Prepared Remarks

FISCAL 2020 Q3

Meridian Bioscience FY2020 Third Quarter Earnings Call

August 7, 2020

CHARLIE WOOD:

Thank you.

Good morning and welcome to Meridian's fiscal 2020 Third 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 H. C. Wainwright Annual Global Investment Conference in September. The details of that event will be posted to our website as they are finalized. Finally, our Q4 and full year fiscal 2020 earnings call is currently scheduled for Friday November 13th, 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, August 7th, 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 diluted 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 earnings release.

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

JACK KENNY:

Thank you, Charlie.

Q3 2020 was no doubt the most remarkable quarter in our Company's history. In the midst of an unprecedented global health crisis, the diversification of our Meridian business enabled our record setting performance. We were successful in both keeping our employees safe and in delivering flawlessly for our customers, which was our goal heading into the quarter.

As anticipated, Diagnostics had its momentum stagnate as a result of the pandemic, with demand at 65% of the same period last year. Meanwhile, demand for our COVID-19 related raw materials contributed to Life Science delivering revenue in Q3 nearly as high as all of last fiscal year. This balance has allowed us to continue investing in all parts of our business, advancing our strategy to position the Company well for when the world emerges from the shadow of this challenging time.

While clinical trials were halted for much of the quarter, our R&D teams continued to advance new product development initiatives. The Revogene® COVID-19 assay achieved design lock and has moved into late-stage development in preparation for a downstream clinical study. The team remains on track to submit for EUA in early Q1 of fiscal 21, in advance of the upcoming respiratory season. Development on the GI panel has completed, now entering the validation phase and the start of clinical trials. On Curian®, *C. diff* clinical trial enrollment started increasing toward the end of Q3 and is gaining momentum. We have begun clinical trials for *Campylobacter* and started feasibility work on the latest assay added to the pipeline, a combination assay for Strep Pneumo and Legionella.

We closed the Exalenz transaction at the end of April and our integration efforts are well underway. Operational leadership from Exalenz remains in place, and we have completed the integration of the two commercial teams under our U.S. based sales leadership. While the limitations on international travel are challenging, the teams are working well together virtually, including collaborating with the broader Meridian executive team as part of our annual strategic planning process.

Our commercial team adapted to the new normal, hosting BreathID® training sessions entirely online, and laid the foundation for new virtual sales strategies. Curian® received the CE mark in June, and the platform was officially launched with the first placement. The team also placed the first BreathID® Smart System, which received FDA clearance in March. Engagement with our customers improved throughout the quarter, one example being the award and execution of a new molecular agreement with a national group purchasing organization, adding Revogene® and its current FDA-cleared assays.

Life Science continues to outperform our expectations. As expected, demand for molecular products peaked in the quarter and demand for our key components used in antibody tests, SARS-CoV-2 antigens, exploded in the quarter, as customers included our products in their EUA approved and CE marked assays. Subsequent to the end of the quarter, we launched a high sensitivity monoclonal antibody pair that can be used by diagnostics manufacturers to develop the much-needed rapid antigen tests for COVID-19. While still early in the validation phase with dozens of our customers, this product could offset some of the expected near term decline in demand for the other products while our customers work through their inventory.

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 the best quarter in the Company's history with **Consolidated Revenues** of $85 million, up 75% from $48 million in the third quarter of fiscal 2019. Excluding the impact of foreign currency exchange rate changes, revenues were up 76%. This was record revenue for any fiscal quarter, driven by Life Science, which also delivered record quarterly revenue.

Gross Profit Margin was 66% in the quarter, up from 58% in the third quarter of last year. Similar to last quarter, this is the blend of a dramatic increase in Life Science gross margin and a reduction in Diagnostics gross margin, which I will discuss further in the segment review.

On an adjusted, or Non-GAAP basis, third quarter **Operating Income** was $30 million, with a margin of 36%. **Adjusted Operating Expenses** were $25 million up $6 million year-over-year. Also, on an adjusted basis, **Non-GAAP Net Earnings** were $24 million and **Non-GAAP Diluted EPS** was $0.55.

The year-over-year increase in operating expenses includes $2 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 $2 million in R&D, primarily on new product development and clinical trials, and experienced an increase of $1 million in purchase accounting amortization from the acquisition of GenePOC late in the third quarter of Fiscal 2019 and the acquisition of Exalenz, which closed this quarter.

On a GAAP basis, **Operating Income** was $35 million with Operating Expenses of $21 million. In addition to the aforementioned operating expense drivers, GAAP operating expenses were impacted favorably by a reduction in the contingent consideration obligation for the acquisition of GenePOC of $6 million. This adjustment reflects an expected agreement with the former GenePOC shareholders regarding milestone payments that were impacted by the pandemic. The contingent consideration obligation reduction is partially offset by acquisition related

expenses of $2 million associated with the acquisition of Exalenz that closed in the quarter. **GAAP Net Earnings** were $28 million and **GAAP Diluted EPS** was $0.64.

Now let's look at the details of our two operating segments:

In **Diagnostics**…

- **Revenues** were $22 million, down almost 35% year-over-year, with no impact from FX. This decline was primarily attributable to softness in demand across all of our products as a result of stay-at-home orders around the globe impacting non-critical care diagnostic testing. Ultimately, the impact was not quite as bad as our expectations, with our lead products rebounding faster than expected late in the quarter. While demand is rebounding, exiting the quarter, we were still experiencing significant headwinds to demand in most products. BreathID® products, acquired with Exalenz, contributed over $1 million in the quarter. In our financials, revenues from BreathID® and its *H. pylori* assay are categorized by platform with non-molecular assays and by disease state with gastrointestinal assays.
- **Gross Profit Margin** for the segment was 52%, down dramatically from 61% 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 $7 million as we continued to invest in new product development and commercial excellence programs despite the lower sales levels. Diagnostics adjusted operating expenses for the quarter were up $5 million year-over-year as a result of planned increases in spending on new product development and clinical trials, costs absorbed from the acquisition of Exalenz, and an increase in intangible asset amortization from both acquisitions. Progress on clinical trials and related product development began to resume late in the quarter, but this spending was still significantly lower than expected.

Our **Life Science** segment recognized…

- **Revenues** of $63 million, delivering nearly as much revenue in the quarter as it delivered in the entirety of fiscal 2019. This performance exceeded our expectations due to robust demand for enzyme mixes used in COVID-19 PCR tests and the SARS-Cov-2 antigens used in high volume antibody tests. We estimate that increased revenue from the pandemic was $48 million, split $32 million for molecular products and $16 million for immuno products. As expected, we saw molecular revenues peak in the early part of the quarter.
- **Gross Profit Margin** exceeded 70% in the quarter, up from 52% in Q3 of last year. This was the result of continued benefit from the large batch sizes for our molecular products, which, as we stated last quarter, does not require a linear increase in cost of goods.
- **Adjusted operating income** was $40 million, a margin of almost 64%, demonstrating the leverage this business brings when operating at such a large scale.

Turning to the balance sheet… As of June 30, we had $63 million in **Cash** and borrowing capacity of $61 million under our line of credit. During the quarter we entered into an interest rate swap transaction to fix an additional $25 million of our borrowing under the revolver at 2.02%. Combined with the interest rate swaps already in place, $50 million of the balance outstanding is now fixed at a blended rate of 2.16% for the term of the revolver.

Turning to Guidance… We had an exceptional quarter, exceeding our expectations on a number of fronts. As a result of that performance, we are raising our guidance for the year. We now expect **Consolidated Net Revenue** for fiscal 2020 to be between $245 and $250 million, which implies Q4 revenue of $55 to $60 million.

As we mentioned last quarter, we expect continued demand for our Life Science products to be higher than normal, but lower than Q3. Our guidance assumes COVID-19 related sales of $12 to $15 million in the fourth quarter, bringing the total impact for the year to $65 to $68 million.

This contributes to full year revenues for Life Science between $127 and $130 million and implies revenue in Q4 of $29 to $32 million. Concern about supply chains led a number of our customers to secure more inventory than usual, contributing to the record demand in Q3. That, combined with the slower than expected ramp of antibody testing, will result in lower demand in Q4, as they work through the inventory, pushing future demand into fiscal 21. This guidance includes a very limited contribution in sales from our new SARS-CoV-2 antibody pairs, used in rapid antigen tests. While there are dozens of customers in the validation phase, it is unclear if any will complete their development in time to place any bulk orders in the quarter.

We expect revenue for the Diagnostics business to be between $118 to $120 million for the full year, which implies $27 to $29 million in Q4. This assumes that diagnostic testing continues to rebound, but still seeing headwinds at roughly 80% of normal volumes. This slight reduction from our prior guidance range reflects the loss of revenue we were expecting from the COVID-19 antibody test partially offset by slightly more favorable expectations on the rebound of our core Diagnostics business.

You should expect that **Gross Profit Margin** will start to revert back towards normal levels, but still with higher margins for Life Science offset by lower margins for Diagnostics. We expect **Adjusted Operating Margin** for the year of between 22% and 23% and **Adjusted Diluted EPS** of $1.01 to $1.05. Based on our year-to-date results, this implies **Adjusted Operating Margin** for the quarter of between 13% and 16% and **Adjusted Diluted EPS** of $0.12 to $0.16. In our calculation of Diluted EPS, we are using 42.8 million shares for Q4 and 43.2 million shares[1] for the full year FY20. Also of note in this guidance is the inclusion of $3 million in R&D spend expected in Q4 as spending on clinical trials continues to pick-up throughout the quarter.

This guidance reflects our current visibility into market conditions and customer order patterns for our products, and our current assumptions about the impacts from resurgence of COVID-19 infections in the U.S. and around the globe.

[1] Read on the earnings call as 42.2 million shares – correct number is 43.2 million

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

JACK KENNY:

Thanks Bryan.

For many companies in the healthcare industry without COVID-19 specific products, the June quarter was a real challenge. The results of our Diagnostics segment in the quarter suggest that should have been the case for Meridian as well, but the strength of our diversified business shined through and resulted in the best quarter of our 40+ year history.

We are trying to maximize our "shots on goal" during this pandemic. It began with our molecular reagents which are now included in more than 35 assays. We then launched the raw materials necessary for COVID-19 antibody tests and those are now included in over 10 assays. We plan to continue increasing the number of shots on goal through the addition of the antibody pairs used in COVID-19 rapid antigen tests and the introduction of our own diagnostic tests. We have the opportunity to benefit when any of these assays see strong market demand, giving us scale and geographic reach beyond what we would be capable of otherwise.

However, not all of these shots will score. We planned to bring an antibody test to market through a partner, but that partner voluntarily withdrew its EUA application in July and we no longer have plans to sell their kits in the U.S. In parallel, we have been looking for another partner to bring a COVID-19 rapid antigen test to market and have recently signed an agreement to do so. The test is CE marked and we are in the process of assisting this new partner in submitting their application for EUA and translating the package insert for distribution in Europe. We will initially sell this test under their brand in Europe and expect to switch to a Meridian private label version upon EUA approval. We anticipate submission to the FDA toward the end of this quarter.

So far these shots on goal have delivered great results, more than offsetting the other market headwinds from this pandemic. Our financial position remains strong, enabling us to continue to invest in the business both for near-term impact and long-term growth. The COVID-19 assay on the Revogene® and partner immunoassays, coupled with our Life Science reagents, should position us well into fiscal 21.

Now Bryan and I are here for your questions.

JACK KENNY (POST Q&A):

As we close this call, I want to thank our long-term shareholders for their belief and trust in our business over the long term and also to welcome the large number of new shareholders that have decided to invest in Meridian. We truly believe that Meridian's best days remain ahead of us and we look forward to consistently delivering on our promises to our shareholders in both the near and long term. Thank you all for joining the call today and we look forward to speaking to you again next quarter.