Prepared Remarks

FISCAL 2022 Q1

Meridian Bioscience FY2022 First Quarter Earnings Call

February 4, 2022

CHARLIE WOOD:

Thank you.

Good morning and welcome to Meridian's fiscal 2022 First Quarter earnings call. With me are Jack Kenny, Chief Executive Officer, and Julie Smith, Senior Vice President, Controller and Principal Accounting 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.

Jack and I expect to participate in at least one conference prior to the next earnings call, but do not have anything to announce at this time. Per usual, details of any events will be announced via press release and posted to our website as they are finalized. Finally, our Q2 fiscal 2022 earnings call is currently scheduled for Friday May 6th, 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, February 4th, 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.

While disappointed that we are fighting yet another wave of COVID-19 infections across the globe, I am pleased to be here recapping another fantastic quarter for Meridian, one of the best in the Company's history. What is really exciting about this quarter is that the strong result is due to both businesses performing ahead of our internal plan. This dynamic bodes well for the quarters to come.

Diagnostics was up 10% year-over-year, and the Omicron wave of this pandemic drove higher demand for our Life Science reagents relative to our fourth quarter of fiscal 2021. Julie will elaborate more, but it should be noted that the first quarter of fiscal 2021 was a record quarter for the Company, and while the metrics will show Life Science down year-over-year, this most recent quarter was one of the best on record, with sales in the first three months nearing levels it would have taken us nearly a full twelve months to achieve pre-pandemic.

Operationally, the company made tremendous progress in the quarter, perhaps outshining the strong financial results.

The Life Science innovation engine in London kept cranking, with the launch of the first sample-specific mixes in our Lyo-Ready™ format, which are designed for use in molecular assays that are lyophilized. These first products were our saliva mixes, and we will be launching more throughout the year.

Enhancements made in fiscal 2021 in our Life Science manufacturing still leave capacity for growth. The team has deftly managed the supply chain challenges plaguing other companies in the industry and we continue to have ample inventory of critical raw materials. As I have mentioned in the past, our ability to meet the demand of our customers, throughout surges in the pandemic, has won awards from our suppliers and helped us win business from the competition. We are being diligent in staying ahead of the situation to protect our reputation as one of the most reliable suppliers in the industry, in addition to being the leading innovator with our Air-Dryable™ format and sample specific mixes.

Also in the quarter, two Diagnostics assays received approval from the FDA, with Curian® Campy receiving 510(k) clearance and the Revogene® SARS-CoV-2 assay receiving emergency use authorization. The later is being updated in response to the Omicron variant and we are working closely with the FDA to get that shipping later this quarter. The LeadCare® team in Billerica has made substantial progress on resolving the issues with the third-party components behind the recall initiated last year. The team is in the process of validating the new packaging components and we remain highly confident that we will have this important product shipping again by the end of this quarter. Of course, exact timing is subject to review with the FDA.

The ramp-up of Revogene® manufacturing continues its pace. The new line in Quebec became operational in the quarter and the first line in Cincinnati just completed validation and recently began producing kits. As we announced earlier this week, the NIH continues to be a strong believer in the benefits of the Revogene® system, awarding us another $2.5 million to support the continued manufacturing scale up and the development of the respiratory panel.

Our *H. pylori* franchise is our most important contributor to the Diagnostics segment and the team keeps delivering results. Integration of both the BreathID® and BreathTek® acquisitions are now complete. This is a perfect example of the expertise we have built in M&A, seamlessly integrating two acquisitions, including a carve-out, in the midst of a pandemic where travel has been greatly limited.

This is a good segue into a new feature I would like to introduce in fiscal 2022. In an effort to provide a better appreciation for the opportunity that lies ahead at Meridian, I would like to take some time to provide further details on important areas of our business. A good place to start is with *H. pylori*, as that franchise is the largest disease state for our Diagnostics segment, accounting for approximately 45% of our Diagnostics revenue in Q1, and offering a tremendous growth opportunity.

As you know, Meridian was the pioneer in stool antigen testing, introducing the first assay of its kind in 1998. We had patents on that testing method, which expired in 2016 and 2017, that yielded extremely high margins. As new entrants emerged following expiration of the stool antigen *H. pylori* patents, we took steps to protect that business. First, we entered into multi-year agreements to annually step down pricing with our largest customers. Second, we entered into a strategic partnership with DiaSorin to accommodate higher volume customers by providing an *H. pylori* assay on the fully automated high-throughput Liaison platform. Adding this product to our portfolio allowed us to diversify our volume-based market segments and complement the other technologies in our *H. pylori* franchise. Both of these strategies have been successful in maintaining our leadership in testing volume, albeit at a lower average selling price.

In 2020 we added urea breath testing (also known as UBT for short) to our already strong *H. pylori* franchise with the acquisition of Exalenz Bioscience, the manufacturer of the BreathID® system. Last year, we acquired the BreathTek® product line from Otsuka, another urea breath

test for *H. pylori*. With these products, we are the only company selling FDA approved assays for both stool antigen and urea breath testing for *H. pylori*. This is an important advantage for our sales force in crafting solutions for our customers. Each test has advantages and challenges, and often clinicians are biased towards one solution over the other. While both testing methods have good sensitivity and specificity, UBT has superior performance relative to stool. UBT also uses a sample type that is easier to collect and process. The downside to UBT is that patients need to stop taking medications that are suppressing their symptoms for two weeks prior to the test.

There is one other minimally invasive approach to detecting *H. pylori,* serology. This was the first method developed for testing *H. pylori,* and has significant limitations. First, it is dramatically less sensitive than either UBT or stool antigen testing. Second, and most importantly, it does not confirm whether you have an active infection. This could lead to misdiagnosis and the overuse of antibiotics. Additionally, it cannot be used to confirm eradication after a patient completes a treatment plan which can lead to long-term consequences for the patient. Poor performance of serology testing has led to reduced or, in many cases, no reimbursement for this type of testing. Further, key medical organizations such as the American College of Gastroenterology and the American Gastroenterological Association have recommended against using serology tests. Despite that, there are still a number of doctors using these tests and we estimate that over 25% of *H. pylori* testing is done with serology.

Globally, *H. pylori* prevalence is very high, as well as in the U.S., where it is estimated that on average 25 to 30% of the population is infected, with greater than 50% infection rates in more ethnically diverse areas. With only an estimated 6 to 8 million tests performed per year, many people remain undiagnosed and untreated. This results in billions of dollars spent on over-the-counter and prescription medications that only address the symptoms and not the underlying infection. When left untreated, *H. pylori* can lead to peptic ulcers and in some cases gastric cancer, where *H. pylori* is the leading cause. So, there are very compelling reasons, both for

patient health and efficiency of healthcare spending, to increase testing. One of our strategies to increase testing is to provide education to both patients and physicians on the disease itself, the prevalence, and negative consequences of not properly diagnosing and treating *H. pylori*. Meridian offers health systems a solution with options for non-invasive, guideline recommended, active infection tests. Regardless of the choice in testing method (stool antigen or UBT), we encourage more testing to accurately diagnose patients and reduce cost related to misdiagnosis and treatments.

Lastly, we have noticed that H. pylori testing volume is weighted more towards the large reference labs than other products in our portfolio. On average, most products see 20% of the testing volume performed at the national reference labs. For *H. pylori*, the volume in roughly triple that. There is an opportunity to shift that testing closer to the patient, enabling a better patient experience and outcome. Additionally, it is possible to obtain a higher ASP that is a win/win for both Meridian and our IDN customers with the removal of one part of the value chain.

In summary, there are three vectors for growth in this disease state: (1) convert existing serology volume to one of our better performing alternatives, (2) grow the market through more testing, and (3) drive higher ASPs through decentralized testing. This makes *H. pylori* one of the Diagnostics segment's best growth opportunities.

Now I will hand the call over to Julie to provide some additional details on the financials for the quarter.

Julie Smith:

Hello everyone.

As Jack mentioned, this was a very strong quarter for Meridian that exceeded our expectations in both the Life Science and Diagnostics segments.

- **Consolidated Net Revenues** were $88 million, down 5% year-over-year, but second only to Q1 of 2021. **Diagnostics segment net revenues** grew 10% to $33 million. This growth was driven by strength in gastrointestinal and respiratory product revenues, partially offset by negligible LeadCare® revenues. In the gastrointestinal category, a significant driver of growth was the addition of BreathTek®, which we did not have in Q1 of fiscal 2021. In respiratory, the primary driver of growth was increased demand for our mycoplasma, Group A Strep and RSV products. Interestingly, flu demand, while up year-over-year is still very light. **Life Science** had a very strong quarter, with **Net Revenues of $55 million**. As we mentioned in last quarter's call, we are no longer reporting the portion of Life Science revenue driven by COVID-19. Many of our customers use our reagents in multiple tests; therefore, it has become too difficult to estimate the portion of molecular reagents that are used solely in the manufacture of COVID-only tests. That said, it is fairly obvious that the year-over-year decline in molecular is driven by decreased demand related to COVID-19 molecular testing. However, what isn't clear is that there is offsetting growth from respiratory panels and non-COVID assays which are manufactured using our molecular reagents. On the immuno side, demand for SARS-CoV-2 antibodies, which are used to make rapid antigen tests, were the biggest contributor to growth. However, non-COVID product revenues were also up more than 30% year-over-year. This was led by our blocker product line, which increased by almost $2 million or 113%.
- **Consolidated Gross Margin** was 56%, with a Diagnostics margin of 48% and a Life Science margin of 60%. While the Diagnostics margin is low by historical standards, it was modestly better than our expectations. The primary driver of these lower margins is LeadCare® being off the market, which is a drag of approximately 400 basis points. Life Science gross margin was down, both year-over-year and sequentially from Q4, due to variation in the mix of revenue between immuno and molecular products. As we have said in the past, due to the nature of the molecular reagent manufacturing

process, which benefits more from scale than the immuno reagents, our molecular products have dramatically higher gross margins than the immuno products.

- **Adjusted Operating Expenses** were $29 million, up $4 million year-over-year due to increases in consolidated G&A costs, R&D spending in Diagnostics, and sales and marketing expense across both business segments. GAAP Operating Expenses were also $29 million, up $2 million versus prior year driven by the aforementioned items, and partially offset by a decrease in legal expenses and contingent consideration expense.
- **Consolidated Operating Income**, on an adjusted basis, was $21 million, a margin of 23%. This breaks down to an **Adjusted Operating Margin** of 48% for Life Science, partially offset by an Adjusted Operating Loss of $2 million for Diagnostics. Overall, the biggest driver of operating margin is the lower gross margin for both segments.
- **Adjusted Diluted EPS** was $0.35, compared to $0.65 in the first quarter of fiscal 21, while **GAAP diluted EPS** was also $0.35 in Q1 of 2022, compared to $0.61 in Q1 of 2021.

If you want to dig deeper into the drivers for the first quarter of fiscal 2022, please refer to our press release and our 10Q, which will be filed today.

Turning to the balance sheet… As of December 31, we had $73 million in **Cash.** During the quarter we also repaid $10 million on our line of credit, putting us in a net cash position. This leaves us with a borrowing capacity of $150 million. As we mentioned on the last earnings call, in October we revised the terms of our existing credit facility to increase the capacity to $200 million, extend the maturity date to 2026, and incorporate other favorable changes in the covenants.

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

Jack Kenny:

Thanks Julie.

As you can see, fiscal 2022 is off to great start and we have even more optimism than we did at the outset. As such, we are raising our guidance. We now expect consolidated net revenues of between $315 and $330 million, which includes between $145 and $150 million of revenue for our Diagnostics segment, and between $170 and $180 million for our Life Science segment. You will notice that the Diagnostics revenue guide remains unchanged. Our current view is that the modest outperformance in the first quarter, coupled with the increased demand we are seeing for our partner SARS-CoV-2 rapid antigen test, will offset any lost revenue from the delay in shipping the Revogene® SARS-CoV-2 assay. We still expect Diagnostics revenue in the second half to be moderately higher than the first half, as LeadCare® production comes back online and we have contribution from the Revogene® SARS-CoV-2 assay. The increase in Life Science revenues reflects the level of demand we are seeing for our reagents, driven primarily by the Omicron wave. As such, you should allocate this increase more to the second quarter than the later quarters.

Adjusted operating margin is expected to be between 21% and 23%. This reflects inflationary pressures on wages and other operating costs, 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.

This all equates to an Adjusted EPS range between $1.10 and $1.30 based on a fully diluted share count of 44.5 million shares.

It is really great being able to present a quarter with both business segments performing above expectations and, yet again, being on a trajectory to exceed the guidance set at the beginning of the fiscal year. The rest of Q2 still requires some strong execution from our Diagnostics R&D, regulatory and operations teams, as well as both commercial teams, but the progress to date is promising and I remain highly optimistic that Q2 will be another quarter with great accomplishments for both segments.

I wanted to close with some brief comments on the governance changes we announced coming out of the annual shareholder meeting last week. After 21 years, our Chairman, Dave Phillips retired from the Board. His contribution in the Board room over that time was tremendous and we will miss his presence. Fortunately, we have developed a strong bench on our Board and did not need to look externally for Dave's successor. We are excited to have John McIlwraith assume the role, and with the depth of talent of the rest of the Board and my management team, we have the leadership to continue this tremendous run we have experienced in the last 24 months.

Now Julie 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.