Please standby. Welcome, ladies and gentlemen, to the fiscal third quarter 2024 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 third quarter 2024 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 fiscal third quarter of 2024; as well as an overview of our strategic priorities;
- Jake will then provide a more in-depth review of our Q3 financial results, as well as our updated financial guidance for the year;
- We will then open the call for questions.

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

Dev….

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

Let's start with Slide 5 where you'll see the three strategic priorities that we have executed since our spin-off in April 2022.

First, we continue to strengthen our base business, while maintaining our global leadership position in the category of insulin injection devices.

Second, we have made significant progress in our separation and stand-up activities necessary to establish ourselves as an operationally independent company.

And finally, we continue to invest for growth, most notably around our insulin patch pump program that is being developed for the Type 2 market, as well as seeking M&A and additional partnership opportunities.

I am proud of the significant progress we have made within each of these goals.

Turning to some third quarter highlights.

During the third quarter, our team's disciplined execution led to financial results that were aligned with our prior expectations. We generated revenue of approximately $272.5 million, which represented a decrease of 4.8% on an as-reported basis and a decrease of 3.9% on a constant currency basis. When normalizing for the transient contract manufacturing revenue that we generate based on the sales of non-diabetes products to our former parent, our constant currency core injection business revenue declined by 4.1% as compared to the prior year period.

While our revenue during the third quarter was lower year-over-year on a constant currency basis, this was something that we had expected and highlighted on our second quarter earnings call, and, was primarily due to inventory rebalancing that occurred with some of our distributors following the ERP implementations that occurred during the first six months of our fiscal year. On a year-to-date basis, our core injection business has remained stable, growing 0.4% on a constant currency basis.

Over the past year, much news has come out regarding GLP-1s, and the impact that they might have on people with diabetes and insulin delivery. Based on what we have seen over the past several years, our view is that while GLP-1s may delay the onset of becoming insulin dependent, they do not eliminate the need for insulin. In fact, as the method of GLP-1 administration continues to evolve over the next several years from the use of an autoinjector, to that of a pen injector which requires a pen needle, we expect that we will stand to benefit.

To that end, we have identified an opportunity to introduce a new small-pack pen needle product that can be used for GLP-1 administration. We intend to first come to market with this product in Germany within the next several months, and eventually expand this product offering to other countries in the future. We believe this will help meet the needs of the growing number of people using pens, and therefore pen needles, for GLP-1 administration.

Turning to separation activities.

I am pleased to report that we made significant progress in the implementation of our own ERP system, operationalization of our distribution network and shared service capabilities. Now, our systems and capabilities are operational in regions which cover approximately 93% of our revenue base.

Looking ahead, with the exception of a few deferred closing jurisdictions, we remain on track to complete all ERP implementations, distribution network, and shared service separation activities by early fiscal year 2025.

Once these implementations are complete, the only remaining separation program will be brand transition, which entails changing the product packaging from BD’s brand to ours. We have been planning this transition since the spin-off, and we intend for the execution of this program to begin in phases during fiscal year 2025. Notably, we are not changing the product names, or color schemes, associated with our packaging. This is important, as people with diabetes will continue to experience the same look and feel on our boxes that they have been accustomed to for many years.

Regarding our insulin patch pump program, we continue to progress on the open-loop patch pump. As a reminder, we submitted a 510(k) application to the FDA in December of 2023, and earlier this year, we received questions from the FDA concerning that application. We have since responded with the necessary data and await feedback from the FDA.

We will continue to provide updates to the investment community on the progress regarding our insulin patch pump at the appropriate times.

Relating to our objective of entering the infusion pump market, we sponsored two abstracts at the American Diabetes Association's 84th Scientific Sessions that point to the potential for adults with type 2 diabetes to better manage insulin delivery through a patch pump with a larger, 300-unit insulin reservoir, which could provide longer wear times and fewer disposable patches over time. The data presented reaffirms what we have learned from speaking with people living with diabetes and their healthcare providers, and validates our thesis that there is a critical unmet need among the Type 2 Diabetes population for pumps with a larger insulin reservoir.

So, to summarize, we had another good quarter of results and based on the year-to-date performance, as well as our expectations for the remainder of the fiscal year, we are again raising and tightening our guidance range for key financial metrics, while reaffirming our revenue guidance range.

Now let's review our third quarter and year-to-date revenue performance in a bit more detail.

As I mentioned before, during Q3 we generated revenue of $272.5 million, which represented a decrease of 4.8% on an as-reported basis, and a decrease of 3.9% on a constant currency basis, or 4.1% when normalizing for the impact of year-over-year changes in the revenue of the non-diabetes products that we contract manufacture and sell to BD.

Within the U.S., during the quarter revenue totaled $143.6 million, which represented year-over-year decline of approximately 6.7% on a constant currency basis. When normalizing for year-over-year contract manufacturing revenue, our underlying Q3 constant currency revenue decline within the U.S. was approximately 7.3%. The lower revenue within the U.S. was expected and was primarily due to distributors normalizing their inventory levels after making advanced purchases ahead of our ERP implementation, as well as our annual price increase that went into effect on April 1st.

This volume decline was partially offset by favorable price and gross-to-net adjustments.

Turning to our International business, during Q3 revenue totaled $128.9 million, which equated to a year-over-year constant currency decline of 0.6%. Like the U.S., the decline in constant currency revenue within International this quarter was expected and was primarily due to the timing of advanced purchases that customers made in advance of our ERP implementation.

Importantly, through all separation activities that have occurred during fiscal year 2024, our core injection business remained stable, growing 0.4% year-to-date on a constant currency basis.

That completes my prepared remarks, and with that, let me turn the call over to Jake to take you through the third quarter financial results, as well as our updated full year financial guidance in more detail.

Jake…

Thank you, Dev, and good morning, everyone.

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

GAAP gross profit and margin for the third quarter of fiscal 2024 totaled $190.1 million and 69.8%, respectively. This compared to $189.5 million and 66.2% in the prior year period.

While on an adjusted basis, our Q3 2024 adjusted gross profit and margin totaled $190.3 million and 69.8%. This compared to $189.6 million and 66.3% in the prior year period.

The year-over-year increase in adjusted gross profit and margin was primarily driven by the impact of inventory revaluation adjustments, which positively impacted year - over-year results by approximately 550 bps, as well as the impact from favorable changes in price and rebates, that Dev referred to earlier. This was partially offset by lower product volumes, the impact of inflation on the costs of certain raw materials, direct labor, freight, and overhead, and the negative impact of foreign currency translation, primarily due to the weakening of the U.S. dollar.

Turning to GAAP operating income and margin, during the third quarter they were $55.9 million and 20.5%. This compared to a $51.3 million and 17.9% in the prior year period.

While on an adjusted basis, our Q3 2024 adjusted operating income and margin totaled $83.3 million and 30.6%. This compared to $79.8 million and 27.9% in the prior year period.

The year-over-year increase in adjusted operating income is primarily due to the adjusted gross profit changes I just discussed, as well as year-over-year decreases in both SG&A and R&D.

The year-over-year decline of approximately $2 million in SG&A was primarily due to cost optimization actions taken in the current period, as well as lower TSA costs. These reductions were somewhat offset by increased freight and warehousing costs.

While the year-over-year decline of approximately $2 million in R&D was primarily due to lower expenses associated with our insulin patch pump platform.

Turning to the bottom line.

GAAP net income and earnings per diluted share was $14.7 million and $0.25 during the third quarter of fiscal 2024, which compared to $15.2 million and $0.26 in the prior year period.

While on an adjusted basis, net income and earnings per share were $43.0 million and $0.74 during the third quarter of fiscal 2024. This compared to $39.8 million and $0.69 in the prior year period.

The increase in year-over-year adjusted net income and diluted earnings per share is primarily due to the adjusted operating profit drivers I just discussed, as well as a reduction in our adjusted tax rate from approximately 25% in Q3 of 2023 to approximately 22% in Q3 of 2024. This was somewhat offset by an increase in year-over-year interest expense associated with the rise in SOFR, and the impact that had on our variable interest rate debt.

Lastly from a P&L perspective, for the third quarter of 2024 our adjusted EBITDA and margin totaled approximately $99.2 million and 36.4%. This compared to $92.2 million and 32.2% in the prior year period.

Turning to the balance sheet and cash flow.

At the end of the third quarter, our cash balance totaled approximately $282 million, while our last twelve months net leverage as defined under our credit facility agreement stood at approximately 3.7x. As a reminder our net leverage covenant requires us to stay below 4.75x.

From a cash flow perspective, our cash balance as of June 30th is approximately $45 million lower than the balance that existed as of September 30th and this is largely attributed to cash that has been used related to separation related activities, which include: (i) product registration and labeling costs; (ii) warehousing and distribution set-up costs; (iii) legal costs associated with patents and trademark work; (iv) temporary headcount resources within accounting, tax, finance, human resources, regulatory and IT; and (v) one-time business integration and IT related costs primarily associated with our global ERP implementations. We estimate that during the first nine months of fiscal year 2024 we used approximately $130 million of cash towards these separation activities.

Additionally, we now show trade receivables globally on our balance sheet given our previously mentioned ERP implementations.

As such, embecta now collects receivables from customers directly, as compared to prior to the ERP implementations, whereby BD factored those receivables on our behalf.

I'm pleased to report that following the implementation of our ERP systems and shared services functionality within approximately 93% of our global revenue base, cash collections associated with those receivables have continued to trend in a positive direction.

Consistent with the comments I made on our second quarter earnings conference call, we continue to expect that we will end fiscal year 2024 with a cash balance of roughly $300 million, or comparable to the balance that existed at the end of the second quarter. This includes an expectation that for the full year, we will use approximately $180 million of cash towards separation activities. This compares to cash used for separation activities of approximately $145 million during fiscal year 2023.

Given that we expect to be largely complete with separation activities by the end of this fiscal year, we expect to see an improvement in our cash balances in fiscal year 2025 and beyond, which would allow us additional flexibility in terms of capital allocation, including more material debt repayment.

That completes my comments on our fiscal Q3 results.

Next, I will provide an update on our full year 2024 financial guidance.

Beginning with revenue.

Given our performance during the first nine months of the year, as well as our expectations for the fourth quarter, we are reaffirming our full year constant currency revenue range to be flat to down 0.5% as compared to 2023.

Likewise, we are reaffirming our previously provided guidance for F/X which called for foreign currency to be a headwind of about 0.4% versus the prior year.

These F/X assumptions are based on foreign exchange rates that were in existence in the late-July timeframe, including a Euro to U.S. Dollar exchange rate of approximately 1.08.

On a combined basis, our as-reported guidance range continues to call for revenue to be down between 0.4% and 0.9% as compared to 2023, resulting in a revenue guide of between $1 billion 111 million and $1 billion 116 million.

Turning to margins.

We are raising and narrowing our adjusted gross margin guidance from a range of between 64.50% and 65.00% to a new range of between 65.25% and 65.50%.

Similarly, from an adjusted operating margin perspective, we are raising and narrowing that guidance from a range of between 25.25% and 25.75% to a new range of between 25.75% and 26.00%.

While in terms of adjusted EBITDA margin, we are narrowing that guidance from a range of between 31.00% and 31.50% to a new range of between 31.25% and 31.50%.

Lastly, due to an improved margin outlook, we are increasing and narrowing our adjusted earnings per share guidance from a range of between $2.20 and $2.30, to a new range of between $2.30 and $2.35, or an increase at the mid-point of approximately $0.08.

This completes my prepared remarks, and at this time, I would like to turn the call over to the operator for questions.

As we wrap up the call, I want to extend my heartfelt appreciation to all my colleagues at embecta across the globe. Our global team has executed on complex, major separation related programs while never wavering from our mission of developing and providing solutions that make life better for people living with diabetes. Finally, we are looking forward to engaging with all of you at our analyst and investor day in mid-December.

Thank you all for attending the call and for your interest in our business.