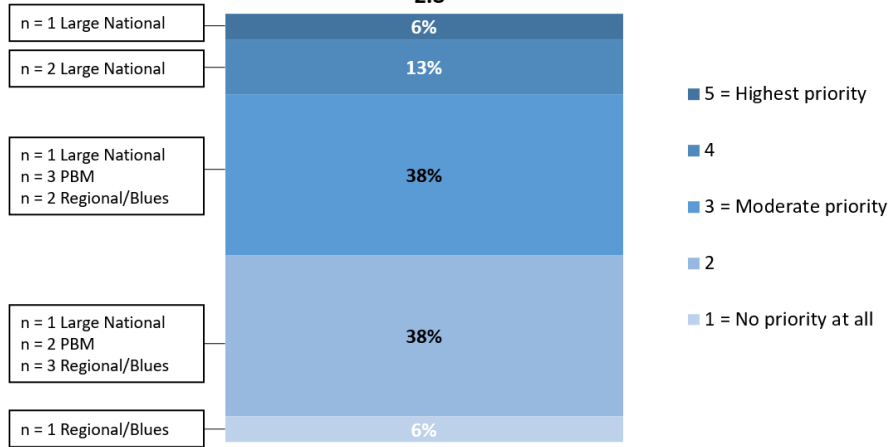
Nearly 80% of panelists rate the priority of PDTs to their organization as low to moderate

Rating of Organization Priority for Prescription Digital Therapeutics (PDTs)

% of Payers (Out of N = 16)

Mean:

2.8



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How much of a priority is prescription digital therapeutics (PDTs) currently to your organization?
Please rate on a scale of 1-5, with 1 = not at all and 5 = highest priority.

N = 16 Payers
Survey Field Dates: 3/18/2022 - 3/25/2022

Source: MMIT.

And marketing these products presents its own problems, not least because “commercialising a digital therapeutic is a playbook that yet needs to be written”, as Mr Karbe puts it.

The size of the market alone is problematic, he says: there are tens of thousands of primary care physicians and around 8,000 endocrinologists in the US. A company of any size, and certainly a small one like Better, will have to approach the market carefully if it is to get traction early without spending hundreds of millions of dollars.

Partnerships might be the answer, both for BT-001 and the follow-up projects Better is working on, which include apps for hypertension, hyperlipidaemia and Nash/Nafld. Mr Karbe says Better is considering working with pharma groups to help bring these apps to a wider audience, but it is also interested in collaborating with medical device players and even pure tech companies like Amazon and Google.

Spac woes

But Better has another problem – one of its own making. Last year the group reversed into the special purpose acquisition company Mountain Crest Acquisition Corp II. Several app developers, including Pear Therapeutics and Akili, have taken similar paths to market. Akili’s deal has not yet closed, but Better and Pear have seen much the same result: a disastrous loss of value.

This cannot be laid at Mr Karbe’s door, since he only joined Better at the start of June, following the departure of Kevin Appelbaum.

“Spacs – not just ours – nowadays seem to have a number of challenges. But if you rewind the clock to two years ago, when the idea was born to use this vehicle, Spacs were all the rage,” he says. “It is what it is.”

He is confident that, once Better has succeeded with BT-001 and its subsequent projects, this success will be reflected in the group’s market cap. For now, over to the FDA.

Prescription app makers' Spac deals

Target	Spac (main backer)	Date merger announced	Date merger closed	SP change since announcement	Time to close (months)
Better Therapeutics	Mountain Crest Acquisition Corp II (Mountain Crest Capital)	Apr 7, 2021	Oct 29, 2021	-82%	6.7
Pear Therapeutics	Thimble Point Acquisition Corp (LJ10)	Jun 22, 2021	Dec 6, 2021	-82%	5.5
Akili Interactive	Social Capital Suvretta Holdings Corp I (Social Capital and Suvretta Capital Management)	Jan 26, 2022	Expected mid-2022	-3%	6.6

Spac=special purpose acquisition company. SP=share price. Assumes \$10 pre-announcement share price. Source: company statements.

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