Prepared Remarks

FISCAL 2020 Q2

Meridian Bioscience FY2020 Second Quarter Earnings Call

May 8, 2020

CHARLIE WOOD:

Thank you.

Good morning and welcome to Meridian's fiscal 2020 Second Quarter earnings call. With me are Jack Kenny, Chief Executive Officer and Bryan Baldasare, Chief Financial Officer.

Please note that our SEC filings, our earnings press 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 a virtual fireside chat as part of the William Blair Annual Growth Stock Conference on Tuesday June 9th, 2020. Details of that event will be posted to our website as they are finalized. We are working on a schedule of other events that will provide opportunities to virtually connect with investors. Finally, our Q3 fiscal 2020 earnings call is currently scheduled for Friday August 7th, 2020.

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. And note in particular that these forward-looking statements may be affected by risks related to the COVID-19 pandemic. Meridian makes these statements as of today, May 8th, 2020, 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 earnings

per 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 press release.

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

JACK KENNY:

Thank you, Charlie.

The last four months have been a tremendous challenge for us as an industry, a company and for me personally. The dynamics of this pandemic have been changing weekly, and at times daily. I am extremely proud of how our Meridian team came together and executed under such uncertainty and demonstrated the strength of the company we are transforming.

First and foremost, our focus was the health and well-being of our employees. All aspects of our business mobilized to support the broader team, from IT, who enabled over 40% of our workforce to seamlessly begin working remotely in a matter of days, to Facilities, who enhanced cleaning procedures and adjusted the office environment to minimize potential exposure to coronavirus and maximize our ability to socially distance in the workplace. As a leadership team, we evaluated Meridian's business continuity plans across our global footprint and made enhancements responsive to the unique situation of this pandemic. We are fortunate that, to date, we have no known cases of COVID-19 among our employees, and our global team continues to meet the needs of our customers.

We are re-building the Company for long-term sustained growth, and as such, our response to this situation was carefully crafted to both keep us on track and efficiently maximize our contribution to the global response. As demonstrated in prior outbreaks, like Zika virus in 2015, our Life Science division is built for rapid response. Back in January we were one of the first companies supporting COVID-19 test development. The team quickly ramped up production of

our molecular reagents optimized for RNA virus detection, and got them in the hands of diagnostic companies in China to develop tests for the growing outbreak. As the virus began to spread around the world, the team accelerated worldwide test development by launching a program to provide samples of our superior reagents at zero cost to diagnostic companies developing new COVID-19 tests. The largest IVD manufacturers want to work with us because of our high performance and quality reputation, and our reagents are now being used in over 35 COVID-19 assays developed by companies in China, Australia, Europe, and the United States. The demand has been extraordinary, and the team should be commended for their continued effort to keep pace with this contagion.

In parallel, the Life Science research and development team began work on the products that would be needed in the subsequent phases of this battle. Last week, we launched a new master mix, designed to bypass the need for a RNA extraction step, which not only saves time and cost, but also eliminates the dependence on the extraction kits that have been in short supply. And recently, we launched a series of recombinant viral antigens necessary for the manufacture of COVID-19 antibody assays. Demand for these products has been high, and we will play a major supporting role in the development and manufacture of millions of serology tests being run around the globe.

On the Diagnostics side, our response was much more tactical to ensure limited disruption to our strategic imperatives. To get test kits to our customers in the shortest time possible, we focused on identifying a U.S. manufactured serology assay with performance that met our standards. After a great deal of diligence, we partnered with Syntron Bioreseach to distribute their QuikPac II™ Coronavirus test. Designed and manufactured in San Diego, this test detects IgG and IgM antibodies to COVID-19 in human serum, plasma or whole blood. Initial customer demand has been positive, and we expect to begin shipments later this month.

In molecular, the Revogene® is an ideal platform for infectious disease testing with its small footprint, simple operation, and ability to deliver results on eight samples simultaneously in

about 70 minutes. The team in Quebec has revised the design of the Revogene® respiratory panel to include a target for COVID-19 in addition to Flu and other respiratory viral targets. We plan to seek EUA status from the FDA for the COVID-19 target later in fiscal year 2020 in time for the next respiratory season, and will follow up with a 510K submission for the Flu A/B, RSV and COVID-19 targets in time for the 2021/2022 respiratory season.

Of course, not everything has been about the coronavirus.

Our Diagnostics research and development team has built key technology centers in Quebec for molecular diagnostics, Cincinnati for lateral flow-based immunoassays, and Billerica for electrochemical sensor-based blood chemistry. These locations are working on a robust pipeline that positions us well for long-term sustainable growth. In March, the first of these products, the Curian® analyzer and HpSA® assay, received FDA clearance. This is a tremendous milestone in the transformation of Meridian as it is the first internally developed product released in several years. Consistent with the innovations of the Revogene® platform, the Curian® platform couples simple sample preparation and workflow with an intuitive user interface and improved performance.

Early in the quarter we were also busy evaluating the acquisition of Exalenz Bioscience and later preparing for its integration. As previously announced, we closed the transaction last Thursday. We could not be more excited to have Exalenz join the Meridian family.

As a reminder, our vision for Diagnostics is centered on gastrointestinal disease and pediatric point-of-care testing, bridged by testing for respiratory illnesses. This acquisition supports continued strength and focus on GI.

There are four approaches to *H. pylori* testing: stool antigen, urea breath, serology and invasive endoscopy procedures. Meridian is the leader in U.S. stool antigen testing and Exalenz has an innovative urea breath test platform called BreathID®. Serology testing can have a lower

sensitivity, as compared to other tests, and may not identify an active infection. In the face of accumulating evidence on this topic, reimbursement for serology tests has declined and in some cases is non-existent. The test has also started to lose favor with clinicians. Not only will we be able to leverage Meridian's U.S. sales force to grow share of the urea breath testing market, but we will also be able to accelerate the shift away from serology as the only U.S. company offering both non-invasive approaches to active infection diagnosis.

We look forward to incorporating the BreathID® analyzer and assay into our portfolio and building off the momentum that the Exalenz team has created.

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

BRYAN BALDASARE:

Thank-you Jack.

As we reported earlier today, Meridian had an excellent second quarter with **Consolidated Revenues** of $57.3 million up 14% from $50.2 million in the second quarter of fiscal 2019. Excluding the impact of foreign currency exchange rate changes, revenues were up 15%. This was record revenue for a fiscal second quarter, driven by Life Science, also with record quarterly revenue.

Gross Profit Margin topped 60% in the quarter, up from 58% in the second quarter of last year. This is the blend of a dramatic increase in Life Science gross margin and an expected reduction in Diagnostics, which I will discuss further in the segment review.

On an adjusted, or Non-GAAP basis, second quarter **Operating Income** was $12.1 million with a margin of approximately 21%. **Adjusted Operating Expenses** were $22.4 million up $4.3 million year-over-year. Also, on an adjusted basis, **Non-GAAP Net Earnings** were $10.0 million and **Non-GAAP Diluted EPS** was $0.23.

The year-over-year increase in operating expenses includes approximately $2.0 million in cash incentive comp, reflecting better performance relative to plan at this stage of the year versus the prior year. Additionally, we spent an incremental $1.6 million in R&D, primarily on new product development and clinical trials, and recognized an increase of approximately $900 thousand in purchase accounting amortization from the acquisition of GenePOC in the third quarter of Fiscal 2019. Despite the year-over-year increase in spending, our operating expenses were still lower than our expectations, driven primarily by the deceleration in spending on clinical trials and product development resulting from the COVID-19 pandemic, as well as delays in filling open positions.

On a GAAP basis, **Operating Income** was $11.8 million with Operating Expenses of $22.7 million. In addition to the aforementioned operating expense drivers, GAAP operating expenses were impacted by a year-over-year reduction in the contingent consideration obligation for the acquisition of GenePOC partially offset by an increase in acquisition related expenses. **GAAP Net Earnings** were $9.4 million and **GAAP Diluted EPS** was $0.22.

Now I'd like to drill into the specifics of our two operating segments:

In **Diagnostics**…

- **Revenues** were $34.9 million, up about 4%, and for the first time in five quarters we saw year-over-year growth. On a constant currency basis, revenues were up about 5%. This growth was driven by the outperformance of our respiratory products, partially offset by declines in gastrointestinal. Towards the end of the quarter, we benefited from increased demand for our respiratory tests as people testing negative for COVID-19 sought further diagnosis for their symptoms. At the same time, we started to see reduced demand for non-urgent testing. Of note, was the continued stabilization of our molecular business, posting modest growth for the quarter.

- **Gross Profit Margin** for the segment was approximately 57%, down from the same quarter last year, but in line with our expectations. The year-over-year decrease was primarily driven by product mix and continued pricing pressure on our higher margin *H. pylori* products.
- Diagnostics **Operating Income** on an adjusted basis was $3.3 million with a margin of approximately 10%. The decreased margin year-over-year is consistent with our plan for the segment, but exceeded our expectations due to lower than expected spending in clinical trials and product development as well as delays in hiring. Progress on clinical trials and related product development stalled as much of the U.S. ceased operations for non-essential businesses. We also have a few vacancies across the functions of the organization that have been slower to fill.

Our **Life Science** segment delivered…

- **Revenues** of $22.4 million, up about 33% year-over-year, or 34% on a constant currency basis, delivering the highest quarterly revenue in the history of the segment. This outperformance was driven by sales of our molecular reagents, primarily as a result of the COVID-19 pandemic. We estimate that increased revenue from the pandemic was approximately $5.6 million. Outside of COVID-19, the business generally performed as planned. Ordering patterns for non-COVID related products with our top IVD manufacturing customers returned to normal for the quarter; however, it is not clear if they will make up all of the shortfall from Q1 during the remainder of the year.
- In addition to outperformance on revenue, **Gross Profit Margin** saw a dramatic improvement, up over 1,200 basis points to 65%. In order to meet the expected demand, batch sizes were increased, which does not require a linear increase in cost of goods.
- **Adjusted operating income** more than doubled in the quarter to $10.9 million, a margin of 49%, as a result of the unprecedented revenue and strong gross margin.

One of our strengths continues to be the balance sheet. During the quarter, we increased the capacity on our line of credit to $160 million in conjunction with the announcement of our acquisition of Exalenz Bioscience. As of March 31, we had $49.6 million in **Cash** and borrowing capacity of approximately $111 million under the line of credit. Subsequent to the end of the quarter, we drew an additional $50 million to fund the acquisition and as of the end of April have borrowing capacity of approximately $61 million.

Turning to Guidance: Our performance fiscal year-to-date was well above our expectations. We are slightly ahead of last year's first half revenue and already delivered **Adjusted Diluted EPS** at the upper end of our guidance range for the full year. Despite the turmoil from the COVID-19 pandemic and related uncertainty, we expect this strong performance to continue with our Life Science business more than compensating for the temporary reduction in demand for non-urgent care tests in our Diagnostics business. Based on this dynamic, we are raising our guidance for the year.

We now expect **Consolidated Net Revenue** for fiscal 2020 to be between $230 and $236 million. The global COVID-19 pandemic has led to unprecedented demand for our molecular Life Science products and we are seeing significant demand for the related immunoassay product lines that were recently launched. Our guidance assumes COVID-19 related sales of $43 to $47 million in the second half, with sales peaking in our third quarter and beginning to taper in our fourth quarter. This results in a revenue range for Life Science of $110 to $114 million for the full fiscal year. At the same time, in the last few weeks of March and throughout April, we saw increasing headwinds on our non-respiratory diagnostics business. As a result of this trend, we now expect revenue for the Diagnostics business to be between $120 and $122 million for the full year. This assumes a 40% reduction in volumes for our third quarter with a recovery to a 25% reduction in volumes for our fourth quarter. This softness in demand is partially offset by modest contributions from the Exalenz acquisition and sales of the COVID-19 serology test that Jack mentioned earlier.

The uncertainty of the impact on revenue mix between products and segments complicates a forecast of **Gross Profit Margin**, but you should expect to see the same dynamics of the second quarter with higher margins for Life Science offset by lower margins for Diagnostics. We expect **Adjusted Operating Margin** of between 18% and 19% and **Adjusted Diluted EPS** of $0.70 to $0.75. This includes lower spending on clinical trials and product development while shelter-in-place orders still remain, offset by the incremental operating expenses from the acquisition of Exalenz and increased cash incentive comp expense from the outperformance relative to our plan.

This guidance reflects our current visibility into market conditions for our products and our current assumptions about the extent and duration of the impacts from this pandemic. We expect that our visibility will improve throughout the quarter as local governments around the world begin to relax shelter-in-place orders and healthcare systems return to normal operations with respect to diagnostic testing for infectious diseases and blood chemistry. We will keep you updated as the situation evolves.

And now I will hand the call back over to Jack to offer some final thoughts.

JACK KENNY:

Thanks Bryan.

We are certainly in strange times and while there is global uncertainty, we think that the value of what we are building at Meridian is becoming more clear. We continue along our journey to execute our strategies towards sustainable revenue and earnings growth, while also investing in our businesses where needed.

The Curian® analyzer is the first of many new, internally developed products we plan to bring to market in the coming years. Combine its new HpSA® assay with the addition of the Exalenz team and BreathID® platform, and we are solidifying our leadership in *H. pylori* testing and

advancing our goal of being the health system's trusted partner in gastrointestinal disease testing.

The Revogene® platform has led the stabilization of our molecular business and repositions us for growth with cutting-edge molecular technology that delivers simple sample prep, high throughput and multiplexing capabilities.

Our LeadCare business returned to growth in the first half of 2020. With our investment in the next generation, we will continue to expand in pediatric point-of-care.

We were one of the first to respond on COVID-19. Yet again, Meridian Life Science has demonstrated its ability to rapidly respond to global health crises with critical materials in volumes that meet the demand. The dynamics of this pandemic have highlighted the quality of our reagents and antigens, and opened the door to future partnerships with diagnostic companies around the globe.

We continue to stay focused on the strategy we laid out 18 months ago, while at the same time contributing to the fight against this global pandemic with the most effective assets of Meridian. I am very proud of the dedication of the One Meridian team in this challenging time and am energized about our future.

Now Bryan and I are here for your questions.