Prepared Remarks

FISCAL 2021 Q2

Meridian Bioscience FY2021 Second Quarter Earnings Call

May 7, 2021

CHARLIE WOOD:

Thank you.

Good morning and welcome to Meridian's fiscal 2021 Second 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 will be participating in the William Blair Growth Conference on June 1st to 3rd and Bryan and I will be participating in the Jefferies Healthcare Conference those same dates. Our Q3 fiscal 2021 earnings call is currently scheduled for Friday August 6th, 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 and post-pandemic outlook 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 7th, 2021, 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. Reconciliations 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 another strong quarter for Meridian. Demand for our Life Science products remained high and Diagnostics continued to rebound from the headwinds of the pandemic. I will let Bryan go deeper into the financials later in the call and will start with some of the operational highlights of the quarter.

As you are aware from our prior announcements, the Revogene® SARS-CoV-2 assay saw a setback, as we withdrew the EUA application to conduct some further studies as requested by the FDA. In March, we conducted a limit of detection bridging study, which showed a significantly better LOD than our initial analysis. While this is positive news for the performance of the assay, it also means that we need to conduct further clinical validation studies before we can resubmit the assay to the FDA. We expect to complete the clinical validation studies and anticipate resubmitting our EUA application in June.

Related to the Revogene® SARS-CoV-2 assay, we were awarded a second grant of $5.5 million from the RADx initiative to ramp production of the assay. Manufacturing expansion remains on track with some revisions on manufacturing volume based on future outlook for the maximum capacity needs. We anticipate initial production on the new lines in Cincinnati happening in our fourth fiscal quarter. At our Quebec site, we have been running two shifts since October of last year, and expect to begin our validation processes for the second line later this month, followed by manufacturing our first production lots by the end of June.

On the last day of the quarter, our Curian® platform hit another significant milestone with the 510(k) submission of the Curian® Campy assay. This assay is the second assay submitted to the FDA for the platform and detects *Campylobacter* in human stool. Congratulations to the immunoassay R&D team here in Cincinnati and we look forward to announcing additional submissions from this team in the future.

Commercially, we saw a slow-down in orders for the Revogene® system, which we attribute to a temporary "wait and see" approach adopted by our customers while we work toward re-submission of our EUA application for the SARS-CoV-2 assay. In total, our Diagnostics team installed a net 37 Revogene® instruments, bringing the current install base to 325, and we continue to have a backlog of pending installs. LeadCare® was the strongest performer in the quarter posting year-over-year growth. Additionally, installs were up over 20% from the first quarter of 2021 and ahead of our expectations for the second consecutive quarter. It appears that the blood chemistry business has fully recovered from the headwinds of the pandemic and we are optimistic that the other core products are on a similar path and not far behind.

Turning to the Life Science segment, besides the strong financial performance in the quarter, the team also had some exciting operational developments. In March, Life Science launched the first of its sample specific master mixes. The Air-Dryable Direct DNA qPCR Blood Mix was specifically designed to facilitate the design and manufacture of assays that use crude whole blood, serum or plasma samples without the need for extraction. It's compatibility for use with crude samples, coupled with the ability to air-dry the assay with our unique mix, can accelerate the development and reduce the manufacturing costs for future cancer detection and other blood screening assays. This product launch is part of our approach to simplifying molecular assay development for our customers by offering mixes optimized for what they are trying to develop. A customer needs only to know whether they want to develop a DNA or RNA based assay and what the sample type will be. We will point them to the appropriate optimized mix, they add their primers and probes, ultimately reducing development time. This approach

should really benefit our customers in the new post-COVID world where more rapid development of new assays is expected to be the norm.

Overall, a productive quarter for both teams. Now I will hand the call over to Bryan to talk about the financial results of the quarter.

BRYAN BALDASARE:

Thank you.

As Jack mentioned in his opening remarks, Q2 was another strong quarter for the company. We recorded **Consolidated Revenues** of $85 million, up 49% year-over-year, driven by the strong performance from the Life Science segment and partially offset by weakness in the respiratory category of Diagnostics. Excluding the impact of foreign currency exchange rate changes, revenues were up 45%.

Consolidated Gross Profit Margin was 68% in the quarter, up from 60% in the second quarter of last year. The story continues to be the same as prior quarters, with this increase driven by strong improvements in Life Science gross margin, primarily as a result of economies of scale from our molecular reagents. Sales for molecular reagents contributed approximately 44% of consolidated revenues for the second quarter of fiscal 21 compared to approximately 20% for the second quarter of fiscal 20.

On an adjusted, or Non-GAAP basis, first quarter **Operating Income** was $32 million, with a margin of 38%, versus 21% last year. **Adjusted Operating Expenses** were $26 million, up a little over $3 million year-over-year. Also, on an adjusted basis, **Net Earnings** were $25 million and **Diluted EPS** was $0.56, growth of 143% from $0.23 in the second quarter of fiscal 20.

The year-over-year increase in operating expenses was driven primarily by the incremental expenses added by the Exalenz acquisition, including purchase accounting amortization, as well as incentive compensation, particularly for our U. S. profit sharing and equity award programs.

On a GAAP basis, **Operating Income** was $34 million with Operating Expenses of $24 million. In addition to the aforementioned operating expense drivers, GAAP operating expenses include $1 million in selected legal spending that is offset by a $3 million decrease in our contingent consideration obligation related to the acquisition of GenePOC. **GAAP Net Earnings** were $26 million and **GAAP Diluted EPS** was $0.60.

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

Diagnostics delivered…

- **Revenues** of almost $32 million. While this was down 9% year-over-year, it is important to note that it was up 5% from Q1, continuing the trend of incremental recovery from the lows during the pandemic. Except for our Respiratory products that were adversely affected by a very light respiratory season outside of COVID-19 testing, the other major parts of our Diagnostics business, GI and Blood Chemistry, performed near expectations with Blood Chemistry posting 4% growth year-over-year. GI was also up 12% year-over-year, but primarily driven by BreathID®, which was not a contributor until we closed the Exalenz acquisition in Q3 fiscal 20.
- **Gross Profit Margin** for the segment was 52%, down approximately 200 basis points from Q1 and down approximately 500 basis points from the same quarter last year. The decline in margin from Q1 was driven by inventory reserve provisions for rapid antigen and antibody tests, as well as product related to our Revogene® SARS-CoV-2 test from our voluntary withdrawal of the EUA application. In addition, 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 had an **Operating Loss** on an adjusted basis of less than $1 million. Similar to prior quarters, this is a result of our continued investment in new product development and commercial excellence programs despite the lower sales levels, in addition to the inventory reserve provisions I just mentioned. Diagnostics adjusted operating expenses for the quarter were up $1.5 million year-over-year, driven by spending on new product development programs, including clinical trials, and costs absorbed from the acquisition of Exalenz, including intangible asset amortization.

Our **Life Science** segment recognized…

- **Revenues** of $53 million, an increase of 139% year-over-year. We estimate that revenue from COVID-19 products was $31 million. Of note, this estimate suggests our core revenue was up over 30% year-over-year, highlighting the initial impact from non-COVID new business we picked up from the customer relationships we built during the pandemic, as well as recovery of our core business.
- **Gross Profit Margin** was 77% in the quarter, up 1,200 basis points from Q2 of last year. This continues to be driven by economies of scale for our molecular products. The second quarter of fiscal 20 was the first in which we saw revenue related to COVID-19, a modest $5.6 million.
- **Adjusted operating income** was $36 million, a margin of 68%, continuing to demonstrate the leverage this business brings when operating at such a large scale.

Turning to the balance sheet… As of March 31, we had $63 million in **Cash** and a borrowing capacity of $110 million under our $160 million line of credit. During the quarter, we repaid $9 million on our revolving credit facility. At this point, you can expect we will not reduce our debt balance further due to the interest rate swaps we have on the remaining portion.

Turning to Guidance…

During the quarter we had a delay in the timing of clearance of our Revogene® SARS-CoV-2 assay, and we continued to explore other partner options for an EUA-cleared rapid antigen test given the continued delay in submission from our current partner. Additionally, Life Science finished the quarter a little behind our expectations as customer orders slowed in March, mirroring the testing declines seen as the vaccine roll-out accelerated. Despite that, we still see good demand for our Life Science reagents and thus, are maintaining our Life Science segment net revenues guidance at this time. As a result of our voluntary withdrawal of our Revogene® SARS-COV-2 EUA application and expected timing of re-submission, as well as no clear line of sight as to when our current partner will submit its rapid antigen SARS-CoV-2 test for EUA clearance, we are lowering the Diagnostics segment net revenues guidance and the corresponding adjusted diluted EPS contribution to remove any significant contribution from these tests during our second half of fiscal 21.

We now expect consolidated revenues of between $305 and $335 million, reflecting reduced Diagnostics revenue expectations by $15 million to between $125 and $135 million, and a re-affirmation of Life Science revenue expectations of between $180 and $200 million.

Flowing through that reduction of $15 million, results in Adjusted EPS of between $1.60 and $1.80 based on the same fully diluted share count of 44.3 million shares.

This guidance reflects our current line of sight into order patterns and assumes that there is no dramatic change in the direction of the pandemic. While lower, this guidance is still above the guidance set at the beginning of the year, with a range that still overlaps the lower end of the guidance range set last quarter.

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

JACK KENNY:

Thanks Bryan.

Overall a great quarter for Meridian.

Diagnostics continues to advance along the path to recovery and new product development continues. Despite the timing setback on the Revogene® SARS-CoV-2 assay, we are pleased with the product the team has developed, which is an important step towards the completion of a high-quality respiratory panel planned for next year.

The strategy of maximizing our shots on goal continues to deliver strong results for Life Science. The number of shots continues to climb, as customers continue submitting assays for regulatory clearance in their target geographies. We are excited for some of the assays in our customers' pipelines including those that address the shift to return-to-normal testing at the point-of-need.

While COVID-19 testing appears to be settling in at a lower level, we believe there will be continued durability in this market, with a long tail. Our Life Science business is well situated to provide solutions to the industry, as it moves from symptomatic to asymptomatic testing with our comprehensive offering of reagents for SARS-CoV-2 testing, including antigen, antibody and point-of-care molecular.

As we begin the transition into a post-COVID world, we have significant optimism for the future of Meridian. Our Life Science segment was transformed by the pandemic and exits with a much larger base and new and fortified customer relationships to fuel future growth. We kept the Diagnostics segment on strategy and did not reduce our investment despite the headwinds of the pandemic. As testing continues the return to normal, Diagnostics is positioned to continue the turnaround that was at the cusp of sustainable growth one year ago. We have generated significant cash, adding to our already strong balance sheet, and we will continue looking for ways to put our balance sheet to work, for both organic and inorganic growth opportunities.

We appreciate your continued interest in the Meridian story and now Bryan and I are here for your questions.

JACK KENNY (POST Q&A):

Thank you for joining today. We look forward to speaking to you at one of the conferences in the coming weeks and again in August after the conclusion of Q3.