Embecta Corp.
Q4 FY 23 Earnings Call Script
November 21st, 2023

Please standby. Welcome, ladies and gentlemen, to the fiscal fourth quarter and full year 2023 embecta Earnings Conference Call.

At this time, all participants have been placed in a listen-only mode.

Please note that this conference call is being recorded and the recording will be available on the Company's website for replay following the completion of this call.

I would now like to hand the conference call over to your host today, Mr. Pravesh Khandelwal, Vice President of Investor Relations. Please go ahead.

Thank you, operator.

Good morning, everyone and welcome to embecta's fiscal fourth quarter and full year 2023 earnings conference call.

The press release and slides to accompany today's call, and webcast replay details, are available on the Investor Relations section of the Company's website at www.embecta.com.

With me today are Dev Kurdikar, embecta's President and Chief Executive Officer; and Jake Elguicze, our Chief Financial Officer.

Before we begin, I would like to remind you that some of the matters discussed in the conference call will contain forward-looking statements regarding future events as outlined in our slides. We wish to caution you that such statements are, in fact, forward-looking in nature and are subject to risks and uncertainties and actual events or results may differ materially. The factors that could cause actual results or events to differ materially include, but are not limited to, factors referenced in our press release today, as well as our filings with the SEC, which can be accessed on our website. In addition, we will discuss certain non-GAAP financial measures on this call, which should be considered a supplement to, and not a substitute for, financial measures prepared in accordance with GAAP. A reconciliation of these non-GAAP measures to the comparable GAAP measures is included in our press release and conference call presentation.

Our agenda for today's call is as follows:

- Dev will begin by providing some remarks on the overall performance of our business during the fourth quarter and full fiscal year of 2023; as well as an overview of our strategic priorities for 2024;
- Jake will then provide a more in-depth review of our Q4 and full year 2023 financial results, as well as our financial guidance for fiscal year 2024 which we introduced in today's press release;
- Finally, Dev will provide some thoughts on the GLP-1 market landscape and we will close the call with a question and answer session.

With that said, I would now like to turn the call over to our CEO, Dev Kurdikar. Dev….

Good morning everyone and thank you for taking the time to join us.

The completion of fiscal 2023 marks our first full fiscal year as a stand-alone company. A company that is dedicated to developing and providing solutions that make life better for people living with diabetes, and I could not be prouder of our teams around the world.

Turning to some fiscal year 2023 highlights.

It is my pleasure to share that our fiscal year 2023 results exceeded our expectations, as our team's commitment, resilience, and strategic focus played a pivotal role in our success.

And the team’s efforts did not go unnoticed, as embecta was recognized as the winner of the MD+DI’s readers’ choice company of the year for 2022, which is one of several external recognitions our team received.

Additionally, our associates have continued to make significant advancements in the process of establishing embecta as an independent company, with the goal of exiting as many transition service agreements with BD as possible by March 31, 2024.

Along those lines, we have made substantial progress by implementing our own global HR information system, launching a new customer relationship management system, and establishing our global IT network. Throughout these activities, we have been diligent in minimizing any potential disruptions to our customers and people with diabetes who rely on our products daily.

As we had mentioned on a prior call, we had initiated the demerger process for our Suzhou, China manufacturing entity so that we could transfer that entity from BD to embecta. This is a multi-step process, and I am pleased to inform you that during the past few months we have achieved several important milestones. These include obtaining business and product licenses, implementing our ERP solution, and transferring ownership of land and buildings. We have also resumed production at that plant for markets outside of China, and we are currently in the final stages of obtaining our manufacturing license, which will enable us to produce domestic products for China.

We also initiated the deployment of our ERP solution, along with the operationalization of our distribution network and shared service infrastructure for the US, including our Holdrege manufacturing plant, and Canada. This implementation began earlier this month, and we are pleased with the progress we have made so far.

As mentioned in the past, to minimize the potential for disruption, we are taking the approach of implementing our ERP system in phases. With the ERP implementations in Suzhou, China; the US; and Canada, we have now implemented our systems in two of our three manufacturing plants, and in markets representing approximately 60% of our revenue.

Turning from separation activities that occurred during 2023 to actions taken to strengthen and optimize our core, we continue to demonstrate a strong commitment to ensuring broad and preferred access to our products for patients. To this end, effective January 2024, three of the top Medicare Part D plans, which are a critical and growing segment of the payer market, providing pharmacy benefits for our seniors, who comprise a disproportionately high percentage of people with diabetes, will advantage embecta as an exclusive or dual-preferred brand on their formulary list. Previously, these Medicare plans were open access and broadly covered all brands of pen needles and syringes, without advantaging any one brand.

Additionally, we remain committed to new product development, and remain excited about the progress we are making in terms of our insulin patch pump that is being developed specifically for the Type 2 market. We are working to achieve critical milestones in fiscal 2024 and plan on sharing more at the appropriate time.

Lastly, we were proud to celebrate this year's Diabetes Awareness Month by ringing the Nasdaq Opening Bell along with representatives of several organizations that make supporting the people who are living with diabetes their sole focus. Our company is honored to recognize the people with diabetes, caregivers, healthcare providers, and advocacy organizations working together to improve access to education and continue to progress towards the vision of a life unlimited by diabetes.

Now, let's review our fourth quarter and full year revenue performance in a bit more detail.

During Q4, we generated revenue of $281.9 million, which represented an increase of 2.7% on an as-reported basis, and growth of 2.1% on a constant currency basis. When normalizing for the impact of year-over-year changes of the non-diabetes products that we contract manufacture and sell to BD, our underlying core injection business grew an impressive 4.9% on a constant currency basis. The constant currency growth of our core injection products was aided, in part, by an easy comparable, as the fourth quarter of 2022 was negatively impacted by the timing of certain distributor orders which positively impacted our revenue in the third quarter of 2022. When normalizing for both the year-over-year contract manufacturing revenue headwinds, as well as the timing of certain distributor orders, our core product lines grew approximately 3.4%.

These results exceeded our previously communicated expectations primarily due to the performance of our pen needle products. While from a geographic perspective, Q4 revenue came in better than we previously expected in most countries, including the U.S., Canada, and Latin America.

Regarding the U.S., during the quarter revenue totaled $151.8 million, which represented year-over-year growth of approximately 1.3% on a constant currency basis. This was driven by higher pricing on certain core injection products, partially offset by lower year-over-year contract manufacturing revenue from the sale of certain non-diabetes products to BD, and unfavorable changes in volume mainly related to our syringe business where end-user demand in the U.S. market continues to decline. Excluding contract manufacturing revenue, our core injection business grew by 6.6% in the US. However, this was aided by the easy comparable I mentioned earlier associated with the timing of certain distributor orders which positively impacted our revenue in the third quarter of 2022. When normalizing for both the year-over-year contract manufacturing revenue headwinds, as well as the timing of certain distributor orders, our core product lines within the U.S. grew approximately 3.8%.

Turning to our performance outside of the U.S.

During Q4, International revenue totaled $130.1 million, which equated to year-over-year constant currency growth of approximately 3.0%. Growth internationally was primarily due to a favorable comparison in China, as last year the country was facing COVID restrictions, as well as year-over-year growth within Canada and Asia.

For the full year, embecta generated revenues of approximately one billion one hundred twenty-one million, which represented a decline of 0.8% on an as-reported basis, but an increase of 1.6% on a constant currency basis. When normalizing for the impact of year-over-year contract manufacturing headwinds, embecta's underlying core injection business grew approximately 1.8% on a constant currency basis.

From a regional perspective, U.S. revenues totaled $601.4 million, which grew by 0.2% on a constant currency basis, or 0.5% when normalizing for the impact of year-over-year changes of contract manufacturing. While International revenues totaled $519.4 million, which equated to year-over-year constant currency growth of approximately 3.2%, driven primarily by performance within emerging markets, as well as the benefit we saw from a competitor product supply shortage.

Lastly, before I turn the call over to Jake, I'd like to share our strategic priorities for fiscal year 2024.

In 2024, we will continue to be focused on the same three core strategic priorities that we had in 2023. These priorities have served as the foundation for our actions and decision-making, driving our company forward. They are:

1. Strengthen and Optimize the Core Base Business: In a rapidly evolving market landscape, we will continue to be diligent in supporting our customers and people with diabetes. While the operating environment and inflation remains unpredictable, we will maintain our focus on managing through any challenges that may arise. And as Jake will go through when he provides our fiscal 2024

guidance, you will see that it is consistent with the expectations we had laid out pre-spin in March of 2022.

2. Separate and Stand-Up as an Independent Company: We have been on a transformative journey to become an independent entity. This process involves complex projects like the implementation of an ERP system, setting up our own distribution network, and exiting many of our transition services agreements with BD.

As I mentioned earlier, we have implemented our ERP solution, and operationalized our distribution network and shared services infrastructure to support our business in US and Canada, and at two out of our three manufacturing plants.

We have learnt a great deal from these implementations and are now focused on accomplishing the same in the remaining markets and at our plant in Ireland.

We have previously commented that our Transition Service Agreements are generally set to expire on March 31, 2024. To allow for phasing of the remaining implementations of our ERP solution, distribution network and shared service capabilities, we requested for an extension of certain TSAs and related agreements from BD. BD recently agreed in principle to grant a limited extension, conditioned upon obtaining a supplemental Private Letter Ruling from the IRS, which would allow us to extend certain TSAs for a limited set of markets until early fiscal year 2025.

We have been expending, and will continue to expend, significant effort across the company to mitigate risk of potential disruption as we have to exit TSAs and replace them with our own systems and processes. While we have been generally successful so far, there could potentially be some temporary disruption of sales in certain countries as we work through obtaining all the appropriate product registrations and licenses, among other requirements.

3. Invest for Growth: Despite the competitive challenges in our industry, we remain committed to investing for growth. We understand that transitioning the company to growth over time via new product development, or inorganic business development initiatives, is an important goal for us, and we are keenly focused on sustainably improving the long-term constant currency revenue growth profile of embecta.

With that, let me turn it over to Jake to go through our financial highlights.

Jake…

Thank you, Dev, and good morning, everyone.

Before I discuss the financial results, I would like to remind the investment community that embecta was spun-off from BD on April 1st, 2022, and that the financial results during the pre-spin periods were based on carve-out accounting principles, and **do not reflect** what embecta's financial results would have been had embecta operated as a standalone public company. Therefore, the financial results for the twelve-month periods ending September 30, 2023, and September 30, 2022, are not meaningfully comparable.

Given the discussion that has already occurred regarding revenue, I will start my review of embecta's financial performance for the fourth quarter at the gross profit line.

GAAP gross profit and margin for the fourth quarter of fiscal 2023 totaled $181.8 million and 64.5%, respectively. This compared to $176.9 million and 64.4% in the prior year period.

The slight year-over-year increase in GAAP gross profit and margin was due to a combination of factors which essentially net each other out. These include tailwinds from product and geographic mix, favorable year-over-year pricing, and cost improvement programs; these items were offset by the impact of inflation on the costs of certain raw materials, direct labor, and overhead; incremental stand-up and separation costs; unfavorable manufacturing variances stemming from the temporary shutdown of our China domestic manufacturing at our facility in Suzhou; and F/X.

While on an adjusted basis, gross profit, and margin for the fourth quarter of 2023 was $182.6 million and 64.8%.

As compared to our prior outlook, our adjusted gross margin during the fourth quarter of 2023 was better than we previously expected, and this was due to higher than anticipated revenue; favorable geographic and product mix; pricing that exceeded our internal expectations; and our ability to manage the costs incurred to stand-up the organization.

Turning to GAAP operating income and margin, during the fourth quarter they were $25.8 million and 9.2%, respectively. This compared to a loss of ($3.0) million and (1.1%), respectively, in the prior year period.

The increase in year-over-year GAAP operating income and margin is primarily due to the GAAP gross profit changes I just discussed, as well as a decrease in year-over-year impairment expense. This was somewhat offset by an increase in costs incurred to stand-up the organization.

While on an adjusted basis, during the fourth quarter of 2023, operating income and margin totaled $65.2 million and 23.1%.

The adjusted operating income and margin performance during Q4 was in-line with our prior expectations, as the overachievement at the adjusted gross profit and margin line was offset by additional R&D spending behind our insulin patch pump program, as well as additional expenses incurred associated with employee benefits and stand-up activities.

Turning to the bottom line.

GAAP net income and earnings per diluted share was $6.0 million and $0.10 during the fourth quarter of fiscal 2023. This compared to a loss of ($17.2) million and ($0.30) in the prior year period.

The increase in year-over-year GAAP net income and diluted earnings per share is primarily due to the GAAP operating profit drivers I just discussed, somewhat offset by an increase in year-over-year interest expense associated with our variable interest rate debt.

While on an adjusted basis, net income and earnings per share were $34.1 million and $0.59 during the fourth quarter of fiscal 2023.

Lastly from a P&L perspective, for the fourth quarter of 2023 our adjusted EBITDA and margin totaled approximately $79.6 million and 28.2%.

Turning to our full year 2023 financial results.

This slide shows guidance progression as we moved throughout fiscal year 2023, ending with our actual fiscal year 2023 results.

As this slide depicts, we are pleased with our ability to raise our financial guidance following each quarter of the year, ultimately ending fiscal year 2023 with revenue of approximately one billion one hundred twenty-one million, which was up approximately 1.6% on a constant currency basis; with adjusted gross margin of 67%; adjusted operating margin of 29.6%; adjusted earnings per share of $2.99; and adjusted EBITDA margin of 33.8%.

The ability to generate these results was no small task, particularly given all the separation-oriented activities that we focused on during the year. This is a testament to the resiliency of our products, and our people, who put in a countless number of hours to make embecta successful.

Now let's take a closer look at our cash flow.

We began the year with a cash balance of approximately $331 million and generated approximately $68 million of cash flow from operations; while using approximately $27 million on capital expenditures; translating into free cash flow generation of approximately $41 million. Additionally, we used approximately $34 million of cash towards our dividend, ultimately ending the year with a cash balance of approximately $327 million, or roughly flat as compared to where we began the year.

However, what you do not readily see is that our ending cash balance was negatively impacted by over $140 million of one-time operating expenses and capital expenditures associated with stand-up and separation activities.

That completes my prepared remarks as it relates to embecta's financial results for the fourth quarter, and full year, of fiscal 2023.

Next, I would like to discuss embecta's preliminary 2024 financial guidance and certain underlying assumptions.

Before I go into all the details surrounding our fiscal year 2024 guidance, let me remind you that in March of 2022, in advance of the spin occurring, we laid out our expectations for our business through fiscal year 2024. Those expectations included that our revenue growth CAGR would remain flattish on a constant currency basis from fiscal year end 2022 through 2024, and that our adjusted EBITDA margin would be approximately 30%.

And despite needing to absorb a significant decrease in the amount of contract manufacturing revenue as compared to our initial expectations; an unprecedented inflationary environment; as well as significant F/X pressure as compared to our original expectations, our initial financial guidance ranges for fiscal year 2024 is aligned with our pre-spin projections.

Beginning with revenue.

On a constant currency basis, we currently anticipate that our revenues will be flat to down 2% as compared to 2023.

At the low-end of the guidance range, we are assuming about half of the decline will result from no additional contract manufacturing revenue in 2024 as compared to 2023. While the remaining 1% headwind at the low-end is associated with continued competitive shifts negatively impacting volume. Lastly at the low-end, we are assuming that pricing will be flattish as compared to the prior year.

While the high-end of our constant currency revenue range includes all the same factors impacting our low-end, except for a slightly smaller year-over-year headwind associated with contract manufacturing revenue, as well as the ability for us to modestly raise prices.

As such, the low-end of our constant currency revenue growth for our core business, excluding contract manufacturing revenue, is a range of between negative one and positive one percent.

Turning to our thoughts on F/X, our initial guidance calls for a foreign currency headwind of approximately 1% during 2024.

This assumption is based on foreign exchange rates that were in existence around the early-November timeframe, including a Euro to U.S. Dollar exchange rate of approximately 1.05.

On a combined basis, our as-reported revenue guidance calls for a decline of between 1% and 3%, resulting in an initial revenue guide of between $1 billion 85 million and $1 billion 105 million.

Turning to adjusted gross margin, we currently anticipate that our 2024 adjusted gross margin will be in the range of between 63% and 64%, with the largest anticipated year-over-year drivers being headwinds associated with foreign exchange; increased raw material and labor costs; and the impact of negative year-over-year manufacturing variances stemming from lower syringe production, as well as the temporary shutdown of our Suzhou, China facility as it relates to production for the domestic Chinese market.

Continuing down the P&L, we expect that our SG&A will increase during fiscal 2024, as we incur additional expenses associated with standing-up embecta, most notably associated with our IT systems and organization, as well as costs associated with shipping and supply chain as we move to our own distribution and transportation network. We expect this to be offset by lower year-over-year TSA expense, inclusive of costs associated with the potential and conditional extension of certain TSAs as described by Dev.

In addition, during fiscal year 2024, we will incur depreciation and amortization expense associated with the implementation of a portion of our ERP system and this will appear in the other operating expense line.

Turning to R&D, we anticipate continuing to invest behind our insulin patch pump program, and because of this, R&D as a percentage of revenue may exceed 7% during 2024.

All totaled, we anticipate that our adjusted operating margin during 2024 will be between the range of 23.75% and 24.75%.

Moving to earnings, during 2024 our initial guidance calls for an adjusted diluted earnings per share range of between $1.90 and $2.10.

This includes an assumption that our annual net interest expense will be approximately $116 million; that our annual adjusted tax rate will be approximately 22%; as well as an assumption that we will have approximately 58.1 million weighted average diluted shares outstanding.

Lastly, our initial guidance for fiscal year 2024 calls for an adjusted EBITDA margin of between 29.5% and 30.5%, which as I mentioned earlier, is consistent with our pre-spin expectations for fiscal year 2024.

And before I turn the call over to Dev for some final remarks, I'd like to highlight some considerations regarding the cadence of quarterly revenue expectations during 2024. Moving forward, we may not provide any further commentary concerning the quarterly cadence of revenue on an ongoing basis.

During fiscal year 2023, we generated approximately 49% of our as-reported revenue dollars during the first half of the year, including approximately 25% during the first quarter.

During 2024, we currently anticipate generating a slightly lower percentage of our annual revenue during both the first quarter and first half of 2024, as compared to the prior year periods, due in part to reduced contract manufacturing revenue as compared to the prior year periods.

That completes my prepared remarks, and at this time, I would like to turn the call back over to Dev for some thoughts on the GLP-1 landscape and market opportunity.

Dev…

Thanks Jake. If you haven't already seen it, we posted a separate presentation on our website this morning titled "Diabetes Considerations". Please refer to this deck as we have tried to lay out the current GLP-1 landscape and how it touches various aspects of our business. GLP-1s have been a significant point of interest for investors, and I would like to take this opportunity to make a few comments regarding our observations on the impact that GLP-1s have had on our business.

As we reflect over the past five years and focus on weekly GLP-1s, we observed significant growth in prescriptions, with an impressive CAGR of over 40%. In contrast, insulin prescriptions have remained relatively stable, experiencing a slight decline on a low single-digit CAGR basis.

Regarding the number of people switching from insulin to GLP-1 drugs, the data shows that is relatively low, at around 1%.

As you know, our business is highly geographically diversified, with almost 50% of our revenue being generated outside the US, where cost considerations usually limit the access of newer, high-priced therapies.

Turning our attention to our US business, we have seen continued stability over a period where weekly GLP-1s have grown at a CAGR of greater than 40%, and pump adoption for insulin delivery has steadily increased. While there may have been small decreases in volume, they have been offset by pricing dynamics, resulting in a generally flat revenue CAGR. This data supports our hypothesis that GLP-1s have delayed the onset of insulinization but not eliminated it.

Let's further focus on the differences between Type 1 and Type 2 diabetes. Type 1 results from an autoimmune response that leads to destruction of insulin producing beta cells in the pancreas. There has not been any data that we have seen demonstrating that GLP-1s have the ability to reverse this process and regenerate beta cells. GLP-1s appear to enhance the body's utilization of available insulin, potentially explaining the delay but not the elimination of insulin use.

Type 2 diabetes is heterogeneous, and at diagnosis, a significant portion of patients already have elevated A1C levels. When the criteria for the diagnosis of diabetes are met, it is the result of beta cells no longer being able to keep up with demand. In this case too, we have not seen data demonstrating GLP-1s ability to reverse this continued degradation of beta cell function.

Moreover, while GLP-1s have demonstrated efficacy in reducing the total daily insulin dose, it's uncertain to what extent this may translates to a reduced frequency of injections and injection devices, which are key metrics for our business.

Finally, we see an opportunity for embecta to participate in the secular growth of GLP-1s over the coming years. GLP-1 presentations include vials, pens, and auto-injectors.

This presents an opportunity for us since, with appropriate regulatory approvals in certain markets, insulin syringes can be used to deliver GLP-1 drugs presented in vials.

Pen needles that we manufacture and supply today are already compatible with the pens used to deliver GLP-1s. While some pharmaceutical companies might package their own pen needles, in other cases, we offer a valuable solution.

While when it comes to auto-injectors, it's worth noting that these devices involve injection-molded parts with needles, an area in which we have a well-established core competency. We produce approximately 8 billion units of high-quality injection-molded parts with needles annually. However, expanding into this market may require embecta to embark upon business development or partnerships. Entering this space organically would involve a longer timeframe, as it would necessitate engaging with pharmaceutical companies during the drug development process and progressing through it with them.

In summary, while we acknowledge the changing landscape brought about by GLP-1s, we see it as an opportunity to potentially expand our product offerings in line with evolving market demands.

This completes my prepared remarks, and with that, let me turn the call over to the operator for questions.