Prepared Remarks

FISCAL 2022 Q2

Meridian Bioscience FY2022 Second Quarter Earnings Call

May 6, 2022

CHARLIE WOOD:

Thank you.

Good morning and welcome to Meridian's fiscal 2022 Second Quarter earnings call. With me are Jack Kenny, Chief Executive Officer, and Andy Kitzmiller, 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, Andy and I are participating in the H. C. Wainwright Global Investment Conference on May 24th. Any additional conferences will be announced via press release and posted to our website as they are finalized. Lastly, our Q3 fiscal 2022 earnings call is scheduled for Friday, August 5th, 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, May 6th, 2022, 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.

Q2 was a fantastic quarter for Meridian and another all-time record for revenue. What makes it even better is that both business units were firing on all cylinders, individually producing record quarterly revenue. Andy, who joined us in February, will go over the financial results in more detail later in the call.

Overall, we saw a quarter with strong demand for COVID-19 products from both Life Science and Diagnostics segments due to the Omicron variant. However, outside of sales of the COVID-19 antigen test, Diagnostics also saw growth in other respiratory products and our urea breath tests for *H. pylori*. As others have reported, we too saw demand for COVID-19 products subside in the last few weeks of the quarter, as one would expect, as Omicron cases have decreased around the world, consistent with the typical end of a respiratory season. In parallel, we are seeing laboratories and diagnostics companies increase focus on their core business of non-COVID testing, which bodes well for a new normal in the endemic stage for this virus.

In February, we completed the work necessary to bring LeadCare® II assay back to the market, six weeks ahead of schedule. The team is still working through a backlog of orders, but the

good news is that demand is high with customers, and they are excited to be able to use our point-of-care lead test for their patients again. In early March, we completed work on the Revogene® SARS-CoV-2 assay and submitted our analysis to the FDA. As part of the dialog with the FDA, they requested some additional data. We have provided some of the data and are in the process of conducting the additional studies necessary to complete their request. We expect to finish those studies in the next few weeks and are hopeful for an expedited review. Bringing this assay to market remains essential for the Revogene® instrument, as customers continue to wait for it to begin shipping before installing new instruments. The Revogene® install base as of the end of the quarter was 375 up from 370 at the end of Q1.

As I mentioned in our last earnings call, our new Revogene® manufacturing line in Cincinnati completed validation of the first line and began producing Group A Strep kits. We have already noticed a positive impact from the automated manufacturing in Cincinnati, as it requires fewer staff to produce the same number of kits per shift than at our Quebec facility. The upcoming second manufacturing line in Cincinnati will have even greater production efficiency and capacity, and is expected to be online later this year. Also in the quarter, the Cincinnati team began validation of the second Revogene® assay, *C. diff*. We expect to complete that validation and begin producing those kits in our new manufacturing facility by the end of the quarter.

With regards to new product development, you will notice in our slides some changes to the FDA submission expectations for this fiscal year. All the assays we planned to submit this year were expected late in the fiscal year. With recent delays in starting clinical trials for the Revogene® gastrointestinal panel and Curian® *C. diff*, it is clear we will not be able to submit those this fiscal year. Additionally, there was another limited flu season, which impacted the timing of the clinicals for the Revogene® respiratory panel and delayed it until the next respiratory season. That said, Curian® Shiga Toxin is currently in clinicals and is still on track for submission late in September.

New to the chart, in February we submitted a new claim to the FDA for our urea breath test on the BreathID® platform. The current package insert states that the test may not be performed if the patient has been taking proton pump inhibitors, or PPIs, within the last two weeks. The new requested labeling modification informs clinicians that they may act upon a positive test result in patients that were using PPIs within two weeks of the breath test. In the event of a negative test result, the test will need to be repeated after two weeks of discontinuing use of PPIs. We believe this new claim will improve marketability and patient usage of the product. The FDA has indicated it could take up to nine months to review our submission and we will provide more details after receiving feedback from the FDA. Congratulations to our team in Israel for getting that work completed.

Turning to Life Science, earlier this week, we announced the acquisition of EUPROTEIN, a company in New Jersey that specializes in the design and manufacture of recombinant proteins. They have quickly integrated into our R&D team, and will help us accelerate our pipeline of new immunoassay reagents. We are excited to welcome EUPROTEIN into the Meridian family and will share more about what they are working on in the coming quarters. Additionally, we expanded the sample-specific master mix portfolio with the launch of the Lyo-Ready Blood-specific Master Mix and launched a new detergent-free Toxo Antigen, ideal for large lab based immunoassay systems.

Continuing with the format I introduced last quarter, I would like to take a few minutes to dive deeper into our Life Science business in an effort to highlight the opportunity ahead of us.

As a reminder, when I joined Meridian, there were two business units that made up what is today known as our Life Science segment, and each was run separately with different strategies. The immuno business had decades of experience selling to the largest diagnostics companies in the world, whereas the molecular business was mainly focused on research and academia. We merged these two segments into one, and at the end of fiscal 2018 we decided to pivot the molecular business to focus on large diagnostics companies. That essentially

required an overhaul of the sales team, as well as the creation of an entirely new molecular product line designed for the needs of global diagnostics companies. Those strategic shifts were timed perfectly, and the Company was well positioned at the beginning of 2020, to meet the unprecedented testing demands of a global pandemic.

The pandemic accelerated the need to develop assays quickly, measured in weeks and not months. R&D scientists turned to our ready-made qPCR master mixes to accelerate their development timelines. Meridian's master mixes became extremely popular due to their performance and our ability to quickly supply the large quantities that were required. As the pandemic unfolded, there were shortages of RNA extraction kits necessary to process patient samples. In response, our team developed the first commercially available inhibitor tolerant mix that did not require RNA extraction. That means you can take the patient sample direct to the assay without further extraction steps.

It was this experience that has shaped our unique strategy to support the diagnostics industry. We view ourselves as a partner to R&D teams around the world, with the goal of supplying them with the best performing master mixes, optimized for their specific need, in order to accelerate the development of world class assays.

We became extremely focused on disrupting the way assays are developed and created a series of master mixes engineered to address inhibitors in the various types of patient samples. We developed ultra-sensitive master mixes that R&D departments do not need to optimize and come in formats for a variety of devices. Our R&D team focused on addressing the most clinically relevant patient sample types such as saliva/sputum, blood/serum/plasma, urine and stool. In addition, we also developed master mixes to target the AgBio and food market, where the sample is plant or food material.

Leveraging our proprietary buffer systems and expertise in using excipients to suppress inhibitors, we set out to create a series of master mixes optimized for each of these sample

types. We currently have the only portfolio of sample-specific master mixes on the market, and by the end of this fiscal year, we will have built-out the portfolio to include mixes for all key sample types across both qPCR and LAMP chemistries. We are disrupting molecular assay development by offering master mixes that do not require any optimization… all you have to do is add your primers and probes and you have a final assay, with direct from sample detection and the flexibility of a wet, lyophilized or air-dried format. This is disruptive in the sense that you can develop assays very quickly and save time on optimizing and troubleshooting, due to difficult sample types that can decrease sensitivity of the assay.

This is a unique approach in the industry and is resonating well with our customers. We have almost 200 customers using these novel mixes year-to-date, and what is really exciting is the diversity of what they are sampling. Our blood mixes have been the most popular, followed by saliva, stool, urine and plant. Not only does this bode well for our approach, but it is also a clear signal that the focus has shifted away from building COVID assays and back to all the other diseases that impact the global population year in and year out.

Lastly, I would like to touch on format types, as this is another area where we differentiate. Assays can be delivered in either a wet format or a dry format. The advantage of dried down assays is that they are stable at room temperature, removing the need for cold-chain shipping and storage. Not only does this lower the cost of shipping and storage for our customers and their customers, but it is also more environmentally friendly, reducing the use of electricity and Styrofoam.

We have developed versions of each of our mixes to work in either a wet or a dry format to meet the needs of our customers. Historically, the only way to dry an assay was through a process called lyophilization. Lyophilization requires capital investment in expensive equipment or multiple days to send the kits to a third party with the right capabilities. This can add upwards of $1 to $3 dollars to the production cost of a single test. In 2020, we introduced an air-dryable formulation that enables drying using inexpensive commercial ovens. We believe

Meridian is the only company in the world that has commercialized air-dryable master mixes for qPCR and LAMP.

As you can see, our Life Science team's approach is disrupting traditional approaches to assay development. Not only do these innovations benefit our customers financially, but they enable the development of the highest quality assays to improve patient care with the added benefit of reducing the environmental impact of diagnostic testing.

In addition to developing products that help our customers be more environmentally friendly, Meridian also is dedicated to two important goals: first, advancing diagnostics to enable better patient outcomes – in sum, helping people; and second, ensuring that our culture is inclusive, diverse and equitable. Those words carry great meaning at Meridian, and we've been intentional and thoughtful about listing them in that order, as we believe that you first have to be inclusive to attract and retain a diverse team.

We are in the early stages of our ESG journey, excited about the prospects, and look forward to sharing more with you as we achieve meaningful progress.

And now its my pleasure to introduce you to our new CFO, Andy, to provide more details on the financial results for the quarter.

ANDY KITZMILLER:

Hello everyone. It's great to be speaking with you today. I've had the chance to meet a few of you and I look forward to meeting more of you at conferences in the coming months.

As Jack mentioned, this was a great quarter, not only for Meridian in total, but also for each of the operating segments.

- **Consolidated Net Revenues** were $111 million, up 30% year-over-year and a new quarterly high for the Company. **Diagnostics segment net revenues** grew 29% to $41 million, also a record for the segment. Growth was driven by urea breath testing for *H. pylori* and the respiratory category. In particular, respiratory included a significant contribution from the GenBody COVID-19 antigen test. **Life Science** also had a record quarter, with **Net Revenues** of $70 million, up 32% year-over-year. This growth was driven primarily by sales of immunological reagents, particularly those related to COVID-19 testing. It is notable that molecular also saw growth year-over-year in the quarter, given that we know there has been a shift away from molecular testing for COVID-19 in favor of antigen testing. Non-COVID related immuno sales were roughly flat year-over-year, attributable to the timing of orders for some of our core native antigen products, limited demand in China due to the lockdowns and a one-off project in the second quarter of fiscal 21 that did not repeat in fiscal 22.
- **Consolidated Gross Margin** was 62%, with a Diagnostics margin of 50% and a Life Science margin of 68%. Diagnostics gross margin was down moderately year-over-year due to the drag of LeadCare® still being off the market for half of the quarter. Life Science gross margin was down due to product mix, as the higher concentration of immunological sales carries a lower margin than our molecular reagents.
- **Adjusted Operating Expenses** were $32 million, up $6 million year-over-year primarily due to increases in accruals for incentive compensation tied to financial performance in the current fiscal year. GAAP Operating Expenses were $32 million, up $9 million versus the prior year driven by incentive compensation related to the current year's outperformance, moderate increases in G&A, sales and marketing, partially offset by lower spend in R&D.
- **Consolidated Operating Income**, on an adjusted basis, was $37 million, a margin of 33%. This breaks down to an **Adjusted Operating Margin** of 58% for Life Science and 4% for Diagnostics. The higher operating profit for Diagnostics was primarily driven by the incremental revenue generated in the quarter and we expect Diagnostics to continue generating quarterly operating profit in the quarters ahead. The lower operating

margin for Life Science is primarily the flow-through impact of the lower gross margin due to product mix.

- **Adjusted Diluted EPS** was $0.66, compared to $0.56 in the second quarter of fiscal 2021, while **GAAP diluted EPS** was $0.65 in Q2 of 2022, compared to $0.60 in Q2 of 2021.

If you would like to dig deeper into the drivers for the second quarter of fiscal 2022, please refer to our press release and our 10Q, which was filed today.

Turning to the balance sheet… As of March 31st, we had $76 million in **Cash.** During the quarter we also repaid $25 million on our line of credit. This leaves us with a borrowing capacity of $175 million. Since joining Meridian, I have been impressed with the strength of our balance sheet. I have encouraged the team to continue to leverage that in order to fortify our inventory of raw materials to minimize or eliminate risks in the global supply chain, as they have successfully done throughout the pandemic. Additionally, I have been working with our operations and procurement teams to further de-risk potential supply chain issues through contractual guarantees on lead-times and reliability with our key suppliers, adding additional suppliers, and optimizing amounts and locations of inventories, among other things. Between the cash on hand and capacity in our line of credit, we have adequate resources to fund investments in opportunities that accelerate growth and provide good returns on capital for shareholders.

Turning to Guidance…

We are raising our consolidated net revenue expectations to between $330 and $345 million. This includes holding Diagnostics net revenue expectations between $145 and $150 million and raising Life Science net revenue expectations to between $185 and $195 million. We anticipate the adjusted operating margin to be between 22.5% and 23.5%, resulting in adjusted net earnings per share of between $1.30 and $1.40.

You will notice that while we have raised Life Science guidance, we are essentially holding our expectations for the back half of the year in-line with our previous guidance. As you have heard in other commentary regarding the pandemic, COVID-19 testing demand has slowed in parallel with infection rates as we exit the respiratory season. This is consistent with our expectations, which will result in a lower second half for our Life Science division, consistent with other more modest quarters we have seen following significant waves of the virus.

I will now turn the call back to Jack to offer some closing remarks…

JACK KENNY:

I want to add to Andy's comments regarding the guidance. As I have mentioned before, we see COVID-19 entering the endemic phase. We believe that COVID-19 testing will continue for years to come, but with higher levels of demand in our first and second quarters aligning with the typical respiratory season. While we cannot control the spread of the virus and the resulting demand for testing, remember that our reagents are in over 100 regulated assays and whenever there is demand for testing, we will benefit. This also does not include the dozens of respiratory panels we are in, which we believe will be an important revenue driver in future periods.

Looking ahead to next fiscal year, we continue to believe that COVID-19 has become endemic, and we will see increases in cases and testing aligned with the respiratory season annually. This would continue to follow the pattern we are expecting for this year, with higher Life Science revenue in the first two quarters of the fiscal year followed by lower revenues in the last two quarters. While we do not expect to repeat the record levels seen this year, the adoption of our master mixes for uses beyond COVID-19 testing, coupled with strong growth in our blocker products and other non-COVID immunoassay reagents, gives us confidence that we have an ongoing Life Science business with revenues believed to be approximately $150 million and generating operating margins of at least 50%. Diagnostics has shown signs of returning to

growth and profitability and with both businesses performing strongly again, we are bullish on Meridian's future in the post-COVID world.

Now Andy and I are here for your questions.

JACK KENNY (POST Q&A):

Thank you all for joining the call today and we look forward to speaking to you again next quarter and hopefully seeing some of you in person at an upcoming conference.