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JPM 2022: Dexcom, Edwards, J&J, Medtronic, ResMed

by Reed Miller

The annual J.P. Morgan Healthcare Conference includes presentations from major medtech companies describing their experience in 2021 and expectations for 2022 as they continue to cope with the impact of the Omicron surge. Here are some of the highlights from the presentations on the first day of the meeting.

Dexcom Is Impressed By G7 CGM Performance

Dexcom CEO Kevin Sayer told investors during his presentation at today's J.P. Morgan Healthcare Conference that clinical data from the G7 continuous glucose monitoring system exceeded all expectations.

"The performance of this product is something I really never thought I would see in nearly 30 years in this business," Sayer said.

The G7 CMG is 60% smaller than the G6, has less than a 30-minute "warm-up" period to acclimatize before getting sensor readings compared to about 2 hours for the G6, and provides more information in the app. But what sets it apart from competitors, is performance, Sayer noted. (Also see "*Exec Chat: Dexcom Continues To Evolve Blood Glucose Measurement Market*" - Medtech Insight, 7 Jul, 2021.)

The G7 outperformed integrated continuous glucose monitor (iCGM) standards established by the US Food and Drug Administration across the board in time-in-range performance, including overall time in range with a tally of 93.3% compared to the FDA standard of 87%. Time in range is the amount of time spend in the target blood sugar range between 70 and 180 mg/dL for most people.

The G7 achieved a mean absolute relative difference (MARD), a common metric used to assess

CGM systems, of 8.2% for adults and 8.1% for pediatric patients. Lower MARD values indicate greater device accuracy.

“You see that G7 very comfortably meets iCGM standards. This data set is three times larger than the G6 dataset and much larger than any dataset anybody else has ever produced in in the industry,” he said.

Sayer noted that this is the data the company submitted to the FDA in the fourth quarter and in Europe is going through the MDR process. He hopes to launch the product “all over the world this year.”

Sayer touts the G7 as the most accurate CGM to date. Asked about the competition, Sayer noted that Dexcom does not have the budgets of larger competitors as far as going to markets, nor the infrastructure – “so we hang our hat on performance.”

Dexcom’s chief rival is *Abbott* , which markets the FreeStyle Libre CGM line. Sayer noted that Dexcom doubled the size of its sales force in the US to gain more market share, particularly in the primary care setting, where Abbott has a strong foothold. Sayer said that Dexcom still needs to increase awareness among primary care doctors to write prescriptions for its product. (Also see "*Market Intel: Glucose Monitor Market Set To Explode As Patients Access Better Devices*" - Medtech Insight, 25 May, 2021.)

The company also announced expected preliminary revenue for the fourth quarter ended 31 December 2021 to reach about $698m, an increase of 23% over the fourth quarter of 2020. In the US, the company expects to report $517m in revenue, a 15% rise over the fourth quarter of 2020 with international revenue expected to be about $181m.

Danielle Antalffy, SVB Leerink Research analyst, wrote in her analyst note from today following a management call on the COVID impact on new patient adds in the fourth quarter of 2021, that Dexcom’s management team acknowledged “lighter than usual” results caused by fewer-than-expected patient add-ons.

“Overall it does seem that COVID-related headwinds have been more of an impact on Dexcom's business in 4Q versus normal, coupled with channel shift headwinds that could persist as Dexcom migrates towards a ~75% mix versus ~50% today [to the pharmacy and Medicare channels as opposed to commercial durable medical equipment],” Antalffy wrote. “Based on the regular work we do in the CGM space, we do not think this signals any slowing adoption momentum and we remain bullish on the market opportunity for all players within the space.”

For fiscal 2021, the company expects revenues of about $2.4bn, a 27% rise over 2020. For 2022,

Dexcom forecasted revenues in the range of $2.82bn-$2.94bn, representing a 15%-20% growth. The company will present fourth quarter earnings on 10 February.

Omicron Has Not Derailed Edwards' Progress

The recent surge in COVID-19 will not prevent *Edwards Lifesciences* from reaching about $5.3bn in sales in 2021, driven by continued double-digit growth in sales of its market-leading Sapien transcatheter aortic valve replacement (TAVR) devices.

Over the last two years, COVID-19 has hindered Edwards' efforts to help hospitals create TAVR programs and complete TAVR procedures. (Also see "*Edwards Stays On Track For 'Mid-Teens' TAVR Growth In 2021*" - Medtech Insight, 27 Apr, 2021.)

The surge in COVID-19 cases, caused by the Omicron variant, is forcing many hospitals – once again – to divert resources from interventions and surgeries to treat COVID-19 patients. A new report from Credit Suisse shows that US hospitals' non-COVID inpatient utilization rate is 61%, its lowest level since March 2021, and overall US surgical capacity has dropped from 98% in July to around 85% at the start of January.

Despite this growing pressure on cardiovascular procedure volumes, Edwards does not expect to return of the struggles it faced earlier in the pandemic.

"We said [in December] that we were expecting a gradual COVID recovery and no significant impact from new variants. Since that time, Omicron is obviously spiked and impacted the health care system and procedures negatively, but considering the range of our sales guidance, we are not updating our sales guidance," Edwards CEO Michael Mussallem said during the J.P. Morgan Healthcare Conference on 10 January.

He affirmed the guidance that the company offered in its 8 December investor conference. At that time, the company projected its overall revenue would grow from $4.4bn in 2020 to between $5.2bn and $5.4bn for all of 2021 while earnings per share would be up 21%-23% to $2.07 to $2.27.

"I'm very proud of our global supply chain and of the investments that we made in 2021 that will pay off into the future," Mussallem said.

Mussallem also highlighted the company's spending on research and development, equivalent to nearly 18% of its revenue.

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Edwards is sponsoring the *PROGRESS* study of Sapien 3 and the new Sapien 3 Ultra in moderate aortic stenosis patients and the *EARLY TAVR* trial of Sapien 3 and Sapien 3 Ultra in asymptomatic patients with severe aortic stenosis. Also, the ALLIANCE pivotal trial of Edward's Sapien X4 next-generation TAVR system recently began enrolling patients, Mussallem said.

The company is also investing in transcatheter mitral and tricuspid repair technology and expects to launch its Pascal Precision transcatheter mitral repair system in the US and Europe by year-end and launch the Evoque tricuspid valve replacement system in Europe in 2022. (Also see "*Cardiovascular Catch-Up: Medtronic And Edwards Make Headlines At TCT Conference*" - Medtech Insight, 16 Nov, 2021.)

"We expect [2022] to be a year of significant milestone achievements and a lot of investments in our future," he said.

J&J Signs Digital-Surgery Pact With Microsoft

Johnson & Johnson's medical device business announced a new strategic partnership with *Microsoft* to become its preferred cloud provider for J&J's digital surgery solutions and to help J&J build out its digital surgery platform and internet of things (IoT) device connectivity.

"Through this partnership, we have the opportunity to transform how decisions are made in the most critical of circumstances – surgery," said Tom McGuinness, corporate vice president for Microsoft's global health care and life sciences business.

During the 10 January presentation, J&J's CEO Joaquin Duato outlined three priorities: Creating the new consumer health company, announced last year, which we will become a separate entity in the next 18 to 24 months; focusing on the new J&J by generating "long-term, above-market growth rates" for the pharmaceuticals division and "improve performance" of medtech. [(A#MT144367])

> *"Through this partnership [with Microsoft] we have the opportunity to transform how decisions are made in the most critical of circumstances – surgery." – Tom McGuinness*

Duato said the ongoing separation of J&J's consumer division from its other businesses should not slow down existing businesses over the next 12 to 18 months. (Also see "*J&J To Split Consumer From Medtech and Pharmaceutical Businesses – Creating Two Companies To Unlock More Value, Growth, Innovation*" - Medtech Insight, 12 Nov, 2021.)

"There's not going to be any slowdown of priorities," Duato said. "The new Johnson & Johnson, the one focused around pharmaceutical and medical devices, will still remain the largest and more diversified health care company, which sells around $80bn [and] we will retain the benefits of scale, but also the ability to streamline our operations, consumer added complexity to Johnson & Johnson, and now being focused only in medical device and pharmaceuticals businesses that share many things as far as the focus on science and technology and similar regulatory environments. It's going to enable us to streamline operations."

The company expects to deliver compounded average annual growth of 5% and reach $60bn in revenue by 2025, Duato said.

Commenting on the medtech business, Duato said that COVID-19 has disrupted the entire medtech market with further fourth-quarter impact seen from the Omicron variant.

Improving competitiveness and gaining market share is especially important for the medtech business, he said. The company has 11 platforms in medtech, worth more than $1bn. (Also see "*Exec Chat: J&J DePuy Synthes' Sharrolyn Josse Outlines Strategy For VELYS Digital Surgery*" - Medtech Insight, 12 Jul, 2021.)

"External innovation" is a key element of growth moving forward in both pharmaceuticals and medtech and over the past five years, J&J invested about $10bn in M&A, Duato noted.

He remained upbeat about the medtech division. In the first half of 2021, J&J launched 17 new medtech products, "which is more than we have done in the past five years," he said. "We plan to continue to see further progress in 2022, barring the volatility that COVID-19 and Omicron are bringing into the market."

Medtronic Adds Cardiac Mapping Tech With Affera

Coinciding with its presentation at the J.P. Morgan Healthcare Conference on 10 January, *Medtronic* announced the acquisition of *Affera*, a Boston-based developer of cardiac mapping and navigation systems and cardiac ablation technologies.

The acquisition is worth $925m, including $250m in contingency payments, according to Medtronic. The company expects the deal to close by October 2023. Medtronic already owns 3% of Affera.

Affera is developing a complete system of cardiac ablation technologies, including the Sphere-9 high-definition mapping and focal ablation catheter, the integrated Prism-1 mapping and navigation system, the Arc-10 linear coronary sinus catheter, and the HexaGEN ablation generator system, that can deliver either pulsed field or radiofrequency energy to ablate cardiac tissue.

Affera recently announced the start of *SPHERE PerAF*, a US Food and Drug Administration-approved pivotal randomized trial, comparing Affera system to Biosense Webster's ThermoCool SmartTouch radiofrequency ablation system for the treatment of persistent atrial fibrillation. (Also see "*Medtronic, Farapulse Advance Pulsed Field Ablation With US Trials*" - Medtech Insight, 11 Mar, 2021.)

"Affera has a number of cardiac ablation technologies in its pipeline that, when combined with our technologies, position us for significant growth in the $8bn cardiac ablation market," Medtronic CEO Geoff Martha said during the J.P. Morgan conference. "Now, with Affera, we'll be entering advanced cardiac mapping and navigation for the first time, giving us a much more complete [electrophysiology] ablation portfolio and enhancing our ability to compete head on in this important high-growth market."

The deal will be less than 1% dilutive to Medtronic's earnings per share in the first three years before turning neutral to accretive thereafter," Martha said. "We were able to get this asset at a very attractive valuation, especially when you look at other deals in the space." (Also see "*Boston Scientific Shoots For Cardiac Ablation Leadership With $387M Farapulse Acquisition*" - Medtech Insight, 24 Jun, 2021.)

Medtronic is already sponsoring the non-randomized *PULSED AF* pivotal trial of its PulseSelect PFA system for treatment of both paroxysmal and persistent atrial fibrillation, but Medtronic executives at the conference said Affera's technologies will complement, rather than replace, the technologies Medtronic is developing. (Also see "*Minute Insight: Pulsed AF Trial Of Medtronic's PulseSelect PFA System Completes Enrollment*" - Medtech Insight, 3 Dec, 2021.)

Martha said Affera's Prism-1 cardiac mapping and navigation platform fills an "important gap" in Medtronic's current electrophysiology product portfolio, so analysts should not assume that

the acquisition of Affera indicates a deficiency in the PFA technology Medtronic is developing. Affera's technology is "a very complementary offering to what we have," Martha said.

Sean Salmon, the president of Medtronic's diabetes and cardiovascular businesses said, "[With Affera's system] you can navigate with good precision and get a really high-density map and also deliver therapy to that catheter. And that catheter can either deliver RF energy or PFA energies, so it's a complement, for sure, across the board for us."

Salmon also stressed that Affera "gives us navigation system that is not only closing a gap for us but it is also highly differentiated, which is important in a crowded market space."

ResMed Handles Supply-Chain Disruptions

ResMed is a leader in the emerging field of digital health and remote patient monitoring, but it is still facing major shipping and supply-chain challenges during the pandemic.

"Obviously, we're in the midst of a global supply chain crisis where we have limited parts in terms of electronic components, specifically semiconductor chips," ResMed CEO Michael Farrell said during the company's presentation at the J.P. Morgan Healthcare Conference. (Also see "*The Post-COVID Mantra For Medtechs: Prioritize, Optimize And Modernize*" - Medtech Insight, 20 Dec, 2021.)

Farrell said the supply-chain problems coupled with a surge in demand caused by the June 2021 recall of sleep apnea devices produced by rival Philips have created a "perfect storm." (Also see "*Philips Releases Toxins Testing Results For Recalled DreamStation Breathing Device*" - Medtech Insight, 23 Dec, 2021.)

"We've spent really six months working through our supply chain – [up to] seven 'layers' up into our supply chain – to negotiate better supply and more parts," he said, predicting the company will be able to catch-up with demand for its devices in 2022.

"I feel more and more confident that as we get to [the summer] and then even beyond that –September or December – we're going to see those supply chain constraints really free up on the device side enough to be able to go after all the incremental demand that's out there," Farrell said.

The company has added a surcharge to its product prices to cover the additional air-freight costs it has incurred lately. "We are now chartering [Boeing] 777s and 787s from Singapore to [Los Angeles] to Atlanta to get our products to market in this global supply chain crisis, and so that has increased our costs with air freight and the component costs to secure components."

However, he said the company is trying to minimize the impact of the shipping-cost increases on

its customers. “We really [must] keep ResMed patients happy,” he said. “Because when we have a happy doctor [and] a happy patient, they become ResMed customers for a very long time.”

Despite the supply problems, the company has been rolling out the new AirSense 11 next-generation positive airway pressure system featuring the Personal Therapy Assistant and Care Check-In digital systems to provide tailored guidance for users.

The company credits these new communication features for improving patients’ experience and acceptance of the sleep therapy system.

According to the company, 60% of patients using AirSense 11 are also using the myAir patient-engagement mobile device app versus just 25% of AirSense 10 users. Also, 87% of device users are adhering to their prescribed sleep therapy, according to the company.

“That's incredible [because] the more patient gets engaged with the therapy, the more they use the therapy, which means the better outcomes, lower costs, [and] improved outcomes.”