Prepared Remarks

FISCAL 2021 Q1

Meridian Bioscience FY2021 First Quarter Earnings Call

February 5, 2021

CHARLIE WOOD:

Thank you.

Good morning and welcome to Meridian's fiscal 2021 First 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 Global Life Sciences Conference on March 9th and 10th and our Q2 fiscal 2021 earnings call is currently scheduled for Friday May 7th, 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, February 5th, 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. 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.

I am excited to discuss with you another incredible quarter for Meridian. Record quarterly revenue and earnings per share, beating out our third quarter of fiscal 20 in the heat of the first wave of the pandemic. The Life Science segment continues to be the driving force with substantial demand for our COVID-19 related reagents, but strength of the core business should not be overlooked. Diagnostics continued its recovery from the pandemic-driven lows in our third quarter of fiscal 20 before hitting a plateau in December. Notably, despite the rampant resurgence of the virus and the return of some restrictive orders, Diagnostics results did not retreat and ended posting single digit gains above Q4. Bryan will elaborate further when he presents the financials later on the call.

We had a number of business achievements in the quarter I would like to highlight, as well as provide an update on initiatives in progress.

In Life Science, we launched the RNA version of our proprietary Air-Dryable Master Mix. If you recall, we launched the DNA version about a year ago, but it was not a focus at the time, as it was not applicable to the COVID-19 pandemic that was beginning to unfold. Even now, I don't think it is getting the attention this innovation deserves. We believe this is game changing for the development of molecular assays, as manufacturing molecular tests in a dry format reduces transportation and storage complexities, a very attractive feature for IVD companies, as well as their customers. Previously, the only option for delivering a dry format assay was to use a process called lyophilization which requires owning specialized equipment or sending the kit to

a third party, both being expensive options that add multiple dollars in cost per test. Our new mix, the first commercially available of its kind, facilitates the same end result but in a much more cost effective and simple manner using a standard commercial oven. Over fifty customers have sampled this mix and initial feedback has been outstanding, with some reporting even better performance than our other highly acclaimed wet or lyophilized mixes. We think this can really revolutionize the way companies approach molecular diagnostic development and help us establish a position in other adjacent markets such as veterinary, environmental, food, and forensic diagnostics.

On the Diagnostics side, in December, we submitted the Revogene® SARS-CoV-2 assay to the FDA for emergency use authorization, and began shipping kits in January. This is an important milestone for Meridian, as it is both the first new assay submitted to the FDA since our acquisition of GenePOC and the first RNA based assay on the Revogene platform. This assay was also developed with funding and other support from the NIH RADx initiative. Meridian was one of forty-seven projects that made the cut and moved to Phase 1 of the program. The Revogene® SARS-CoV-2 assay is a real-time RT-PCR test with the same simplified workflow of the other Revogene assays using nasopharyngeal specimens. It returns results in 85 minutes with an early call for positive samples as soon as 47 minutes. We look forward to receiving EUA approval in the coming weeks.

As I mentioned, we recently began shipping the first kits to select customers in the U.S. As with any new assay, particularly the first of its kind for a platform, it will take some time to optimize the production. Further, we are taking the approach of maintaining necessary production volumes of the other core Revogene® assays to meet the needs of our customers, some of whom we have won in recent months from competitors that have put their non-COVID products on backorder or allocation. We continue to play the long game, focused on building strong customer relationships through exceptional customer service and reliable supply.

Anticipation for the Revogene® SARS-CoV-2 assay receiving EUA has led to an acceleration of instrument placements resulting in 57 net new placements in the quarter, bringing the total install base as of December 31, 2020 to 288 systems, and we continue to be in a backorder situation. To address the expected demand for the COVID-19 assay, we have developed a plan for ramping production of Revogene® PIEs and I can share some of those details today. As we announced earlier this week, in conjunction with over $5.5 million of new awards from Phase 2 of the NIH RADx initiative, Jobs Ohio and the Village of Newtown, we are opening a new facility down the street from our corporate headquarters here in Cincinnati. This new facility will house two automated productions lines. Coupled with the addition of a second shift and another manual line in Quebec, we are targeting a ramp to a maximum capacity of 800,000 PIEs per month by the end of the calendar year. As this requires new, custom machinery, there is still much to do to get this facility on-line and we will provide further updates on the progress as the year continues.

Diagnostics new product development continues to progress, but clinical trials for gastrointestinal assays continues to be slow due to challenges in obtaining patient specimens. Despite this challenge, we still anticipate starting clinical trials for Curian® *C. difficile* in February, while the Curian® Campylobacter assay has completed its clinical trials with preparation for an expected FDA submission early in Q3. The Revogene® GI panel continues to be on track to start clinical trials later this year. In respiratory, the Revogene® RI panel clinical trials are being delayed as a result of the light respiratory season we are experiencing, limiting access to patient specimens, as well as the need to redirect resources to focus on the new production ramp plans for the SARS-CoV-2 assay. This will likely push FDA submission for this assay out of the fiscal year, but with the progress on the other assays, still puts us on track to submit four new assays in fiscal 21, consistent with our strategy to submit 2-4 new assays per year.

Lastly, I thought it would be good to provide some update on the progress we have made in our Billerica facility. Over the last year, we submitted a number of written responses and worked

hard on our remediation plans to address the issues raised by the FDA in the 483 comments received in June 2017 and October 2019. In October 2020, the FDA closed the inspections from June 2017 and October 2019. The Warning Letter issued in October 2017 remains outstanding, pending a future FDA inspection, and we have notified them that we are ready. While not fully resolved, we have made meaningful progress and we look forward to welcoming the FDA to complete their inspection.

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, Q1 was another record quarter for the company. We recorded **Consolidated Revenues** of $93 million, up 96% year-over-year, driven largely by the strong performance from the Life Science segment. Excluding the impact of foreign currency exchange rate changes, revenues were up 93%.

Consolidated Gross Profit Margin was 66% in the quarter, up from 58% in the first quarter of last year. The story remains consistent, 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 50% of consolidated revenues for the first quarter of fiscal 21 compared to approximately 11% for the first quarter of fiscal 20.

On an adjusted, or Non-GAAP basis, first quarter **Operating Income** was $37 million, with a margin of 40%, versus 15% last year. **Adjusted Operating Expenses** were $25 million up a little over $4 million year-over-year. Also, on an adjusted basis, **Net Earnings** were $28 million and **Diluted EPS** was $0.65, growth of 550% from $0.10 in the first 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 for our cash bonus and equity award programs.

On a GAAP basis, **Operating Income** was $35 million with Operating Expenses of $27 million. In addition to the aforementioned operating expense drivers, GAAP operating expenses include $1.2 million in selected legal spending and a $1 million increase in contingent consideration related to the acquisition of GenePOC. **GAAP Net Earnings** were $27 million and **GAAP Diluted EPS** was $0.61.

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

Diagnostics delivered…

- **Revenues** of $30 million. While this was down 13% year-over-year, it is important to note that it was up 2% from Q4 and up 40% from the low seen in Q3 during the heat of the first wave of the pandemic. The early part of the quarter saw continued progress in the recovery and has since flattened as infection rates climbed and people stayed home more. We think it's a positive sign that the recovery only stalled and did not retreat, and we remain optimistic.
- **Gross Profit Margin** for the segment was 54%, an improvement from 53% in Q4, though down from 60% 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 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. Diagnostics adjusted operating expenses for the quarter were up $2 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 $63 million, an increase of 396% year-over-year. We estimate that revenue from COVID-19 products was $43 million. Of note, our core revenue was up 55% year-over-year, highlighting the initial impact from non-COVID new business we are picking up from the customer relationships we are building during the pandemic.
- **Gross Profit Margin** exceeded 72% in the quarter, up from 53% in Q1 of last year. This continues to be driven by economies of scale for our molecular products. Keep in mind that we did not have any COVID-19 revenue contributions in our first quarter of fiscal 20.
- **Adjusted operating income** was $40 million, a margin of 64%, continuing to demonstrate the leverage this business brings when operating at such a large scale.

Turning to the balance sheet… As of December 31, we had $63 million in **Cash** and a borrowing capacity of $101 million under our $160 million line of credit. During the quarter, we repaid $10 million on our revolving credit facility. Over the next few quarters, we plan to leverage our strong balance sheet to further fortify our production capacity in Life Science and build out the new Revogene® manufacturing lines, so expect to see significantly higher capital expenditures than our historical average as we make those investments.

Turning to Guidance…

As mentioned when we pre-announced our revenue for the quarter, we expect demand for our Life Science products to continue to be robust in Q2. While the current level of infection in the U.S. continues to suppress growth in Diagnostics, we are still optimistic that recovery will continue throughout the fiscal year. As such, we are raising our fiscal year guidance. We now expect consolidated revenues between $320 and $350 million, holding Diagnostics revenue

expectations to between $140 and $150 million and raising Life Science revenue expectations to between $180 and $200 million. Like many companies, it continues to be difficult for us to forecast during these uncertain times. We expect that you will notice that the second half of the year is implied to be lower than the first half. In Life Science, the forecast for the second half of the year assumes we return to levels similar to the fourth quarter of fiscal 2020 in anticipation of declining infection rates as the COVID-19 vaccines are administered around the world. Even so, we expect this would result in Life Science revenue significantly above pre-pandemic levels and Diagnostics revenue contributions from our COVID-19 assays offsetting lingering headwinds from the pandemic. As we mentioned previously, it is becoming more difficult to distinguish between COVID revenue and non-COVID revenue in the Life Science segment as more customers receive product shipments destined for inclusion in both COVID and non-COVID assays. We will continue to report this metric as long as we are able to; however, we are not going to call-out the revenue contribution expected from the pandemic going forward. While we are not quantifying it, our guidance raise does contemplate more Life Science revenue coming from COVID-19 demand than in our original guidance issued back in November.

Adjusted operating margin is expected to be between 31% and 33%…

This raised guidance results in an expected Adjusted EPS between $1.70 and $1.90 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 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, adversely affecting our supply chain for raw materials, or delaying the buildout of our new Revogene® manufacturing facility.

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

JACK KENNY:

Thanks Bryan.

Another great quarter in the books and another quarter that demonstrated the continued impact we are having on the global COVID-19 testing demands.

I would like to go back to something that Bryan mentioned about our Life Science results. Not only was there a strong contribution from COVID-19 related products, but our core business was up significantly as well. This speaks to the durability of the business we are building. I'm sure you've heard this phrase too many times in the last few weeks, but it is certainly applicable to us… we are a COVID beneficiary, but not COVID dependent. In the last few weeks, we received supplier awards from two of the top global IVD companies recognizing us for our partnership during the past year, as they managed their COVID business. This is an example of the great relationships we are building with our Life Science customers that will continue to produce results long after the pandemic.

We continue to tell our story and are grateful for all the new, as well as existing, investors that see the long-term potential in what we are building and continue to support us.

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 again in May.