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Dexcom COO On Stelo CGM Plans, Apple Watch Developments, And Why Non-Invasive Glucose Monitoring Still Leaves Much To Desire

Stella CGM is 'a lot more about insights and a lot less about dealing with acute blood sugars,' says COO Jake Leach.

by Marion Webb

Exec Chat: Dexcom's COO Jake Leach joined a panel discussion on the future of biosensing at CES 2024, where biowearables and glucose tech ranked among hot topics. He also spoke to *Medtech Insight* about plans for the company's new CGM called Stelo, designed for people with type 2 diabetes who do not use insulin, Dexcom's work with Apple to enable CGM users, and non-invasive monitoring prospects.

After a successful 2023, *DexCom, Inc.* kicked off the New Year by announcing a major milestone at the J.P. Morgan Healthcare conference – $1.030bn in fourth-quarter revenues, marking the diabetes company's first billion-dollar quarter. It also laid out plans for a new continuous glucose monitor (CGM) called Stelo, specifically for type 2 diabetes patients who do not need insulin.

Dexcom's chief operating officer Jake Leach flew directly from the big investor meeting in San Francisco to CES 2024 in Las Vegas to partake in a panel discussion on "The future of biosensing technology: diabetes and beyond." He also took the opportunity to talk to members of the media about Stelo, which is currently under review by the US Food and Drug Administration and expected to debut this summer. (Also see "*JPM 2024: Dexcom Touts Strong Results, Speaks On New Stelo Glucose Sensor*" - Medtech Insight, 9 Jan, 2024.)

During the panel discussion on 10 January, Leach expressed his excitement about Dexcom's

move from developing CGM products for people with diabetes to expanding the technology's use more broadly to people with type 2 diabetes. (Also see "*Exec Chat: Dexcom's CEO On Meeting New CGM Markets While Scoping Consumer Opportunities*" - Medtech Insight, 27 Jun, 2023.)

"One in every four health care dollars in the United States is spent on diabetes; 15% of the adult population in the United States has diabetes," Leach told the audience. "Most of those people do not have access to CGMs."

> ***Chatted with @dexcom COO Jake Leach about Stelo CGM for non-insulin T2 diabetes users expected launch summer. Cash price will be competitive to Abbott's FreeStyle Libre, he said no details yet. New: Apple Watch users can get CGM info w/out carrying phone. @CES #diabetes pic.twitter.com/w7RmpZXoj0***
>
> ***— Marion Webb (@medtechMarion) January 10, 2024***

Stelo is specifically designed for people with type 2 diabetes, which make up roughly 90 to 95% of all people with diabetes. Unlike people with type 1 diabetes, whose bodies cannot make insulin and whose disease onset tends to be sudden and at an early age, type 2 diabetes typically develops over years and may not show any symptoms early on. In the early stages, type 2 diabetes tends to be managed with medication, diet and exercise to mitigate progression of the disease. It is in the later stages where supplemental insulin is needed.

"The target patient population for Stelo is this group of people in the United States – it's about 25 million people that have diabetes and don't treat their diabetes with insulin, they're on other medications," Leach told *Medtech Insight* at the event. "Right now, insurance coverage for CGM for that group isn't there yet. What we want to do with Stelo is to offer a cash-pay, affordable, competitive price on that for users to be able to access the product."

In his nearly 20 years working at Dexcom, Leach has led the company's R&D team and as COO is responsible for operations, manufacturing, quality control, regulatory affairs and the customer service teams.

The interview that follows has been lightly edited for content and length.

Q **Medtech Insight: 2023 was a great year for Dexcom with the release of the next-generation G7 CGM in the US, successful expansion of Medicare coverage for CGMs to provide reimbursement for all people with diabetes using any type of insulin, and the major milestone of reaching more than $1bn in quarterly revenues. And now you've kicked off the New Year with big announcements.**

A Jake Leach: There's a whole bunch of improvements made to the G7. One that we just announced on Monday (8 January) is a feature where the sensor can talk directly to an Apple Watch. So today, our users can get their readings on their Apple Watch through the iPhone, which is a tethered connection. With the new feature, you can walk away from your iPhone and still be able to get the readings on your watch. That's been a long-awaited feature for our users. We've been working closely with Apple on making the Apple WatchOS capable of being a fully functional display device for our technology.

Q **When will Apple Watch users be able to see their glucose readings on the watch without the presence of the iPhone?**

A Leach: We submitted it to the FDA in December 2023 [this was Dexcom's announcement on 8 January] and we're eagerly awaiting the approval. As soon as it's approved, we'll start rolling it out. Approvals generally take three months or so.

Q **What information will Apple Watch users be provided on their display?**

A Leach: It's a fully functional display device. They get their real-time glucose reading and also information about how their glucose is changing whether it's rising or falling and how fast, which is super important for determining how to treat diabetes. They also get glucose alerts. The Apple Watch will notify you when your glucose goes out of range. It also notifies you if your glucose is going low, and it'll be predicted in 20 minutes, so it lets you know you're going low before it happens. Hypoglycemia is a challenge for people who take insulin and it could be very dangerous, so it's a significant safety blanket.

Q **In the future, will this direct connection be available for other wearables like, for example, a Garmin Watch?**

A Leach: We have a partnership with Garmin. Today, you have to have your phone with you to make that connection on the Garmin Watch. We started the direct connection with Apple, but we are looking at other wearables that we can put the technology onto [in the future].

Q **This will require FDA clearance for every use case, correct?**

A Leach: It does, because of the importance of the features functioning properly. You never want to give somebody on their wearable the wrong reading. The Apple product serves a large portion of our customers – larger than Android at this time – but we have a pretty strong group of Android users as well. The focus is on Apple right now. We want to learn how Apple users use it and also learn from the feedback we get. All our products are designed based on user feedback.

Q **Stelo is expected to be launched this summer. What can you tell us about its features and your marketing strategy?**

A Leach: Stelo was built on the same hardware as G7, but will be branded differently. We haven't talked about pricing for competitive reasons, but we will be announcing pricing closer to launch. We're not going to talk about our complete go-to-market strategy [right now], but it'll be accessible, affordable, and really purpose-built for this group. There are people who pay cash for our current product in this market, and what they tell us is that they want all the data insights that the CGM gives them without the interruptions.

They don't want glucose alerts that tell them their glucose is out of range because their condition isn't as acute as those that are taking insulin where you're worried about trying to manage insulin, all of which G7 is designed for. Stelo is designed around providing that real-time information, but helping users connect the dots to their diet, their exercise, and how that it is impacting their glucose day to day. It's a

lot more about insights and a lot less about dealing with acute blood sugars.

Q **Can you give some examples of the insights Stelo will provide users?**

A Leach: It's going to help you understand when you eat a meal what that meal did to your blood sugar readings. It's also going to help you understand what exercise did to your glucose and how it changed. The idea is providing people with in-the-moment feedback with how things are going with their metabolic health [all through a new app which is not available to demo]. It'll show you that your glucose levels spiked and try to connect that to what you ate or whether you exercised. For us, it's not about counting the spikes, but connecting the dots. (Also see "*Abbott Lingo Leaders On Consumer Biowearable Outlook: 'A Lot Of Appetite For Glucose As A Biomarker For Your Health'*" - Medtech Insight, 24 Jan, 2024.)

Q **Abbott's consumer biowearable Lingo is currently under US FDA review. Is Dexcom also eyeing the consumer market or people who do not have diabetes?**

A Leach: I think there's opportunity in the long run for CGM use outside of diabetes. We're seeing a lot of that. We support research. We have invested in Signos, which is focused on weight loss. They are using our CGM to put together a digital weight loss program. We also work with Levels [among others] that use our CGM data. Our idea is to work with partners and continue to explore that space. Our focus is on people with diabetes that don't have insurance coverage, but need CGM. We will seek reimbursement for Stelo once we generate the evidence that shows the benefit of Stelo. Some payers are ahead of the curve and are already covering CGM for most people with diabetes; it is just a very small number. (Also see "*Minute Insight: CMS Expands Medicare Coverage For CGM*" - Medtech Insight, 17 Apr, 2023.)

Q **What are your plans for Stelo outside of the US?**

A Leach: One of the differences between the US market and outside the US is that the US market has very good coverage for CGM for anyone who uses insulin. In most countries outside of the US, people who take basal insulin, so one shot of insulin a

day, don’t have coverage for CGM. The first step is to get better coverage for people who take basil insulin outside of the US.

Q **What is your opinion on the prospect of non-invasive glucose monitoring – ie, measuring glucose levels without puncturing the skin?**

A Leach: I've been working on CGMs for more than 25 years and the non-invasive concept is a beautiful concept, but when you look at CGMs now, they’re pretty small and super accurate and reliable. We’ve not seen any technology that comes even close to the level of accuracy required. One of the questions I often get is, ‘Does it have to be that accurate if you’re not dosing insulin and things?’

We found that it has to be just as accurate for the average healthy person that wants to wear a CGM. Let’s just say the CGM was off by 10% and telling me my glucose was 10% higher than normal. That would suggest over time that I have some sort of a metabolic condition, right? That will put me in the pre-diabetes category if you’re off by an average of 10 to 15 points. Hence, accuracy is really important.

People would be misled if the sensors are not accurate into thinking that they have a metabolic condition. We've got a venture research group where we have committed $100m in venture investments with the idea of incubating early technologies that are evaluating opportunities. We haven't seen anything that would meet the requirements of what we feel is necessary for a product.