Prepared Remarks

FISCAL 2021 Q4

Meridian Bioscience FY2021 Fourth Quarter Earnings Call

November 12, 2021

CHARLIE WOOD:

Thank you.

Good morning and welcome to Meridian's fiscal 2021 Fourth 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 in the Piper Sandler 33rd Annual Healthcare Conference November 30th to December 2nd and the H. C. Wainwright Bioconnect Conference January 10th to 13th. The details of those events will be posted to our website as they are finalized. Finally, our Q1 fiscal 2022 earnings call is currently scheduled for Friday February 4th, 2022.

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 may differ materially from those projected. Meridian makes these statements as of today, November 12th, 2021, and undertakes no obligation to publicly update them. Additionally, the Company's remarks also include market data based on management's knowledge of the industry and good faith estimates of management. The market data referenced involves a number of assumptions and limitations, and you are cautioned not to give undue weight to

such estimates. While we believe the estimated market position, market opportunity and market size information is generally reliable, such information, which in part is derived from management's estimates and beliefs, is inherently uncertain and imprecise and has not been verified by any independent source. Lastly, 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. A reconciliation 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.

Fiscal 2021 was another wild year. We started the year at the beginning of another wave of coronavirus infections affecting the world, with hopes that vaccines would bring us relief from the pandemic. While the introduction of vaccines has brought some relief to the spread of the virus and allowed most individuals to return to a more "normal" life, many countries are still battling this disease and it is clear that COVID-19 will be present to varying degrees for years to come.

This time around, rather than being depressed due to government lockdowns, non-COVID testing demand was negatively impacted by healthcare systems that were stressed by surges in the virus. As compared to last year, testing volumes recovered throughout the year and for us, remain fairly close to pre-pandemic levels. This suggests that we are at the point where the pandemic headwinds are limited to locations where healthcare systems see a surge in hospitalizations, limiting available care for non-COVID patients. That said, it still remains to be seen if this upcoming respiratory season will see infections at pre-pandemic levels or if continued masking in schools and among certain populations result in limited spread of

seasonal infections. The consensus seems to be that this will be a stronger respiratory season relative to last year.

As a company, Meridian had a second consecutive record year, building off the record year of fiscal 2020. We exceeded the upper end of our original guidance both at the top line and the bottom line, delivering substantial growth over the prior year. That performance, however, was not without a mix of both achievements and setbacks along the way. Expected growth for the Diagnostics segment was slowed by the delay in the EUA authorization of our Revogene® SARS-CoV-2 assay and the LeadCare® recall. These were more than offset by the continued commercial success of our Life Science segment's reagents, both for COVID and non-COVID-19 applications. Fortunately, these setbacks are just that… setbacks. The team is executing through them and we look forward to seeing the benefits of the full strength of our product portfolio in the coming months.

With that, I would like to provide some further updates on a number of specific items beginning with our Diagnostics segment and then our Life Science segment.

As you know, we resubmitted our Revogene® SARS-CoV-2 EUA to the FDA at the end of June, and earlier this week, announced that the FDA has now approved the EUA. As with any new product launch, you can expect that it will take a few weeks for us to begin shipping product as we finalize labeling and begin working with customers to validate the new assay. This is an important milestone as it is the first RNA assay for the Revogene® platform. We look forward to delivering this to our customers again, later this quarter.

Development of both the respiratory panel and the gastrointestinal panel continue, and we anticipate those assays entering clinicals before the end of the fiscal year. Currently our plans are to submit the GI panel for 510(k) clearance first, followed by the respiratory panel. Both of these panels will incorporate our own Life Science segment's molecular reagents to improve both cost and performance.

On the production side, the buildouts of the new manufacturing lines have gone well. The second line in Quebec has completed its product performance qualification and, after some minor delays from equipment suppliers, the product performance qualification has begun on the first manufacturing line in Cincinnati. We expect to be producing salable product by the end of the month. The installation and validation of the second line in Cincinnati should begin towards the end of the quarter. As a reminder, these two new lines in Cincinnati, coupled with the two lines in Quebec, enable a maximum production capacity of 40,000 pies per day and offer significant opportunities to improve margins on the Revogene® products.

As of September 30, the Revogene install base was 359 instruments. Commercially, installs of new Revogene® instruments remained slow, as customers continued to wait for the authorization of the SARS-CoV-2 assay. We did see a pick-up in new orders in Q4, but still below our expectations and the peaks that we saw during the second half of calendar year 2020. The approval of the SARS-CoV-2 EUA, and the panels in development, will be important additions to the portfolio and drive increased demand for the Revogene® platform.

The Curian® platform made modest progress in growing its base. At the end of Q2, we submitted the Curian® Campy assay for FDA 510(k) clearance. Due to the pandemic and FDA resource constraints, timelines for approval of non-COVID-19 products have been delayed. While this assay is an important addition to add to the Curian® portfolio, further menu expansion is needed for the platform to really gain steam. On that front, the Shiga Toxin assay has begun clinical trials and we expect to submit for 510(k) clearance within the fiscal year. The Curian® *C. diff* assay has gone back into development to improve performance. With the addition of these three assays, we believe we will have a comprehensive, market leading gastrointestinal assay menu.

Our *H. pylori* breath testing business, led by BreathID®, had a tremendous year. Operations are now fully integrated and while the U.S. based team has been unable to visit the team in Israel,

members of the BreathID® team have joined leadership in the U.S. on numerous occasions. From an R&D perspective, the team is focused on enhancements to the product that will yield significant reductions in manufacturing costs, as well as feature enhancements that customers are asking for.

At the end of July, we added to the portfolio with the acquisition of BreathTek® from Otsuka. That acquisition added over $20 million of revenue annually to the *H. pylori* franchise for an acquisition cost of approximately $20 million. Integration of those operations is ongoing, the bulk of which is expected to be complete in the first half of fiscal 22. As a reminder, this was a product line carve out and we are integrating it without taking on any new employees from Otsuka, which provides for a significant operating margin contribution.

H. pylori testing remains Meridian's largest disease state with our strongest portfolio of products. Not only is there a growth opportunity from incremental testing volume for this under-tested-for disease, but there are opportunities to shift the industry in favorable ways. Serology testing is not clinically recommended, does not detect an active infection, has high false positive rates leading to inappropriate antibiotic treatment, and is often not reimbursed. We estimate that approximately 25% of the testing volumes in the U.S. are from serology testing and one of these growth areas is in shifting testing from serology to a Meridian testing solution. Both our stool antigen and urea breath tests confirm active infection, produce results with significantly higher sensitivity and specificity, and have solid reimbursement rates. Second, we estimate that approximately two-thirds of all *H. pylori* testing is performed in national reference labs. This compares to approximately 25% of typical diagnostic testing done at national reference labs providing an opportunity for us to decentralize this testing at our hospital or IDN customers, a win-win for both Meridian and the customer. As the only company with both stool antigen tests and urea breath tests for *H. pylori*, Meridian is well positioned to capitalize on these market dynamics.

Next, I would like to provide an update on the LeadCare® recall situation. As you know, in May we initiated a voluntary recall after identifying an issue with testing of the controls included in the test kits for all of our LeadCare® systems, including Plus and Ultra. This recall expanded to additional lots in June and again in August. As we announced in early September, we have stopped shipping LeadCare® test kits while the team identifies and implements changes that address the issue. As of today, we are still not manufacturing kits and anticipate that we will not be shipping product for three to five months. To be clear, this is a complex supply chain issue involving contamination in the plastic treatment reagent tubes that occurred at the supplier's manufacturing site. We are actively testing alternative tubes, both in plastic and glass forms, across multiple suppliers. In order to ensure that any replacement tubes are free from contamination, this process takes some time, and we are working in conjunction with the FDA to do this as quickly and safely as possible. LeadCare® II is the only CLIA waived lead test on the market in the U.S., so it is critical to get this back on the market as soon as possible, and we have all hands on deck to do so.

The Life Science segment had yet another blockbuster year, beating our expectations on all levels. First, the team continues to launch new, innovative products at an exceptional rate. In Q4, the team added an Air-Dryable™ mix for isothermal amplification and completed the portfolio of sample specific Air-Dryable™ master mixes with the introduction of products optimized for stool, blood and urine. This is a truly disruptive approach in the industry as evidenced by the number of companies starting to adjust their marketing to make similar claims. The difference with Meridian is that we have used our deep expertise to modify critical components in our mixes to address complex inhibitors present in a given sample type, resulting in increased assay sensitivity even with crude clinical specimens. The pandemic has created an environment where R&D teams are expected to develop high performance assays in shorter periods of time, and we are facilitating that by removing the need for our customers to optimize their own mix. They simply need to know the sample type and whether the target is RNA or DNA, and we have a fully optimized "off-the-shelf" mix for them to use. Currently, no

one else in the industry can match this. Looking ahead to fiscal 22, the team will expand this portfolio of sample specific mixes to our Lyo-Ready™ and isothermal amplification formats.

The team also launched a new thermostable reverse transcriptase enzyme. This allows us to enter the multi-hundred million dollar market for RTase. We are working to incorporate this enzyme into our new master mixes, further improving manufacturing cost, while at the same time improving performance and thermostability. We have also introduced two REACH compliant enzymes that are Triton-free and continue to look for other opportunities to make our products more environmentally friendly without sacrificing performance.

Commercially, fiscal 21 was another successful year. We continued to build upon the relationships forged during the early days of the pandemic and are collaborating with customers on new assays across multiple disease states. A common concern of investors is the sustainability of these customer relationships post-COVID. I would like to offer a few statistics to demystify this a little for you. In fiscal 19, before the pandemic, only seven of our IVD customers generated sales of greater than $1 million, accounting for approximately 30% of total Life Science revenue. In fiscal 21, we had 40 $1 million accounts which made up approximately 75% of total Life Science revenues. Each of those accounts are using our reagents in one or more regulated assays, which makes a recurring revenue stream probable given the cost and effort to change components of a regulated assay. While all but four of those IVD customers have our reagents in a COVID-19 assay, approximately 80% use our reagents in their respiratory panel and over 70% use our reagents in at least one non-COVID regulated assay. In total, approximately 95% of our top IVD accounts use our reagents in at least one non-COVID assay and over 50% use our reagents in their single-target COVID test, their respiratory panel and at least one other assay. If you look beyond these top customers to include IVD customers with greater than one-hundred thousand dollars in sales, approximately 90% use our reagents in at least one non-COVID regulated assay. As you can see, not only do we have a highly diversified customer base, but we are imbedded in them beyond just COVID.

Overall, a great year for Meridian. I will now turn the call over to Bryan to go into the financial results of the quarter and the year.

BRYAN BALDASARE:

Thank you Jack.

It is a pleasure to recap what was another record year in financial performance for the Company.

Starting with Q4…

- Meridian recorded **Consolidated Net Revenues** of $76 million, up 19% year-over-year. Life Science accounted for $42 million, up 22%, and Diagnostics accounted for $34 million, up 15%. In Diagnostics, we are seeing strong demand for our respiratory products with the exception of Flu. Demand began increasing much sooner than usual and it is unclear if this is an early sign of a solid respiratory season or simply a shift in timing. In Life Science, we estimate that products included in COVID assays accounted for $23 million, an increase of approximately 29% year-over-year, while other non-COVID related revenue was up approximately 11%.
- **Consolidated Gross Margin** was 59%, with a Life Science Gross Margin of 69% and a Diagnostics Gross Margin of 46%. Gross margin was and continues to be negatively impacted by the LeadCare® recall, with the overhead and manufacturing staff in Billerica recorded in cost of goods without offsetting revenue. Life Science continues to benefit from the increased scale, particularly from our molecular products.
- **Consolidated Operating Income**, on an adjusted basis, was $13 million, a margin of 17%. This is comprised of an Adjusted Operating Margin for Life Science of 55%, partially offset by an Adjusted Operating Loss of $7 million from Diagnostics. We recorded a charge of approximately $5.6 million in Diagnostics for costs associated with the LeadCare recall. We have decided to proactively credit our customers for the recalled kits, given the uncertainty around when replacement kits will be available. The

combination of these factors led to a greater loss than in recent quarters for the segment.

- **Adjusted Diluted EPS** was $0.23, up 21% compared to Q4 fiscal 20, while **GAAP diluted EPS** was $0.15, flat to Q4 fiscal 20.

We finished FY21 with…

- **Consolidated Net Revenues** of $318 million, up 25% year-over-year. Life Science drove that growth with a contribution of $190 million, 43% growth over fiscal year 20. COVID-19 related sales for the year were an estimated $112 million. Diagnostics segment revenue also posted growth of 5% to $128 million. The primary driver of the year-over-year revenue increase is Life Science COVID related demand, coupled with a full year of BreathID® and two months of BreathTek® revenues, partially offset by soft demand for the Diagnostics respiratory products and the LeadCare® recall.
- **Consolidated Gross Margin** was 63%, with a Life Science margin of 72% and a Diagnostics margin of 51%. Consolidated Gross Margin was favorably impacted by scale benefits in Life Science, but was partially offset by a drag from the LeadCare® recall, Revogene scrap rates and provision for short-dated products stemming from depressed sales levels during the pandemic.
- **Consolidated Operating Income**, on an adjusted basis, was $95M, a margin of 30%. This breaks down to an Adjusted Operating Margin of 61% for Life Science, partially offset by an Adjusted Operating Loss of $9 million for Diagnostics, including the cost associated with the LeadCare® recall.
- **Adjusted Diluted EPS** was $1.66, up 55% compared to fiscal 20, while **GAAP diluted EPS** was $1.62, up 51% over fiscal 20. All of these consolidated metrics we guided to exceeded our original guidance set in November of last year and were in-line with our revised guidance set in August.

If you want to dig deeper into the drivers for Q4 or the full year fiscal 2021, please refer to our press release and our 10K, which will be filed by November 25th.

Turning to the balance sheet… As of September 30, we had $50 million in **Cash.** In late October, we amended our line of credit, which among other favorable changes, increased the total capacity to $200 million, maturing in 2026. During the quarter, we paid approximately $20 million for the BreathTek® assets with cash-on-hand, and settled the remaining GenePOC acquisition earnout obligation for $20 million, with a combination of $10 million of cash-on-hand and a $10 million draw under our line of credit. We also repaid $5 million of contingent grant obligations due to the Israel Innovation Authority. With all that taken into account, we currently have borrowing capacity of $140 million.

Turning to Guidance…

In fiscal 2022, we expect revenue of between $285 and $300 million, which includes between $145 million and $150 million of revenue for our Diagnostics segment, and between $140 million and $150 million for our Life Science segment. We expect Diagnostics revenue in the second half to be moderately higher than the first half as LeadCare® production comes back online. For the purposes of guidance, we are assuming that we begin shipping LeadCare® kits in April. Life Science revenues assumes solid double-digit growth on the core, non-COVID related business, offset by lower demand for reagents used in COVID-19 testing. As we have mentioned in the past, because our molecular reagents are disease target agnostic, and the same products can be used in multiple tests, accurately reporting the split of COVID and non-COVID related revenue is becoming increasingly challenging. For that reason, we are no longer going to provide guidance on the amount of revenue generated from COVID testing and will not report a split in our quarterly commentary. Our view is that we have moved into a period where COVID is endemic and will just be a part of the regular testing landscape. To that end, our guidance contemplates higher revenue in the first half of the year aligning with the respiratory season. We are not forecasting this first half to second half decline to be as dramatic as last year and expect it to somewhat mirror the second half increase we are expecting in Diagnostics.

Adjusted operating margin is expected to be between 21% and 22%. This reflects slightly lower gross profit margin in Diagnostics due to the impacts of the LeadCare® recall and a lower Life Science gross profit margin due to a combination of lesser scale with our molecular products and an increased mix of our lower margin immuno products. On a blended basis, this implies a consolidated gross margin range of 58.5% to 59.5%, lower than fiscal 21 due to the aforementioned reasons coupled with revenue contribution mix changes between the segments. In operating expenses, we are increasing our investments in R&D and our commercial infrastructure which among other things includes an assumption that travel returns to pre-pandemic levels throughout the year. Combined with the gross profit margin impacts I mentioned, Life Science operating margin is expected to be greater than 50%, and Diagnostics is expected to be break-even to having an operating margin in the low single-digits.

Our expected tax rate of 23.5% reflects a greater percentage of revenues and taxable income coming from the United States. This ultimately leads to expected Adjusted EPS between $0.98 and $1.08 based on a fully diluted share count of 44.5 million shares.

Similar to last year, there are a number of unknowns that make setting guidance challenging, in particular timing of FDA approval for the Curian® Campy assay, the resolution of the LeadCare® recall situation, the anticipated demand for COVID-19 testing globally, and supply chain interruption considerations. The guidance presented today reflects our current visibility into these matters and overall market conditions.

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

JACK KENNY:

Thanks Bryan.

As you can see, we fully expect FY22 to be another strong year for Meridian. While we still have some operational challenges to overcome, the consolidated business is 50% larger than FY19, the last full pre-pandemic period. We believe this is the new base from which we will be able to grow consistently.

After a period of heavy investment through acquisitions, new product development spending and manufacturing expansions, Diagnostics will be focused on operational execution. Our key strategic focus areas will be advancing new product development including the submission of 3-4 new assays, the commercial launch of the Revogene® COVID-19 and Curian® Campy assays, completing the integration of BreathTek®, expanding Revogene® pie production capacity, and executing on a number of operating efficiency initiatives. These will position the Diagnostics segment for strong organic growth in fiscal 2023 and beyond.

Life Science will continue to focus on growing relationships with our largest customers and meeting their supply demands. As I mentioned earlier, we have a number of new master mixes in the pipeline that will continue to solidify Meridian as a leader of innovation. Additionally, the team will be hard at work supporting the dozens of customers testing and validating our products in new assays across a variety of disease states to fill the funnel for future growth beyond fiscal 2022.

Fiscal 21 was truly a transformative year for Meridian. All of our hard work over the previous two years prepared us to both weather the storm in Diagnostics and excel as a critical partner to the IVD industry battling a global pandemic in Life Science. We are excited about our opportunities that lie ahead. The best is yet to come.

Now Bryan and I are here for your questions.

JACK KENNY (POST Q&A):

As we close this call, I want to again thank our team for their hard work this year. They helped deliver another record year and have positioned us to establish the new post-pandemic base from which we expect continued growth. Thank you all for joining the call today and we look forward to speaking to you again next quarter.