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Exec Chat: Dexcom's CEO Bullish On Year Ahead With G7 CGM Launch, Dexcom One CGM Expansion

by Marion Webb

In an interview with *Medtech Insight* following the J.P. Morgan Health Care Conference, Dexcom CEO Kevin Sayer discussed marketing plans for the next-generation G7 continuous glucose monitoring system and for the simpler CGM, Dexcom One, and outlined plans ahead.

DexCom, Inc. reported "lighter than usual results" during the fourth quarter dealing with COVID-related headwinds, but Wells Fargo analyst Larry Biegelsen remains upbeat that the upcoming launch of the next-generation G7 continuous glucose monitoring device could turn out to be a major catalyst for the San Diego, CA-based CGM maker.

On 10 January, Dexcom reported *preliminary fourth-quarter revenue* of about $698m, which were in line with Dexcom's guidance and Wall Street expectations, but a departure from its track-record of consistently beating projections.

At the recent J.P. Morgan Health Care conference, Dexcom's CEO Kevin Sayer provided conservative guidance with projected revenues of $2.28bn to $2.94bn for 2022, representing a 15%-20% growth, but expressed excitement for the year ahead.

Foremost, he's upbeat about the planned global launch of G7, which is still waiting US Food and Drug Administration 510(k) clearance as well as the CE mark in Europe.

"We've submitted a filing that is just very, very pristine and certainly meets their criteria very easily as far as approving our product as an iCGM, so we shouldn't have any problem there," Sayer told *Medtech Insight* about working with US regulators. (Also see "*Dexcom's Q2 Earnings Exceed Wall Street Expectations; Holds G7 Launch*" - Medtech Insight, 30 Jul, 2020.)

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DEXCOM CEO KEVIN SAYER *Source: Dexcom*

Sayer does not foresee any problems with the CE-mark process and hopes that European marketing approval will come "relatively quickly." (Also see "*Exec Chat: Dexcom Continues To Evolve Blood Glucose Measurement Market*" - Medtech Insight, 7 Jul, 2021.)

Analysts expect G7 to be a growth driver for Dexcom. For example, on 19 January, Wells Fargo's Biegelsen wrote, "The G7 launch in 2022 will be a major catalyst given the best-in-class clinical data." Given that review times at the FDA diabetes division have been delayed, he expects that US clearance could be delayed until around the American Diabetes Association meeting in June.

Sayer talked to *Medtech Insight* about the company's plan for 2022.

Q **Medtech Insight: What are your marketing plans for the G7 in the US?**

A Kevin Sayer: We will focus our US rollout on our larger markets, and, in particular, on markets where we have a direct presence and larger markets where CGM is more reimbursed, because we want to get to as many people as fast as we can – As you break down our OUS revenues, we're certainly direct in Canada, we're direct in Great Britain, in the UK, we're direct in Germany. We have a very large presence in Northern Europe and Scandinavia as well. We do very well in Italy. We'll look at the places where we have the biggest customer base, and [where] we can get it approved. We haven't given anybody all the specific countries and launch dates, but we have a very well thought-out plan.

Q **What does that mean for your G6 customers?**

A Sayer: With G6, we have a transmitter that lasts for three month, and sensors only last for 10 days. It's a relatively short-term commitment, so they can switch over to G7 as soon as reimbursement authorities are willing to pay for it. It should be a relatively smooth switch for those who are on G6. Where it will be a while is for patients to switch are the integrated systems (patients who use a *Tandem Diabetes Care, Inc.* or

> *Insulet Corporation* insulin pump). They will not be ready with G7 when we are commercially ready. So those patients will stay on G6 until Tandem and Insulet will have their systems upgraded to accept the G7 signal and that will take a little time. Both companies are working vigorously to do that.

Q **How long do you foresee will it take to get reimbursement for the G7?**

A Sayer: [Outside the US] we were able to at least discuss G7, so they know what's coming. We're hopeful we can go very quickly with those. In the US, there are so many different market segments. For example, [Centers for Medicare and Medicaid requires] a 90-day process. We can't start until we get approved. And the same, with the PBMs (pharmacy benefit manager) and that channel. The distributors and the durable medical equipment can actually move relatively quickly on their relationships with the payer. It is much more complicated to launch a product now than it was when we didn't have the base that we have today.

Q **What can you tell us about the shift from the durable medical equipment market to the pharmacy channel?**

A Sayer: Medicare goes to the durable medical equipment channel, and we don't see that changing given the nature of our device. We do give patients and customers the option. If the payers want to stay in durable medical equipment they can, but it's just much easier for the end-users – the physicians and the customers to get it through the pharmacy. The place where people like to stay in medical equipment are our customers who are on integrated systems where they're getting everything from one supplier. To make it easier, we've shifted as much of the business to the pharmacy as we can. That's why we say our long-term goal is a 75% to 25% mix knowing full well 25% want to stay in the other channel.

Q **The G7 offers several benefits over the G6 such as smaller size and faster warm-up time, but it is a 10-day wear device. Are you planning on introducing a longer-wear device [Abbott's FDA-approved FreeStyle Libre 2 system is a 14-day wear as well as the CE-marked Libre 3 device]?**

A Sayer: It was easier to do now a 10-day sensor than it was a 15-day sensor. One of our 2022 R&D initiatives is to extend the life of that product to more days. You could see two products – a 10-day and a 15-day configuration going forward [on the G7]. We have an OUS approval for G6 to 15 days so we piloted and decided not to do it. You know [just a simple issue as adhesive tape] you got to have the right tape. There are so many components to this area. You have to consider hypoallergenic, you have to consider sticky.

Q **Abbott recently announced it is developing a new line of biowearables for consumers. Is that something Dexcom is also exploring?**

A Sayer: It's something we've looked at for quite some time. We do advanced research in this area [including in] many of the similar analytes that *Abbott* brought up in their presentation. But we have so much to do with glucose. (Also see "*CES 2022: Abbott CEO Robert Ford Announces New Biowearables Line For Consumers, Paving The Way From Measuring Glucose To Ketone, Lactate, Alcohol*" - Medtech Insight, 6 Jan, 2022.)

There are a lot of sensing technologies out there that we ultimately could see adding to our platform and giving our customers the experience they want – things like your *Apple Inc.* Apple Watch or what we get from your Apple Watch or those apps, Fitbits or rings, Whoop bands. All these things produce a different set of data and there is an opportunity with the APIs in the future for us to send our data to other sensors and for other sensors to send their data to us.

I'd even take the Abbott data into our API platform, if they share with us. I doubt that phone call is going to be answered. (Also see "*Dexcom, Abbott File Dueling Lawsuits On Diabetes Management Technology*" - Medtech Insight, 7 Jul, 2021.) There's so much to do with glucose still, that that's where the majority of our efforts are focused. I'm happy to let the other guy build a market and get in later while we perfect what we're doing a little bit more.

Q **Where do you see the impact of the coronavirus on your business moving forward into 2022?**

A Sayer: We tried to contemplate the impact of coronavirus on our business for 2022 and the guidance that we provided, and I think, it's more of an acute situation for the current period. I'm hopeful that we get through the Omicron variant and by the time we're looking at the last half of the first quarter that things are a little bit more normal. Nobody really knows what is going to happen. (Also see "*Dexcom Outlines Three-Pronged Growth Strategy To Reach $4-4.5BN Revenue Goal By 2025*" - Medtech Insight, 11 Dec, 2020.)

In the fourth quarter a couple of things happened for us. The first one was our new patient ads in the US in particular were a little lighter than we planned on. We are trying to expand our efforts and reach more health care professionals with the salesforce expansion we did and successfully execute in 2021. We saw in the US – in Q3 with the Delta variant and certainly with the Delta variant and Omicron in Q4 – places that aren't familiar with us had a very hard time letting us get in and that's where we need to expand. The other thing that's happened is the shift to the pharmacy channel financially in the US is very real for us. As more of our customers go to the pharmacy channel, two things happened in this fourth quarter: the average revenue per patient is a little bit lower. And while it's a more efficient channel for us and a more efficient channel for the customer, the fact is as we add new customers and the revenue for customers is lower, it is harder to grow. You've got to depend on getting more new customers.

The other piece is seasonality. In two of our fastest-growing channels – the US pharmacy channel and the Medicare channel -- the seasonality aspect versus durable medical equipment is not there. In durable medical equipment, particularly in the lives of our customers, they have met all their co-pay maximums, stop losses and all the terms you hear about insurance. (Also see "*Market Intel: Glucose Monitor Market Set To Explode As Patients Access Better Devices*" - Medtech Insight, 25 May, 2021.)

Their goal used to be to buy as much product in the fourth quarter as they could. And our business used to be extremely seasonal. You'd see a huge jump from Q3 to Q4 and then a huge drop from Q4 to Q1 whereas last year that drop was only I think 12 or

13% from Q4 to Q1, because the seasonality is going away related to that activity in the US. We are so US-centric that our revenue, although our OUS revenue performed extremely well in the fourth quarter, it has a big effect on what our overall financials look like. Our volume still grew between 35 and 40% in the fourth quarter.

Q **The American Diabetes Association recently updated its recommendations for CGM for type 2 basal insulin patients based on the Mobile study? What does that mean for Dexcom?**

A Sayer: What this clinical data does, combined with ADA guidelines on basal insulin, it gives us another category for expansion. And if we can get an expanded coverage in that area, that's a great place for us to grow. These patients [in the study] loved wearing the sensor, they learned a great deal and they got much better health care outcomes from it. We look at it as a category expander. We will focus efforts on a number of the payers and also CMS and Medicaid programs. Let's see if we can expand this coverage and get it onto more people. (Also see "*ADA 2021: Encouraging Trial Data On CGMs, Insulin Pens, Digital Solutions, And More*" - Medtech Insight, 1 Jul, 2021.)

Q **What are your plans for the Dexcom One CGM for 2022?**

A Sayer: There are two ways we'll expand this product going forward. The first way is in markets where we don't have a presence and really don't plan on having a presence, we can enter a geography with this new product and sell it online as a cash pay product and leave it that – so it's a geography expander for us. The other thing is its category expander for us. In Europe, in particular, in some of the countries, there are two categories of CGM. There's the category where people absolutely have to have CGM like kids, or they use a pump or are hyperglycemia-unaware, and that is a premium-price product and we played very well in those markets. Since we have lowered the price for the end-user or to the reimbursement authority [for Dexcom One], it will open up other patients like type 2 patients on multiple daily injections and many geographies that aren't covered for Dexcom reimbursement. This is a product we could put into that channel. It's a channel expander in some markets and

an ability for us to expand in some new geographies as well.

Q **In 2020, the FDA opened the door for Dexcom [and Abbott] to bring their CGMs into hospitals to help minimize exposure to Covid-19 patients. Can you give us an update on what this could potentially mean for Dexcom in terms of marketing the product in the hospital setting or health care facilities in the future?**

A Sayer: We've taken this opportunity to gather data from the hospitals where we created a registry of the data. We're in the middle of a pivotal study, creating the necessary documentation to show that G6 will perform in this environment. We actually hired a general manager of the hospital system to design that product and the features necessary for it. And again, you've got a situation where the core technology can perform wonderfully in an environment. It measures glucose more accurately than anything else on the marketplace and it can be connected to anything. The question we have to answer is 'how do we connect it?' 'What do we connect it to?' And how do we put it into the workflows of the health care providers?' (Also see "*ACC 2020: Medtronic's Resolute Onyx DES Meets Goals In US/Japan High Bleeding Risk Patients*" - Medtech Insight, 9 Apr, 2020.)

Those are some of the questions we are asking before we'll roll it out on a broad commercial basis. I think you'll see some baby steps this year. What I'd like to do personally, and I talked to the team about the strategy, particularly when we can get an approval, is really focus on several key centers who want to commit and get that right product designed and ready to go, because there are a number of places to connect.

You connect to the health care professionals' iPad, you connect to the other devices in the room, somehow go straight to the cloud, get to the medical record. Those are some of the questions that we're answering and dealing with. I think the hospital market is a huge win and we can certainly make this a standard of care, if it's easy enough.

[Sayer's answers have been slightly edited in the interest of length and clarity].