Prepared Remarks

FISCAL 2021 Q3

Meridian Bioscience FY2021 Third Quarter Earnings Call

August 6, 2021

CHARLIE WOOD:

Thank you.

Good morning and welcome to Meridian's fiscal 2021 Third Quarter earnings call. With me are Jack Kenny, Chief Executive Officer, and Bryan Baldasare, Chief Financial Officer.

Please note that our SEC filings, earnings release and slides to accompany this call are available on our website at investor.meridianbioscience.com. We will post a copy of these prepared remarks after the call.

With regards to our calendar, Jack and Bryan will be participating virtually in the H. C. Wainwright 23rd Annual Global Investment Conference September 13th to 15th. Other events may be added as we approach the fall. Our last earnings call of fiscal 2021 is currently scheduled for Friday November 12th, 2021.

Before we begin today, let me remind you that the presentation and the Company's remarks include forward-looking statements. Forward-looking statements are subject to numerous risks and uncertainties, many of which are beyond the Company's control, including risks and uncertainties described from time to time in the Company's SEC filings. The Company's results and post-pandemic outlook may differ materially from those projected, and note in particular that these forward-looking statements may be affected by risks related to the COVID-19 pandemic including its "Delta variant". Meridian makes these statements as of today, August 6th, 2021, and undertakes no obligation to publicly update them. Additionally, throughout this presentation, we refer to non-GAAP financial measures, specifically operating expenses, operating income, operating margin, net earnings and net earnings per diluted share, each on

an adjusted basis. Reconciliations of these non-GAAP financial measures with the most directly comparable GAAP measures and other related discussion are included in our earnings release.

And now I would like to turn the call over to Jack.

JACK KENNY:

Thank you, Charlie.

As has been the case throughout this pandemic, predicting the volume of testing demand has been a challenge across our industry. The impact of COVID-19, particularly due to the Delta variant coupled with the global rollout of the vaccine, remains unpredictable and somewhat volatile. We have thus far been directionally correct with where we see things going and this quarter is another example of that. From the beginning of the fiscal year, and again in May, we forecasted slowing reagent demand related to the pandemic in the second half. This quarter's performance in Life Science was in-line with that forecast. However, what should not be overlooked is that fiscal year-to-date performance has been exceptional. In looking at this quarter alone, Life Science performed significantly better than a typical pre-pandemic quarter, further validating our message that we have a much stronger business coming out of the pandemic. The Diagnostics segment continues to face headwinds, but continued advancement of our strategy is positioning us well for future growth. Let me expand on some of the operational highlights of the quarter and then Bryan will cover the financial results in more detail.

Consistent with our messaging in May, we concluded the remaining studies for the Revogene® SARS-CoV-2 assay and re-submitted our EUA application to the FDA. Unfortunately, we cannot predict when the FDA will review the application, and we eagerly await their response. We finished the quarter with an install base of 343 Revogene® instruments. The story with new commercial activity remains the same, with customers continuing to wait for the approval of the COVID-19 assay. We expect the pace of installs to return to normal levels once the COVID-

19 assay receives EUA clearance. On the manufacturing front, the production expansion in Cincinnati and Quebec are progressing, with initial production on-track by the end of September.

As you know, when I joined Meridian almost four years ago, there were a number of FDA related issues with our LeadCare® manufacturing facility in Billerica, Massachusetts, including a FDA warning letter issued in October 2017. Our Regulatory and Quality teams have worked tirelessly on improving our quality system and procedures in Billerica in collaboration with the FDA. In June, the FDA conducted an inspection of our Billerica facility and earlier this week officially closed that warning letter.

Lead testing and demand for new LeadCare® II instruments continue to be a bright spot in the recovery from pre-pandemic lows. For the third quarter in a row, installs exceeded our expectations and our Q3 sales this year were on track to post the best quarter in the product's history. However, in May we initiated a recall of specific lots of our LeadCare® assays due to, based on our current assessment, apparent contamination with one of the components supplied by a third party. This recall serves as an example of our quality system at work, identifying an issue, investigating the root cause, and taking active steps to resolve the issue. Unfortunately, the recall and supply related issues resulted in a backlog situation, pushing some revenue out of the quarter. The recall is still in progress and continues to be a headwind.

In addition to LeadCare®, the *H. pylori* franchise, led by BreathID®, is seeing strong momentum. BreathID® had the best quarter in its history and the closing of BreathID® orders picked up significantly, as our commercial team was able to leverage our broad portfolio of *H. pylori* testing options. We have leading urea breath tests, stool antigen ELISA and rapid tests, and in partnership with DiaSorin, high throughput stool antigen immunoassays. Whatever testing modality the customer requires, we have a solution, and that is reflected in the continued strong commercial performance of this franchise.

In new product development, the team continues to advance the pipeline of products. Clinical trials continue to be a bottleneck for some of our products and during the quarter we redirected resources to the COVID-19 resubmission project. As a result, at this point it looks like completing clinical trials and preparing a 510(k) submission for *C. diff* on Curian® and the GI panel on Revogene® will be delayed until next fiscal year. There are many exciting products on the horizon for the Diagnostics segment that we look forward to commercializing.

In Life Science, the team had another strong quarter. We continued the expansion of the new Air-Dryable™ master mix portfolio, with mixes optimized for saliva and plant-based samples. The first mix has already been included in an EUA approved COVID-19 assay, with saliva as the specimen type, and the second is getting the attention of the AgBio industry because of the simplicity it enables. Inhibitor tolerant properties of our mixes enable lab technicians to bypass a number of typical preparation steps and simply add a plant sample. Additionally, we released both DNA and RNA based versions of our Lyo-Ready mix, optimized for LAMP technologies. The pandemic highlighted the benefit of quicker, point-of-care friendly molecular technologies, and our new mixes can accelerate product development time for our customers. The pipeline of additional master mixes to be launched in this quarter is robust and it will address critical clinical samples such as stool, urine and blood. Our Life Science business continues to launch solutions that accommodate a broad array of the most common patient sample types and test chemistries while ensuring the performance of the test. We believe this unique approach and pipeline of products provides us a strong competitive advantage in the market by accelerating development of molecular assays.

Lastly, as you know we recently closed the acquisition of the BreathTek® business from Otsuka. This is another great example of how we are putting our strong balance sheet to work to drive greater returns on the business. Meridian remains focused on offering best-in-class solutions for GI, respiratory and pediatric point-of-care. Consistent with that strategy, this acquisition is another example of our commitment to the GI diagnostics area. According to the CDC, approximately two-thirds of the world's population is infected with *H. pylori*. Meridian is a big

proponent of non-invasive testing for this highly under-diagnosed infection. If tested and treated, patients see great outcomes, and when not treated it is a leading cause of gastric cancer.

This is a customer centric acquisition. Otsuka's organization was moving in another direction strategically and as such, Otsuka was looking for the right partner to support the business and their customers. They could see our commitment to *H. pylori* testing and our reputation for strong customer focus. Otsuka's customers will continue to be able to utilize their BreathTek® solutions, but will now have the service and support of Meridian. We look forward to working with these customers in driving awareness and emphasizing the importance of non-invasive testing for this condition. We expect to take the opportunity to introduce Meridian's other *H. pylori* products including the option to upgrade to the BreathID® solution when the time is right for the customer.

Meridian acquired this business for approximately one times revenue, which is a good value for our shareholders. This business generates over $20 million a year in sales and as Bryan will discuss in more detail, we see this as being accretive immediately. We are able to absorb this product line with our current infrastructure and do not plan a material increase in headcount.

Now I will hand the call over to Bryan to talk about the financial results of the quarter.

BRYAN BALDASARE:

Thank you.

As we start to transition from COVID-19 being a pandemic to being endemic, meaningful comparisons to prior periods will be challenging. Despite being down from the pandemic highs, Q3 was a strong quarter for the company relative to pre-pandemic levels. We recorded **Consolidated Revenues** of $64 million. Remembering that Q3 fiscal 20 was the peak quarter of

that year, revenues are down 25% year-over-year. Looking back to Q3 fiscal 2019, a good example of pre-pandemic performance, we are up 31%.

Consolidated Gross Profit Margin was 58% in the quarter, down from 66% in the third quarter of the prior year and roughly flat to Q3 of fiscal 19. The year-over-year and subsequent quarter reduction in consolidated gross profit margin is primarily a result of a change in business segment mix. This quarter was nearly 50/50 between the Diagnostics and Life Science segments, vs 25/75 in favor of Life Science for Q3 2020.

On an adjusted, or Non-GAAP basis, third quarter **Operating Income** was $13 million, with a margin of 20%. **Adjusted Operating Expenses** were $24 million, down approximately $1 million year-over-year. Also, on an adjusted basis, **Net Earnings** were $10 million and **Diluted EPS** was $0.22. Again, while down year-over-year, this represents a greater than 37% increase over the $0.16 generated in Q3 of fiscal 19.

The year-over-year decrease in adjusted operating expenses was driven primarily by lower Diagnostics R&D spending and corporate-wide G&A expenses, partially offset by one additional month of expense from the Exalenz acquisition that closed last year on April 30th.

On a GAAP basis, **Operating Income** was $16 million with Operating Expenses of $21 million. In addition to the aforementioned operating expense drivers, GAAP operating expenses include a credit from an adjustment to lower the fair value of our contingent consideration obligation for the GenePOC transaction. **GAAP Net Earnings** were $12 million and **GAAP Diluted EPS** was $0.26.

Now let's look at the details of our two operating segments:

Diagnostics delivered…

- **Revenues** of $31 million, up from the pandemic low point by 44%. Unfortunately, this was down sequentially by approximately 2% due to the backorder situation that Jack mentioned in his opening remarks. We estimate the Q3 impact of the LeadCare® backorder to be $1.5 million and expect to be working through the backorder situation through the end of the calendar year. Respiratory as a category continues to lag the recovery, while both GI and Blood Chemistry continue to post strong gains. While we did have one extra month of BreathID® revenue in this quarter versus the prior year, both our *H. pylori* and foodborne product lines are performing very well, contributing significantly to the 86% year-over-year growth in the category.
- **Gross Profit Margin** for the segment was 51%, down approximately 150 basis points from Q2 and down approximately 140 basis points from the same quarter last year. The decline in margin from Q2 was driven by a lower level of royalty revenue in the current quarter. In addition, the year-over-year decrease was driven by pricing pressure in our *H.pylori* stool Ag products that we have mentioned in previous quarters.
- Diagnostics had an **Operating Loss** on an adjusted basis of less than $1 million. Similar to prior quarters, this is a result of our continued investment in new product development and commercial excellence programs despite the lower sales levels. Diagnostics adjusted operating expenses for the quarter were down $0.8 million year-over-year, driven by lower R&D spending and incentive comp.

Our **Life Science** segment recognized…

- **Revenues** of $32 million, a decrease of 49% year-over-year. This was more in-line with what we saw in Q4 of last year when we saw the first break in the pandemic demand. This level of sales is still dramatically above our pre-pandemic averages and we are seeing good growth in non-COVID product sales in addition to the continued contribution from COVID related sales. Also, of note, we had a backorder of approximately $1 million affecting our Life Science segment revenues at the end of the quarter related to core immunoassay blocking-reagent products. We estimate that revenue from COVID-19 products was approximately $14.5 million. This estimate

suggests our core revenue was up approximately 15% year-over-year and would have been even higher had it not been for the backorder.

- **Gross Profit Margin** was 66% in the quarter, down 500 basis points from Q3 of last year. Margins continue to be strong at this level of sales, despite the year-over-year impact of product mix changes.
- **Adjusted operating income** was $16 million, a margin of 50%, demonstrating that this business still produces strong margins even off the peak revenue levels realized during the pandemic.

Turning to the balance sheet… As of June 30, we had $70 million in **Cash** and a borrowing capacity of $110 million under our $160 million line of credit. As you know, subsequent to the end of the quarter, we closed the acquisition of the BreathTek® business, funding it with approximately $20 million of cash on hand.

Turning to Guidance…

As Jack said in his opening remarks, predicting the impact of the pandemic is very challenging. Going into the quarter, we knew that the second half of the year was going to see slower demand for products used in COVID-19 assays. While demand was lower than we would have liked, it was still consistent with our range of expectations. As such, we are holding the low end of our guidance and simply tightening the range and layering in the impact of the BreathTek® acquisition.

We now expect consolidated net revenues of between $308 and $314 million, which includes Diagnostics revenues of between $128 and $130 million and Life Science revenues of between $180 and $184 million. We anticipate adjusted operating margin to be between 30% and 31%, resulting in adjusted net earnings per share of between $1.61 and $1.67.

And now I will hand the call back over to Jack.

JACK KENNY:

Thanks Bryan.

Meridian has delivered a strong nine months and we are on pace to have another record year, eclipsing $300 million in revenue. We have made significant investments to reinvigorate our Diagnostics segment, and our Life Science segment has solidified its strong position with key diagnostics customers during the Covid 19 pandemic. Meridian emerges from this pandemic much stronger. In the last 18 months, Diagnostics has submitted new products to the FDA and has advanced a robust pipeline expected for submission in the coming months. Life Science has established new relationships with the largest IVD customers and grown relationships with existing partners, while pioneering new master mix technology with a focus on what Diagnostics customers need in this new environment. Exciting times in each of our business segments!

Before I finish up, I want to acknowledge and thank our team in Billerica and our regulatory and quality teams. They have worked very hard over the past four years to remediate our quality system. As you know, you are never done working on quality and we will continue to invest in the improvement of our quality system, but the closure of the warning letter is an important milestone for the team.

We remain committed to our strategy and laser focused on execution. We appreciate our shareholders continued support of VIVO as we transform our business. We are proud of the progress made, but confident our best days remain ahead of us.

And now Bryan and I are here for your questions.

JACK KENNY (POST Q&A):

Thank you for joining today. We look forward to speaking to you at one of the upcoming conferences and again in November after the conclusion of Fiscal 2021.