Prepared Remarks

FISCAL 2020 Q4

Meridian Bioscience FY2020 Fourth Quarter Earnings Call

November 13, 2020

CHARLIE WOOD:

Thank you.

Good morning and welcome to Meridian's fiscal 2020 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 Canaccord Genuity MedTech and Diagnostics Forum next Thursday, the Piper Sandler 32nd Annual Healthcare Conference in early December, and the Singular Research Virtual Conference in mid-December. The details of those events will be posted to our website as they are finalized. Finally, our Q1 fiscal 2021 earnings call is currently scheduled for Friday February 5th, 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 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, November 13th, 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 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.

Without any doubt, fiscal 2020 has been quite a wild ride. We began the year with expectations of accelerating investment in our new product development pipeline, with our sights set on the diagnostics segment finally turning the corner, and expecting modest growth in the Life Science segment. Through March, that plan for Diagnostics was playing out better than expected with the segment delivering a positive growth quarter for the first time in five quarters and ahead of schedule. As we all know, March saw the shift from COVID-19 being an epidemic to a pandemic, greatly altering all our lives for the foreseeable future, and turning every company's plans on its head.

While we do not want to lose sight of the damage this pandemic has done across the globe, both to individuals and businesses, I do want to celebrate the heroic response of our team to support the diagnostics industry and our healthcare professionals in such a time of need. In early January we noticed the growing concern in China from this new coronavirus, prompting our Life Science team to take action. On January 27th we issued a press release highlighting the application of our Lyo-Ready qPCR master mix in COVID-19 molecular assays. From there, demand grew rapidly for our molecular master mixes and our teams increased Meridian's manufacturing capacity to meet the demand through bringing new equipment online, process efficiency enhancements, and sheer dedication of time and effort.

While demand was high for our existing products, our R&D teams knew their work was not done. This situation is not new to the team, having been the first to respond to the Zika outbreak in 2016 and the African Swine Fever outbreak in 2018. Over the subsequent eight months, we brought 19 new products to market, each playing a distinct role in expanding the testing approaches that needed to be deployed globally. These new products included high performance antibodies and antigens, for rapid lateral flow testing and serology assays, and our Inhibitor Tolerant mix that facilitated the development of molecular assays that did not require RNA extraction kits, which were in short supply. This continued innovation has positioned Meridian with the most comprehensive offering of key components for any COVID-19 diagnostics testing in the industry.

Not only does our Life Science division strive to be first-to-market with its innovations, but also second to none in quality and performance. According to comparative data from reputable regulatory agencies around the world, our key components are included in some of the top performing tests in both molecular and serology COVID-19 testing. Our outstanding performance has led to inclusion of Meridian products in over 100 approved COVID-19 assays, as of today, with dozens of new samples for COVID-19 assays still being tested by potential customers. These tests are being deployed across the globe in North America, Europe, the Middle East, and Asia, including both China and India.

Beyond COVID-19, our Life Science division has one of the most comprehensive portfolios of antigens, antibodies and molecular reagents for in vitro diagnostics on the market. In this fiscal year, we also released a novel air-dryable master mix that facilitates shipping dry test kits without the need for expensive lyophilization. This mix is for DNA based assays and an RNA version is under development, to be launched this quarter. Just this past month, we launched a master mix specifically designed for liquid biopsy diagnostics. You should expect to see more targeted products from us in the future as we look to support our customers pushing the bounds of diagnostic test performance. We are already seeing the impact of new and

strengthened relationships, built during this pandemic, resulting in our products' inclusion in several new non-COVID assays.

On the Diagnostics side, the journey has been a bit different with a mix of struggles and successes. In Q2, the segment posted year-over-year growth for the first time in five quarters, a milestone in the multi-year turnaround for that business. The pandemic quickly stalled that growth as stay-at-home orders reduced testing for anything other than critical care and respiratory illnesses. We did not let that stand in the way of advancing our strategic plan, closing the acquisition of Exalenz, bringing urea breath testing to our *H. pylori* diagnostics portfolio, and launching the Curian® instrument and HpSA® assay. The team in Quebec also adapted the development plan for our respiratory panel on Revogene® to include SARS-CoV-2. I am happy to announce that we have completed development of the stand-alone COVID-19 assay and today we informed the FDA of our intent to submit an application for Emergency Use Authorization in the U.S. We also entered into an agreement with a partner to bring a rapid antigen test to market, which is now being sold in Europe and Latin America under the CE mark and is working towards FDA EUA approval in the US.

While Q3 was slow on the sales front, the team adapted to the situation conducting online training sessions and moved towards virtual sales calls. That work paid off, with interest in new placements of our instruments picking up in the fourth quarter. That was particularly true for the Revogene®, which has now surpassed 200 installations, ending the year at 231. In-person access at customer sites remains limited and focus continues to be on COVID-19 testing; nonetheless, the quarter did see the first wins for combo placements of both BreathID® and Curian®, validating our strategic approach to *H. pylori*.

Clinical trials have been a mixed bag. Q3 brought everything to a halt and heading into Q4 we were optimistic things would return to normal. While some trials did get back to full swing, others got off to a slow restart especially those in the GI syndromic area, driven by lack of qualified participants, decreased disease prevalence, and availability of predicate devices that

have been de-prioritized by our peers in favor of COVID-19 assay production. I will discuss our pipeline in more detail later in the call.

This has been a truly monumental year for both of our businesses and our company in executing the strategic plan. Now I will hand the call over to Bryan to talk about the financial results of the quarter and the year.

BRYAN BALDASARE:

Thank you Jack.

It is a pleasure to recap what was a record year in financial performance for the company. We finished FY20 with **Consolidated Revenues** of $254 million, up 26% year-over-year. Life Science drove that growth with a contribution of $133 million, a whopping 106% growth over fiscal year 19. COVID-19 related sales for the year were $72 million. That growth was partially offset by Diagnostics, declining 11% to $121 million. Importantly though, Diagnostics revenue in Q4 was up 38% over Q3, reflecting a rebound in our core assays outside of the respiratory category. **Consolidated Gross Margin** was 62% and **Consolidated Operating Income**, on an adjusted basis, was $62M, a margin of 24%. This was a blend of 2% for Diagnostics and 52% for Life Science. GAAP diluted EPS was $1.07, up 88% over fiscal 19. All of these metrics exceeded our original guidance set in November of last year as well as our revised guidance set in August. If you want to dig deeper into the drivers for the year, please refer to our press release and our 10K, which will be filed by November 25th.

Now let's focus on the fourth quarter … **Consolidated Revenues** were $64 million, up 26% from $51 million in the fourth quarter of fiscal 2019. Excluding the impact of foreign currency exchange rate changes, revenues were up 25%.

Gross Profit Margin was 60% in the quarter, up from 57% in the fourth quarter of last year. The story remains the same with this increase driven by strong improvements in Life Science gross

margin partially offset by a decline in Diagnostics gross margin, which I will discuss further in the segment review.

On an adjusted, or Non-GAAP basis, fourth quarter **Operating Income** was $12 million, with a margin of 19%, an improvement from 15% last year. **Adjusted Operating Expenses** were $26 million up $5 million year-over-year. Also, on an adjusted basis, **Net Earnings** were $8 million and **Diluted EPS** was $0.19.

The year-over-year increase in operating expenses was driven by cash and equity incentive compensation, reflecting better performance relative to plan, incremental spending in R&D, primarily on new product development programs, including clinical trials, and the operating costs of the Exalenz acquisition.

On a GAAP basis, **Operating Income** was $9 million with Operating Expenses of $29 million. In addition to the aforementioned operating expense drivers, GAAP operating expenses were impacted by $1.1 million increase in contingent consideration related to the acquisition of GenePOC, $700,000 increase in selected legal expenses, partially offset by a reduction in restructuring costs of $1.1 million. **GAAP Net Earnings** were $6 million and **GAAP Diluted EPS** was $0.15.

Now let's unpack those results by looking at the details of our two operating segments:

We saw great progress in **Diagnostics** with…

- **Revenues** of $30 million, up 38% from Q3. While we recognize that this is still down about 11% year-over-year, we are pleased with the strong momentum and rebound from Q3 that we are seeing. As expected, the year-over-year decline is primarily attributable to continued softness in demand resulting from the slow return to pre-pandemic conditions. Most of our products saw better than expected demand in the quarter, but notably, non-COVID-19 respiratory products are lagging the recovery.

While this better than expected recovery is promising, we are still experiencing headwinds to demand in most products that we expect to continue into FY21.

- **Gross Profit Margin** for the segment was 53%, an improvement from 52% in Q3, though down from 58% in the same quarter last year. The year-over-year decrease was driven by lower sales volumes and also affected by the continued pricing pressure on our higher margin *H. pylori* stool antigen products, which we have mentioned in prior quarters.
- Diagnostics suffered an **Operating Loss** on an adjusted basis of $3 million. Similar to last quarter, this is a result of our continued investment in new product development and commercial excellence programs despite the lower sales levels. Our Diagnostics new product pipeline is included in our Q4 2020 Investor Presentation posted on our website. Diagnostics adjusted operating expenses for the quarter were up $3 million year-over-year driven by planned increases in spending on new product development programs, including clinical trials, and costs absorbed from the acquisition of Exalenz, including intangible asset amortization. Progress on clinical trials and related product development ramped up in the quarter, but ultimately resulted in lower spending than anticipated.

Our **Life Science** segment recognized…

- **Revenues** of $34 million, an increase of 97% year-over-year. We estimate that increased revenue related to the pandemic was $18 million, with 80% coming from molecular products and 20% coming from immuno products. This sequential quarter-over-quarter decline was as expected, and as you can see, demand for our COVID-19 products remains robust.
- **Gross Profit Margin** exceeded 65% in the quarter, up from 55% in Q4 of last year. This continues to be driven by economies of scale for our molecular products.
- **Adjusted operating income** was $17 million, a margin of 50%, demonstrating the leverage this business brings when operating at such a large scale.

Turning to the balance sheet… As of September 30, we had $54 million in **Cash** and a borrowing capacity of $91 million under our line of credit. During the quarter, we repaid $30 million on our revolving credit facility, bringing our net repayments to $7 million, after consideration of $50 million in borrowings for the Exalenz acquisition. We view our financial condition as strong, evidenced by a current ratio that exceeds 3-to-1 and a debt-to-equity ratio of 42%.

Turning to Guidance…

We are expecting another banner year at Meridian for fiscal 21 with Diagnostics revenues rebounding and Life Science demand remaining strong. While forecasting is still challenging given the ever changing state of the pandemic, we plan to continue our approach from last year of providing guidance including some of the key underlying assumptions.

We expect revenue of between $290 and $310 million, an 18% increase over fiscal 20 at the midpoint. That includes between $140 and $150 million of Diagnostics revenue and between $150 and $160 million of Life Science revenue. We see the core Diagnostics revenue stabilizing as the year progresses, returning to pre-pandemic levels in the back half of the year. Additionally, we expect to see COVID-19 assays making a contribution to Diagnostics beginning in the second fiscal quarter. Those dynamics combine not only to deliver growth over fiscal 20, but also growth over fiscal 19. This assumes that there are no further lock-downs resulting in lower healthcare utilization or elective procedures. Life Science demand remains robust and we expect it to continue through fiscal 21, with between $80 and $85 million for COVID-19 key components, albeit with some of the same quarter-to-quarter volatility we saw in fiscal 20. Expect to also see some contribution from reagents included in new non-COVID-19 assays, particularly respiratory panels, coming out of our deeper relationships.

Adjusted operating margin is expected to be between 23.5% and 24.5%, roughly in line with fiscal 20. This is a result of a few key things. First, we continue to invest in future growth

opportunities. Diagnostics R&D is expected to be around 18% of Diagnostics revenue as we complete the clinical trials delayed in fiscal 20 and start new trials. Additionally, we are investing in Life Science infrastructure across sales, R&D and manufacturing, to support the new scale of the business. Second, we are absorbing the cost structure acquired with Exalenz. And finally, we have the annualization of headcount increases from FY20 and some return of normal travel.

Our expected tax rate of 23% to 24% reflects a greater portion of earnings coming from the U.S. as the Diagnostics business rebounds. This ultimately leads to expected Adjusted EPS between $1.14 and $1.28 based on a fully diluted share count of 44.3 million shares.

This guidance reflects our current line of sight into order patterns and assumes that we do not encounter any significant reductions in manufacturing capacity as a result of the pandemic causing either partial or full site closures for an extended period of time, or adversely affecting our supply chain for raw materials.

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

JACK KENNY:

Thanks Bryan.

As you can see, FY21 is shaping up to be another fantastic year for Meridian. Diagnostics is positioned to deliver strong growth, not just as compared to a depressed FY20, but growth over FY19. Our key strategic focus areas will be advancing new product development, the launch of an EUA approved COVID-19 test, completing the integration of Exalenz, expanding Revogene® pie production capacity, and executing on a number of operating efficiency initiatives. We plan to complete the clinical trials for the Curian® Campylobacter and *C. diff* assays and begin clinical trials for the Revogene® RI and GI Panels as well as the Curian® Shiga Toxin assay. This will

position us to launch four new products in FY21 and between two and four new products per year in FY22 and beyond.

Life Science will be focused on continuing to meet the demand of our customers driven by the ongoing pandemic as well as delivering new innovative products. We have a number of new master mixes in the pipeline that will raise the bar for performance in molecular assays. Additionally, the team will be hard at work supporting the dozens of customers testing and validating our products in new, non-COVID assays to fill the funnel for future growth beyond the pandemic.

Fiscal 20 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 opportunity that lies 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 the best year in company history and have positioned us to do it again in Fiscal 21. Thank you all for joining the call today and we look forward to speaking to you again next quarter.