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Exec Chat: Dexcom's CEO On Meeting New CGM Markets While Scoping Consumer Opportunities

by Marion Webb

In this first of a series of Exec Chats with leaders at major diabetes companies presenting at ADA's Scientific Sessions 2023, CEO Kevin Sayer discusses Dexcom's ambitious R&D map to expand into metabolic health and develop innovative new products for diabetes and consumer markets.

DexCom, Inc. kicked off the American Diabetes Association (ADA) on a bullish note.

The San Diego-based leader in continuous glucose monitoring raised its 2025 revenue targets by $600m to a range of $4.6bn-$5.1bn at its 23 June Investor Day meeting.

CEO Kevin Sayer and his team were excited about CGM's future total addressable market and expansion prospects, driven in large part by the *Centers for Medicare and Medicaid Services*' historic expansion of CGM coverage, effective in April, which removes the prior requirement of multiple daily insulin injections to be eligible for reimbursement. Coverage now extends to a much broader population including people with non-insulin-treated diabetes and those with a history of problematic hypoglycemia. (Also see "*Minute Insight: CMS Expands Medicare Coverage For CGM*" - Medtech Insight, 17 Apr, 2023.)

Currently, only about 25% of people with type 2 diabetes, who are taking multiple insulin shots a day, use a CGM. BTIG analyst Marie Thibault said the CMS decision increases access for about 1.5

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million people who take basal (daily) insulin in the US covered by Medicare, and could expand to 3-4 million people more as US commercial payors follow suit.

"That is a market Dexcom has not participated in before," Sayer told *Medtech Insight* at the ADA conference, noting that on top of Medicare, about 60% of commercial insurers now also cover the basal insulin-only population. The CMS expansion, he said, adds about 7 million people total between the two groups, which Dexcom plans to address by stepping up marketing efforts for its newest-generation CGM, the G-7, in the second half of this year and in 2024.

The G7, which received regulatory clearance in the US and Europe, was off to a solid start in the US in the first quarter with more users than in any other quarter in Dexcom's history, management said during its first-quarter earnings call. (Also see "*Dexcom Doubles Down On Jonas Branding To Hail G7 Launch*" - Medtech Insight, 9 Feb, 2023.)

In addition, Dexcom announced plans for a new 15-day sensor designed specifically for people who don't use insulin, which is about 70% of Americans living with diabetes, in the second half of 2024. The company also has a next-generation vision for the G-series, such as a smaller footprint, more reusable materials, and integration into the Apple Watch. Further, the company announced a partnership with pharmaceutical giant *Roche Diabetes Care* to bring its Dexcom ONE CGM to Argentina.

The Dexcom One first launched in 2022 for people with type 1 or type 2 diabetes outside of the US.

In our sitdown with Sayer on 25 June, which has been lightly edited below for content and length, the CEO discusses Dexcom's R&D roadmap, outlook for the future, and where AI may have a role.

Q *Medtech Insight*: What can you tell about plans for about the new 15-day wear product?

A Kevin Sayer: It is a next-generation product that we will launch in the second half of next year. If you're on basal or intensive insulin therapy, we want you to use our G7 product. But this new product is designed for somebody not on insulin. This device will give people tools to manage their type 2 diabetes and possibly even health and wellness. There are more than 25 million in the US who have type 2 diabetes who are not on insulin and not at high risk of hypoglycemia.

That's a much bigger population than we ever served. We have to figure out how to create an experience that will engage those people to use the product and better their health. I think our first release will be simple, but I promise you people are going to come back and say, make it more simple. That's a continual learning that we have. We want this to be an educational tool, but we don't want this to be a punishing tool like, 'You ate too much today.' People aren't getting engaged with that. People don't want to be coached. They want to learn. We're trying to create an experience that has that balance between providing them useful actionable information versus coaching them too much, versus not providing anything at all. It's going to be an experience that people want to engage with. It's going to be positioned in a distribution channel where they can get it, and we haven't disclosed any of those things yet. But we're working on those plans. Someday, I would like to see a menu of features that you can have, click the ones you want. That type of software platform would be spectacular.

Q **With the cash-pay option, how much will this device cost?**

A Sayer: We are still debating a number. We need to get the product approved and see what features are in it.

Q **You announced plans for several new products in your R&D pipeline.**

A Sayer: We will have a direct-to-watch product by year-end. It will be a similar experience to what users have on their phone. We try to make our screens have uniform themes. When you look at a Dexcom screen, you know what it is. Our hallmark with our phone app is that circle with the arrow. This new app we want to create trademarks that. Everybody will know exactly what they're looking at. We will also start a clinical study on a different configuration of an extended life product that has some new technologies in it that we've learned since we launched G7. I didn't give a launch date or end date, but we'll launch that study. The characteristic of that product is it's going to be more accurate, it's going to be more reliable, and I've been given the challenge to make it longer than a 15-day wear product.

We know people don't like changing their sensors, so if we can go longer, we will, as

long as we perform well. Those are three very tangible things that one would expect to see over the next 12 to 18 months. I also talked about the markets we will continue to go to. That is in addition to the intensive insulin and automated insulin delivery markets – we're not going to leave that. We'll continue to be aggressive there. We need to develop solutions for pregnancy.

We also continue to do work in the hospital – that is going slow. It's a very different environment than a consumer product. It's hard to execute a clinical study with somebody lying in an ICU bed. (Also see "*Dexcom Works With FDA To Bring CGM To Hospitals After Pandemic*" - Medtech Insight, 2 Mar, 2022.) We're still pursuing it, because I can't tell you the comments I get from physicians who use this in the hospital – they say it's spectacular. (Also see "*New Frontier: COVID-19 Crisis Opens Door For Dexcom, Abbott To Bring CGMs Into Hospitals For First Time*" - Medtech Insight, 14 Apr, 2020.)

We had to get G7 done to get ready for the next hardware configuration. From G6 to G7, everything is different. We built a bunch of automated equipment for G6 that we will be phasing out over the next few years, because the G7 manufacturing lines are completely different. Our next platforms will incorporate the way we build G7 into everything we build in the future. We'll just swap out manufacturing stations. We've built ourselves a very flexible, highly automated manufacturing process going forward, so we can build new hardware configurations. It will have a smaller footprint, more reusable materials and more powerful electronics. We are working on sensors that would measure things outside of glucose and we have active programs there. The question we always ask ourselves is, 'Is what we're measuring a real business opportunity?' We're looking at things like ketone sensing or lactic acid sensing.

Q We see Abbott working on a dual monitoring system that will measure glucose and ketone levels.

A Sayer: The ketone sensor use case is interesting. Some of the data we presented at our investor presentation was from a 500-patient study that lasted six months on

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Dexcom G5. In the six months the people were in the study, not a single one had a DKA (diabetic ketoacidosis, a serious complication of diabetes) event. So, if you're going to measure ketones, there has to be a reason other than just marketing noise. That's the challenge I give our people. Now, if ketones turn out to be an incredibly valuable medical tool, we'll certainly develop something. But it's just one of the things we're pursuing. It's not the primary one, or the only one.

Q **Do the types of sensors in development address both the diabetes and consumer markets?**

A Sayer: Yes, we're looking at both -- people with diabetes and the consumer market, depending upon the use case. Our lactate sensor, for example, can be wildly useful for athletes combined with a glucose sensor. But we also know many things about lactate measurement with respect to the interaction of glucose in the blood versus lactate in the blood and how those things react to each other. It can be very useful for somebody with diabetes as well, if we write the proper algorithm.

Q **What can you tell us about new algorithm technology coming out of your TypeZero subsidiary?**

A Sayer: We own the algorithm that _Tandem Diabetes Care, Inc._ uses in their pump, they license it from us. We have next-generation technology coming out of that. We've run some preliminary clinical studies and it's very much geared towards [developing] an automated insulin delivery system where you don't do any work. You don't have to bolus, you don't do anything. We're running studies in New Zealand right now that are taking people whose time in range is below 20% – train-wreck patients for a lack of a better word – and they're getting them to above 50% time in range, some in the mid-60s, and they're not bolusing at all with this new prototype algorithm.

Q **You are also planning new G7 iterations. What can you tell us about that?**

A Sayer: We'll look at multiple software experiences. We literally have new iterations of G7 on a regular basis. I can give you an example. We will be launching in Europe in the not too-distant-future a G7 app that will accept insulin data from _Eli Lilly and_

Company's insulin pen. We will launch in the US within the next 12 months a version of the G7 app that will accept activity data from your Apple Watch. We'll do integration with other signals, in some cases different displays, different alerts and alarms, if we find them useful. We just launched the G7 in the US. There was an alert available in Europe to silence all your alerts. We called it "Silence All." When we submitted that to the FDA, they said we won't accept that, because we're afraid patients will forget their alerts and die in the middle of the night. So we rewrote all the software to take that out for the US version of the app. And then we submitted it. In the middle of the review, the FDA came to us – because they've heard so many good things about the feature in Europe – and said, 'Will you put it back in?' We said no, we'll wait. We got the product approved, we launched and just added the Silence All feature back in here in the US. (Also see "*Dexcom Touts G7 As 'The Most Accurate CGM' As It Prepares For US Launch*" - Medtech Insight, 9 Dec, 2022.)

Q **What are your thoughts on non-invasive glucose monitoring?**

A Sayer: People have tried that forever, and there are different technological approaches. People use radiofrequency, raman spectroscopy, and stuff like that. We've never seen anything accurate enough for us to continually compute a glucose value. We look at all of them. If the technology has made significant progress, we're not arrogant enough to not look at it. We haven't seen anything that moves the needle. We're very comfortable with where we are.

Q **What role does AI and machine learning play at Dexcom now and in the future?**

A Sayer: It's something I talk to the team about regularly. We have more than a trillion data points in our servers of glucose values for millions of people. If you took the right AI tools and went through all that data, there's a lot of things you can learn. Some of the algorithms that the pump companies use, and even our next-gen generation algorithm, learns from your behavior and adjusts your insulin dosing based on what it learns. I believe if we you looked at all the hypoglycemia events in our database, how would you predict it? One of the things we need in this artificial intelligence database is more information or more variables.

For example, if we had insulin usage as a variable along with glucose, so we knew how much insulin was on board, our predictions would be stronger. If you went so far as to have activity data with respect to what comes from your watch in there, now you got three variables. Where this gets interesting to me though, is how does the FDA approve that? What do you file to say we can predict 87.2% of the time you're going to go hypoglycemic based on the variables that we have? Do they let us do something that works 87.2% of the time, or do they say it needs to work 100% of the time? And who is going to be liable for the 13% that it misses?

I think there's an incredible opportunity for us within our business practice and business models. If we can take that sensor data and predict [for example] sensor failure in advance, that makes our business much more efficient. Even the G7 hardware in and of itself makes things like that better. Every G7 has a unique serial number that's transmitted to us by the transmitter when you put it on. That sensor has a unique identifier – there's all sorts of things we can learn over time. We're not there. This is all Kevin's future vision.

Q What is your view on large language models like ChatGPT?

A Sayer: I played with it a little bit personally. I had it write a poem for my sister's birthday and it went to all of her social media accounts. And it talked about her and her three daughters and all the fun things they do and how everybody says positive things about her. She's literally in tears and she was so touched that I spent all this time writing her poem. I said, I need to stop and I absolutely confessed. And then it was my birthday and I had it write a poem for my birthday and it talked a lot about Dexcom and business.

Then my fifth son asked ChatGPT to write an episode for the Sopranos where me and Tony [Soprano] sat down to discuss a deal. And it wrote a script and said, 'Kevin left the restaurant not quite sure what exactly he'd agreed to.' So how do you make this a tool into our business when all the business arrangements with other companies has to be figured out, because if you give all your data to ChatGPT, it's now in the public

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universe. Our users don't want all their data in the public universe. We're a custodian of their data and we take that very seriously, but if we can learn something from their data, then we should. I think you can use ChatGPT to give you some initial ideas how to do something, but I think you have to finish it. I don't think there is enough in ChatGPT to write a marketing plan. (Also see "*'This Is The Way Of The Future': Digital Health Experts Share Thoughts, Experiences With Generative AI*" - Medtech Insight, 18 May, 2023.)

I've asked what's good about Dexcom and it wrote me a beautiful essay about how great Dexcom was.

Q **Did it say anything about the competition?**

A Sayer: It just said that *Abbott* is known for X, but Dexcom is known to have the best product.