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# Cardio Conversations: iRhythm Prepares To Deliver 'Standard-Of-Care' Cardiac Monitoring

by [Reed Miller](#)

Quentin Blackford, CEO of iRhythm, talked to *Medtech Insight* about his company's plans to bring its Zio long-term cardiac monitoring platform to more patients by building its evidence base and marketing in more countries outside the US.

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[iRhythm Technologies](#) is building momentum in 2023 with the development of new Zio electrocardiogram monitoring devices, clinical trial results, and expansion into new markets.

iRhythm markets the Zio XT and Zio AT long-term ECG patches along with an artificial intelligence platform that identifies symptoms of arrhythmias in ECG data.

The company reached a major milestone in late 2022; after many years of lobbying and data collection, the US Centers for Medicare and Medicaid Services set national Medicare reimbursement rates for long-term cardiac monitoring. (Also see "[CMS Proposes National Payments For Long-Term Continuous Electrocardiogram Monitoring](#)" - Medtech Insight, 8 Jul, 2022.)

In the first quarter of 2023, the company recorded \$111.4m in revenue – up 21% year over year. "Our commercial teams did a terrific job building upon the discipline and rigor introduced in the back half of last year to capture key strategic wins, driven by a continued push into primary care [accounts], as well as increasing penetration into large and national accounts," CEO Quentin

Blackford said during a 4 May sales and earnings call.

The company continues to invest in clinical studies to demonstrate the clinical benefits of long-term cardiac monitoring with the Zio system. For example, recently published results from the [CAMELOT](#) study of more than 287,000 Medicare claims showed that long-term continuous monitoring with Zio XT provide a higher “diagnostic yield” and faster time to clinical diagnosis than other ambulatory cardiac monitors.

iRhythm is also constantly improving its monitoring devices. It expects to launch the next-generation [Zio Monitor](#) later this year. “The early feedback we're getting with our trials in the marketplace are significant from a patient experience perspective, but also from a return-device-rate perspective, which has a direct impact on our revenue,” Blackford said during the JP Morgan Healthcare Conference in January. (Also see “[JPM 2022: Abbott, iRhythm, Novocure, Zimmer Biomet](#)” - Medtech Insight, 11 Jan, 2022.)

The company is also preparing for the roll-out of the Zio MCT long-wear patch incorporating the same breathable patch ECG monitor as the Zio Monitor with additional upgrades to the underlying ZEUS System software. The company expects to complete a submission to the US Food and Drug Administration for Zio MCT later this year.

iRhythm is planning to begin the launch of the the long-awaited Zio Watch in 2024. (Also see “[FDA Clears iRhythm's Afib-Detecting Wearable Running Software Co-Developed By Verily](#)” - Medtech Insight, 22 Jul, 2022.)

Blackford told *Medtech Insight* that the company has made progress on several important “operational issues.” For example, the company is trying to improve the rate at which patients return their Zio devices. The device return rate is important for iRhythm because the device cannot provide a report to the patient if the company never gets it back, if it falls off the patient early, or if the company receives it with no data. This loss rate hinders patient care as well as iRhythm's ability to recycle the device and ultimately bill for the service.

Also, a lot of the company's physician customers are struggling with staffing shortages.

But he is confident the company can eventually establish its technology as the “standard of care” for long-term ECG monitoring. “2023 is off to a good start and we're happy with the progress we're making coming out of 2022,” Blackford said.

Here are some more edited highlights from that interview.

**Q** *Medtech Insight:* What are the company's top priorities for the next year?

**A** Quentin Blackford: It's been a fun journey for us and I would say, 2023 is off to a good start and we're happy with the progress we're making coming off in 2022.

There were a few operational issues that we were focused on – like our return device rates, which have had an impact on our revenue and was something that we'd spent quite a bit of time talking about on our Q3 and Q4 calls.

And we're making some good headway around those issues. We were dealing with a bit of noise around the Zio AT product in the marketplace as well, coming off the end of 2022 and into 2023. And again, we've done a nice job of addressing some of those challenges.

I think at this point, you know, as we think about 2023, the focus is really on ensuring we continue to make progress around those operational matters that we've discussed, publicly. But we are also getting really excited around the launch of our Zio Monitor that will get put into the marketplace in the back part of this year. I believe it'll be the single largest launch in the history of this company. It's another transformational sort of product coming into a space that just hasn't been disrupted in years.

It's 72% smaller than our existing XT product. It's 55% lighter and 20% thinner and it all leads to a much better patient experience, and physician experience as well.

Beyond that, we're committed to getting into new countries outside of the UK. We're planning to launch into three additional international countries as well in the back part of the year, so our focus is really ensuring we do well and have success in those efforts.

**Q** There's a lot of concern in the industry about hospital staffing shortages. Are there other variables that you cannot directly control? How can you address those?

**A** Blackford: I think that, more than anything, it is the staffing challenges that we that we deal with and continue to hear a lot of noise around. But I also believe that these physicians and their offices are finding ways to navigate through the capacity issues. They're finding ways to be more efficient with their workflow with the prescription patterns and how they're seeing patients.

It's also one of the greatest opportunities.

We can help with those workflow efficiencies, particularly as they deal with capacity challenges. We send a Zio device to the patient's home, the patient puts it on, and then can have a report generated before they even come in to see that physician for an office visit. That creates tremendous efficiency.

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*"We are focusing on operating the business and driving this product to become the standard of care in the industry." – Quentin Blackford*

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**Q** In the last few years, iRhythm put a lot of energy into improving the Medicare reimbursement for long-term cardiac monitoring. Where does that stand now and is there more work to be done to ensure you get paid enough for what you sell?

**A** Blackford: There was tremendous progress made over the course of 2022 to the point where CMS finally made a decision around getting a national rate put in place, right, and there's a national coverage decision now in place that we're all working under across this entire industry. That went into effect January 1.

We were pleased with where the rate was set and we continue to believe there's tremendous value this technology offers in the marketplace. So we continue to work with CMS on articulating what that value looks like and how to value artificial

intelligence into the future, because that's a big part of what differentiates our products. To get the national rate established and put in place was a huge, huge hurdle that we had been working to get over. And we're now over it.

Now we are focusing on operating the business and driving this product to become the standard of care in the industry.

One of the things that sets us apart is we have tremendous amounts of clinical data that stand behind our product – more than anybody else in the industry. And we will continue to invest in those sorts of things. The [mSToPS](#) trial was incredibly exciting for us as it demonstrated the economic benefits associated with proactively monitoring or screening patient populations.

In mSToPS, there was an incremental cost-effectiveness ratio per quality-adjusted-life-year-gained of \$17,000. To put that into perspective, from a payer's point of view, anything less than \$100,000 per quality adjusted life year gained is interesting to them and certainly something they pay attention to. Anything less than \$50,000 is what they consider to be of high value.

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*"Nearly 70% of patients who are recommended to get an implantable loop recorder turn it down." – Quentin Blackford*

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**Q** Your company developed a Zio Watch in collaboration with Verily. Why is it important to put the ECG technology in a watch device?

**A** One thing that's very unique and different about our watch capability is that it has true medical-grade diagnostic capabilities. That's how it's been approved by the FDA. Other wearables out there are not medical grade diagnostic tools, but we are.

We can identify and diagnose AFib right from the wrist off of this device. It allows us

to put a different form factor of monitoring into the marketplace.

And, more importantly, it allows us to start to monitor patients for longer duration of time. So if 14 days of monitoring is not quite right for the physician or the patient today, we can begin to bring alternative ways of monitoring that patient with the watch – you could almost identify any period that you wanted to and we could monitor that over that longer duration.

One of the things that I get excited about with the watch is that it has the potential to go right up against implantable loop recorders. Nearly 70% of patients who are recommended to get an implantable loop recorder turn it down. Maybe there's a better way to monitor that patient with a watch that they could wear for 30 days or more. So it opens up a lot of different pathways for a different segment of the population that we can now monitor in a better way.

**Q** Is there anything else we should look forward to from the company in the next year or 18 months?

**A** Blackford: The CAMELOT data that we just published is transformational. In this marketplace, it is clear that Zio should be the standard of care. We reduce retest rates. We have diagnostic yield far beyond the other competitive products that are out there in the market. We have the fastest time to diagnosis.

You're going to continue to see us invest in clinical data articulating why we're unique and better than others in the space.

There will be more data that will continue to come out around that. Getting Zio Monitor launched in the back half of the year will be a significant effort for us and certainly one that's got a lot of focus.

But also we are continuing to transform our Zio AT product and we expect to add

incremental feature sets to that product filed with the FDA in 2023, which would allow us for an opportunity to get that product into the market in 2024.

**Q** If this technology becomes the standard of care, how can iRhythm can hold this space? What else do you bring that nobody else can just replicate?

**A** Blackford: One of our greatest advantages is the data that we have that stands behind the product – well over a billion heartbeats within the dataset. Nobody has datasets like that.

And we have unique [deep-learning algorithms](#) that are powering our product versus other competitors who might use expert rules or machine learning capabilities. We're using true deep learning capabilities off a massive data set that nobody else has in terms of the size, that that brings with it a lot of opportunity.

We will continue to invest in those algorithms continue to refine those and continue to build the data sets and ensure we stay ahead of the competition. But there's no question more competitors are going to come into this space. And I think the market is going to more than double over the next several years as it moves further up the care pathway into primary care.

But the CAMELOT data were very clear – Zio was far superior in terms of diagnostic rate, time to diagnosis, lower retest rate – all the things that matter to the health care system. We are going to continue to tell that story and invest in the data that demonstrates that.

## *Further Reading*

For more information on iRhythm, cardiac monitoring and ECG technologies, check out these articles at [Medtech Insight](#).

[Cardio Conversations: Vektor Addresses 'Global Health Crisis' With Arrhythmia Mapping](#)

[CMS Proposes National Payments For Long-Term Continuous Electrocardiogram Monitoring](#)

[FDA Clears iRhythm's Afib-Detecting Wearable Running Software Co-Developed By Verily](#)

[Exec Chat: As Reimbursement Questions Get Answers, iRhythm Looks To The Future](#)

[JPM 2022: Abbott, iRhythm, Novocure, Zimmer Biomet](#)

[Exec Chat: New iRhythm CEO Foresees Enormous Opportunity In AI For Arrhythmia Detection](#)

[Dexcom COO Quentin Blackford Takes CEO Job At iRhythm](#)

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