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PRESENTATION

Operator

Greetings, and welcome to Meridian Bioscience Fiscal Second Quarter 2022 Earnings Call. (Operator Instructions) As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Charlie Wood, Vice President of Investor Relations. Thank you. You may begin.

Charles Wood - *Meridian Bioscience, Inc. - VP of Corporate Strategy, Business Development & IR*

Thank you, Operator. Good morning and welcome to Meridian's fiscal 2022 second quarter earnings call. With me are Jack Kenny, Chief Executive Officer, and Andy Kitzmiller, 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, Andy and I are participating in the HC Wainwright Global Invest Conference on May 24th. Any additional conferences will be announced via press release and posted to our website as they're finalized. Lastly, our Q3 fiscal 2022 earnings call is scheduled for Friday, August 5th, 2022.

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. Meridian makes these statements as of today, May 6th, 2022 and undertakes no obligation to publicly update them.

Additionally, the company's remarks also include market data based on management's knowledge of the industry and good faith estimates of management. The market data reference involves a number of assumptions and limitations and you're cautioned not to give undue weight to such estimates. While we believe the estimated market position, market opportunity and market size information is generally reliable, such information, which in part is derived from management estimates and beliefs, is inherently uncertain and imprecise and has not been verified by any independent source.

Lastly, 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'd like to turn the call over to Jack.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO & Director*

Thank you, Charlie. Q2 was a fantastic quarter for Meridian and another all-time record for revenue. What makes it even better is that both business units were firing on all cylinders, individually producing record quarterly revenue. Andy, who joined us in February, will go over the financial results in more detail later in the call.

Overall, we saw a quarter with strong demand for COVID-19 products from both Life Science and Diagnostic segments due to the Omicron variant. However, outside of sales of the COVID-19 antigen test, Diagnostics also saw growth in other respiratory products and in our urea breath tests for H. pylori. As others have reported, we too saw demand for COVID-19 products subside in the last few weeks of the quarter, as one would expect as Omicron cases have decreased around the world, consistent with the typical end of a respiratory season. In parallel, we are seeing Laboratories and Diagnostics increase focus on their core business of non-COVID testing, which bodes well for a new normal in the endemic stage for the virus.

In February, we completed the work necessary to bring LeadCare II assay back to the market 6 weeks ahead of schedule. The team is still working through a backlog of orders, but the good news is that demand is high with customers, and they're excited to be able to use our point-of-care lead test for their patients again.

In early March, we completed work on the Revogene SARS-CoV-2 assay and submitted our analysis to the FDA. As part of the dialogue with the FDA, they requested some additional data. We have provided some of the data and are in the process of conducting the additional studies necessary to complete their request. We expect to finish those studies in the next few weeks and are hopeful for an expedited review. Bringing this assay to market remains essential for the Revogene instrument as customers continue to wait for it to begin shipping before installing new instruments. The Revogene install base, as of the end of the quarter, was [375], up from [370] at the end of Q1.

As I mentioned in our last earnings call, our new Revogene manufacturing line in Cincinnati completed validation of the first line and began producing Group A strep kits. We've already noticed a positive impact from the automated manufacturing in Cincinnati, as it requires fewer staff to produce the same number of kits per [chip] than at our Quebec facility. The upcoming second manufacturing line in Cincinnati will have even greater production efficiency and capacity, and is expected to be online later this year.

Also in the quarter, the Cincinnati team will begin -- began validation of the second Revogene assay, C. diff. We expect to complete the validation and begin producing those kits in our new manufacturing facility by the end of the quarter.

With regards to new product development, you will notice in our slides, some changes to the FDA submission and expectations for the fiscal year. All the assays we plan to submit this year were expected late in the fiscal year. With recent delays in starting clinical trials for the Revogene gastrointestinal panel and [Kurian] C. diff, it is clear that we will not be able to submit those this fiscal year. Additionally, there was another limited flu season in which impacted the timing of the clinicals for the Revogene respiratory panel and delayed it into the next respiratory season. That said, Kurian Shiga toxin is currently in clinicals and is still on track for submission late in September.

New to the chart, in February, we submitted a new claim to the FDA for our urea breath test on the breath ID platform. The current package insert states that the test may not be performed if the patient has been taking proton pump inhibitors or PPIs within the last 2 weeks. The new requested labeling modification informs clinicians that they may act upon a positive test result in patients that were using PPIs within 2 weeks of the breath test. In the event of a negative test result, the test will need to be repeated after 2 weeks of discontinuing use of PPIs. We believe this new claim will improve marketability and patient usage of the product. The FDA has indicated it could take up to 9 months to review our submission and we will provide more details after receiving feedback from the FDA. Congratulations to our team in Israel for getting that work completed.

Turning to Life Science, earlier this week, we announced the acquisition of EUPROTEIN, a company in New Jersey that specializes in the design and manufacture of recombinant proteins. They have quickly integrated into our R&D team and will help us accelerate our pipeline of new immunoassay reagents. We are excited to welcome EUPROTEIN into the Meridian family, and we'll share more about what they're working on in the coming quarters. Additionally, we expanded the sample-specific Master Mixes portfolio with the launch of the Lyo-Ready blood-specific Master Mixes and launched a new detergent-free [toxo] antigen ideal for large lab-based immunoassay systems.

Continuing with the format I introduced last quarter, I would like to take a few minutes to dive deeper into our Life Science business in an effort to highlight the opportunity ahead of us. As a reminder, when I joined Meridian, there were 2 business units that made up what today -- what today is known as our Life Science segment and each was run separately with different strategies. The immuno business had decades of experience selling to the largest diagnostic companies in the world, whereas the molecular business was mainly focused on research and academia. We merged these 2 segments into one and at the end of fiscal 2018, we decided to pivot the molecular business to focus on large diagnostic companies. That essentially required an overhaul of the sales team as well as creation of an entirely new molecular product line designed for the needs of global diagnostic companies. Those strategic shifts were timed perfectly, and the company was well positioned at the beginning of 2020 to meet the unprecedented testing demands of a global pandemic.

The pandemic accelerated the need to develop assays quickly, measured in weeks and not months. R&D scientists turned to our readymade qPCR Master Mixes to accelerate their development timelines. Meridian's Master Mixes became extremely popular due to their performance and our ability to quickly supply the large quantities that were required. As the pandemic unfolded, there were shortages of RNA extraction kits necessary to process patient samples. In response, our team developed the first commercially available inhibitor tolerant mix that did not require RNA extraction. That means you can take the patient sample direct to the assay without further extraction steps.

It was this experience that has shaped our unique strategy to support the Diagnostics industry. We view ourselves as a partner to R&D teams around the world with the goal of supplying them the best performing Master Mixes optimized for their specific need in order to accelerate the development of world class assays. We became extremely focused on disrupting the way assays are developed and creating a series -- and created a series of Master Mixes engineered to address inhibitors in the various types of patient samples.

We developed ultrasensitive Master Mixes that R&D departments do not need to optimize, and come in formats for a variety of devices. Our R&D team focused on addressing the most clinically relevant patient samples, such as saliva, sputum, blood serum, plasma, urine, and stool.

In addition, we also developed Master Mixes to target the ag bio and food market where the sample is plant or food material. Leveraging our proprietary buffer systems and expertise in using excipients to suppress inhibitors, we set out to create series of Master Mixes optimized for each of these sample types. We currently have the only portfolio of sample-specific Master Mixes on the market. And by the end of this fiscal year, we will have built out the portfolio to include mixes for all key sample types, across both qPCR and LAMP chemistries.

We're disrupting molecular assay development by offering Master Mixes that do not require any optimization. All you have to do is add your primers and probes, and you have a final assay with direct from sample detection and the flexibility of a wet, lyophilized or air-dried format. This is disruptive in the sense that you can develop assays very quickly and save time on optimizing and troubleshooting due to difficult sample types that can decrease the sensitivity of an assay.

This is a unique approach within the industry and is resonating well with our customers. We have almost 200 customers using these novel mixes year to date, and what is really exciting is the diversity of what they're sampling. Our blood mixes have been the most popular, followed by saliva, stool, urine and plant. Not only does this bode well for our approach, but is also a clear signal that the focus has shifted away from building COVID assays and back to all other diseases that impact the global population year in and year out.

Lastly, I would like to touch on format types as this is another area where we differentiate. Assays can be delivered in either a wet format or a dry format. The advantage of dried-down assays is that they are stable at room temperature, removing the need for cold chain shipping and storage. Not only does this lower the cost of shipping and storage for our customers and their customers, but it is also more environmentally friendly, reducing the use of electricity and Styrofoam. We have developed versions of each of our mixes to work in either a wet or dry format to meet the needs of our customers.

Historically, the only way to dry an assay was through a process called lyophilization. Lyophilization requires capital investment and expensive equipment or multiple days to send the kits to a third party with the right capabilities. This can add upwards of $1 to $3 to the production of a single test. In 2020, we introduced an air-dryable formulation that enables drying using inexpensive commercial ovens. We believe Meridian is the only company in the world that has commercialized air-dryable master mixes for qPCR and LAMP.

As you can see, our Life Science teams' approach is disrupting traditional approaches to assay development. Not only do these innovations benefit our customers financially, but they enable the development of the highest quality assays to improve patient care, with the added benefit of reducing the environmental impact of diagnostic testing. In addition to developing products that help our customers be more environmentally friendly, Meridian is also dedicated to 2 important goals. First, advancing Diagnostics to better -- to enable better patient outcomes and in sum, helping people. And second, ensuring that our culture is inclusive, diverse, and equitable.

Those words carry great meaning at Meridian, and we've been intentional and thoughtful about listing them in that order as we believe that you first have to be inclusive to attract and retain a diverse team. We're in the early stages of our ESG journey, excited about the prospects and look forward to sharing more with you as we achieve meaningful progress.

And now it's my pleasure to introduce you to our new CFO, Andy, to provide more details on the financial results for the quarter.

Andrew S. Kitzmiller - *Meridian Bioscience, Inc. - Executive VP & CFO*

Hello everyone. It's great to be speaking with you today. I've had a chance to meet a few of you and I look forward to meeting more of you at conferences in the coming months. As Jack mentioned, this was a great quarter, not only for Meridian in total, but also for each of the operating segments. Consolidated net revenues were $111 million, up 30% year-over-year, and a new quarterly high for the company. Diagnostics segment net revenues grew 29% to $41 million, also a record for the segment. Growth was driven by urea breath testing for H. pylori and the respiratory category. In particular, respiratory included a significant contribution from the GenBody COVID-19 antigen test.

Life Science also had a record quarter with net revenues of $70 million, up 32% year-over-year. This growth was driven primarily by sales of immunological reagents, particularly, those related to COVID-19 testing. It is notable that Molecular also saw growth year-over-year in the quarter, given that we know there's been a shift away from molecular testing for COVID-19 in favor of antigen testing. Non-COVID related immuno sales were roughly flat year-over-year, attributable to the timing of orders for some of our core native antigen products, limited demand in China due to lockdowns and a one-off project in the second quarter of last year that did not repeat this year.

Consolidated gross margin was 62%, with a Diagnostics margin of 50% and a Life Science margin of 68%. Diagnostics gross margin was down moderately year-over-year due the drag of LeadCare still being off the market for half of this quarter. Life Science gross margin was down due to product mix as a higher concentration of immunological sales carries a lower margin than our molecular reagents.

Adjusted operating expenses were $32 million, up $6 million year-over-year, primarily due to increases in accruals for incentive compensation tied to financial performance in the current fiscal year. GAAP operating expenses were also $32 million, up $9 million versus the prior, driven by incentive compensation related to the current year's outperformance, moderate increases in G&A, sales and marketing, which were primarily offset by lower spend in R&D.

Consolidated operating income on an adjusted basis was $37 million, a margin of 33%. This breaks down to an adjusted operating margin of 58% for Life Science and 4% for Diagnostics. The higher operating profit for Diagnostics was primarily driven by the incremental revenue generated in the quarter, and we expect Diagnostics to continue generating quarterly operating profit in the quarters ahead. The lower operating margin for Life Science is primarily the flow-through impact of a lower gross margin due to product mix.

Adjusted diluted earnings per share was $0.66 per share, compared to $0.56 per share in the second quarter of fiscal year 2021, while GAAP diluted earnings per share with $0.65 in Q2 of 2022, compared to $0.60 in Q2 of 2021. If you'd like to dig deeper into the drivers for the second quarter of fiscal year 2022, please refer to our press release and our 10-Q, which were both filed today.

Turning to the balance sheet, as of March 31, we had $76 million in cash. During the quarter, we also repaid $25 million on our line of credit. This leaves us with borrowing capacity of $175 million. Since joining Meridian, I have been impressed with the strength of our balance sheet. I've encouraged the team to continue to leverage that in order to fortify inventory of raw materials to minimize or eliminate risks in the global supply chain, as the team has successfully done throughout the pandemic.

Additionally, I've been working with our Operations and Procurement teams to further de-risk potential supply chain issues through contractual guarantees on lead times and reliability with our key suppliers, adding additional suppliers and optimizing amounts and locations of inventories, among other things. Between the cash on hand and capacity in our line of credit, we have adequate resources to fund investments and opportunities that accelerate growth and provide good returns on capital for our shareholders.

Turning to guidance, we are raising our consolidated net revenue expectations to between $330 million and $345 million. This includes holding Diagnostics net revenue expectations between $145 million and $150 million, and raising Life Science net revenue expectations to between $185 million and $195 million. We anticipate the adjusted operating margins to be between 22.5% and 23.5%, resulting in adjusted net earnings per share of between $1.30 and $1.40.

You will notice that while we have raised Life Science guidance, we are essentially holding our expectations back for the back half of the year in line with our previous guidance. As you've heard in other commentary regarding the pandemic, COVID-19 testing demand has slowed in parallel with infection rates as we exit the respiratory season. This is consistent with our expectations, which will result in a lower second half for our Life Science division, consistent with other more modest quarters we have seen following significant waves of the virus.

I'll now turn the call back to Jack to offer some closing remarks.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO & Director*

Thank you, Andy. I want to add to Andy's comments regarding the guidance. As I've mentioned before, we see COVID-19 entering the endemic phase. We believe that COVID-19 testing will continue for years to come, but with higher levels of demand in our first and second quarters aligning with the typical respiratory season. While we cannot control the spread of the virus and the resulting demand for testing, remember that our reagents are in over 100 regular assays, and whenever there is demand for testing, we will benefit. This also does not include the dozens of respiratory panels we are in, which we believe will be an important revenue driver in future periods.

Looking ahead to next fiscal year, we continue to believe that COVID-19 has become endemic and we will see increases in cases in testing aligned with the respiratory season annually. This will continue to follow the pattern we are expecting for this year with higher Life Science revenue in the first 2 quarters of the fiscal year, followed by lower revenues in the last 2 quarters.

While we do not expect to repeat the record level seen this year, the adoption of our Master Mixes for uses beyond COVID-19 testing, coupled with strong growth of our blocker products and other non-COVID immunoassay reagents, gives us confidence that we have an ongoing Life Science business with revenues believed to be approximately $150 million and generating operating margins of at least 50%. Diagnostics has shown signs of returning to growth and profitability and with both businesses performing strongly again, we are bullish on Meridian's future in the post-COVID world.

Now Andy and I are here for any questions you may have. Operator, can you open it up for the questions please?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Dustin Scaringe with William Blair.

Dustin G. Scaringe - *William Blair & Company L.L.C., Research Division - Research Analyst*

This is Dustin on the line for Brian. For the first question, I know you gave a little bit of guidance for long-term and Life Sciences segment. It looks like in the back half of this year, you're, kind of, annualizing $130 million in the second half. Is it fair to assume that this business is going to grow, kind of, double digits organically off of this in 2023?

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO & Director*

Yes, we do believe that we have a double-digit growing Life Science business. So the big question for everybody of course, is where's your jump-off point with COVID? So our general view of the approximately $150 million business is that you have some element of COVID in there, and then you've got the underlying rest of the business. But we are anticipating a low double-digit growing Life Science business as we go forward. We believe we've got that in the tank and then some.

Dustin G. Scaringe - *William Blair & Company L.L.C., Research Division - Research Analyst*

Great. And then on a Diagnostics business, I know you didn't really, kind of, guide to the second quarter, but it looks like you beat us by about $7 million but kept the guide flat. I know LeadCare was in there and came back a little sooner than earlier. But just wondered what's going on the back half of the year, because that still, kind of, looks conservative.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO & Director*

So our Diagnostics business, we're at about $74 million at the midpoint of the year, and we're guiding to that being essentially at the 50% point of our guidance, if you will. And the way we look at it, Dustin, first of all, is that we have some elements of seasonality in our Diagnostic business. And Andy, you can add to this at the end if you want, but we certainly have a stronger respiratory season typically in our Diagnostic business. So that, kind of, decreases it as you move into Q3 and Q4. But as we get into Q4, we do see some seasonality with some of the food products as well as LeadCare and other things. So we do feel that the guidance we have, we're holding it for the year. We think that it's on track for that, but high-30s types of quarters is, kind of, what we see in these Q3, Q4 types of quarters going forward.

So Andy, I don't know if you want to add to that.

Andrew S. Kitzmiller - *Meridian Bioscience, Inc. - Executive VP & CFO*

No, I would say one thing I've noticed is that the breath products that the team has brought on in the last 2 or 3 years have really performed well and I think they're a strength to build on, so it doesn't seem to be any issue to be hitting that those numbers Jack said.

Dustin G. Scaringe - *William Blair & Company L.L.C., Research Division - Research Analyst*

Okay. And then commentary on M&A, I'm wondering if you can give us a little more perspective on that, what you're seeing in the landscape right now for other deals, especially in the Life Sciences segment where it seems like the market is particularly fragmented.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO & Director*

Yes. So we've -- over the last 3 plus years, we've really worked to build a more consistent approach to M&A, and it's, what -- this is our fourth acquisition now in about 3 years that we've done. So we have a more programmatic approach to our M&A, Charlie's been a big part of helping us to build that out. We've got the systems in place to assess opportunities, to build a funnel and to really work them through the funnel. And as well as of course, then integrating them on the back end for the ones that we do decide to acquire.

So we're very excited about EUPROTEIN. It's a small bolt-on situation for us, but it's a technology enhancement that's going to really help us in our business. So we're excited to bring that one on. We do have a continual funnel that we're looking for in the Life Science, whether it be small bolt-ons. There are also some large assets that are out there that we certainly will look at to see if they make sense for us.

Life Science valuations have historically been a bit challenging. So we're, kind of, keeping an eye on some of those valuations as we go forward. But I think you can expect us to continue to look to use our cash to acquire things to strengthen the overall Life Science business. Andy, I don't know if you want to that.

Andrew S. Kitzmiller - *Meridian Bioscience, Inc. - Executive VP & CFO*

[That's right.]

Operator

Our next question comes from the line of Yi Chen with H.C. Wainwright.

Unidentified Analyst

This is [Chase] on behalf of Yi. Congratulations on all the progress. You've already answered a few of my questions in your previous response, but I was just wondering if you could perhaps summarize all the catalysts or events across both your business units that we should definitely keep an eye out for in the coming months this year.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO & Director*

So I'll throw some and Andy, you can wrap around me. So first of all, on the Life Science side of things, as you guys know, as we move into the endemic phase, we're going into a new phase on the Life Science side of the business. So for us, it will be harder to predict what happens with the COVID part of our business, because we're not exactly sure what'll happen in the endemic environment. But for us, there are some key things that we're doing on the Life Science side. This acquisition of EUPROTEIN is a good signal that we believe that there's real opportunities for us, not just on the molecular side of things, our mixes -- Master Mixes continue to do great in the market. We think there's real opportunity on the immunoassay side of the business as well.

And so strengthening our capabilities with recombinant proteins and bringing new products to market there. Looking at non-animal derived products over time is something that we're working on as well to move to more recombinant in general and moving away from native antigens.

So we see strong growth in our Life Science business, clearly from the Master Mixes that we have as we work to get them into more and more assays, non-COVID related assays. Those are happening as we speak, but as you know, the regulatory process, it's a long process. So we have a lot in the funnel that we're working there. And then the immunoassay piece is really the other key growth area that we wanted to accelerate with this acquisition.

On the Diagnostic side of things, for us getting the LeadCare II back and getting it back early was really important to us. As you know, we have the only point-of-care led testing available on the market, and there's really a strong need in the marketplace for this type of testing. And so we were really excited to get that back. We're actively working with our customers to make sure that they're up and running again, that they're utilizing the technology. And so for us, it's about what can we produce in the near term, but ultimately going back to focusing on the organic growth. So we are optimistic that we are seeing a significant number of placements of new systems in that area that we look forward to reporting as we go forward. So I think that that's going to be a continued nice area for us. The leadCare should provide a nice tailwind for us as we go forward in the coming years.

Andy also mentioned the urea breath testing, that is a huge area for us. We have a strong H. pylori franchise between H. pylori stool antigen, and the urea breath testing. And our position there is one that we think that can provide good tailwind to us in that business. So you have other forms of testing, like we talked about, that we can convert over to urea breath testing that we think can provide continual tailwind, if you will, to that business.

So those are a couple key areas. Of course, getting the Revogene COVID assay is important for us. We have a lot of customers in those smaller hospitals that really still are looking for this technology. And so I think that'll open up things for us. So those are some of the key things. Andy, sorry that I jumped all over you there and I took them all.

Andrew S. Kitzmiller - *Meridian Bioscience, Inc. - Executive VP & CFO*

That's great.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO & Director*

Look, I will tell you this, we're excited about both businesses and thankfully we invested heavily in Diagnostics over the last couple of years, even when we knew the business was going to suffer during COVID. And now we're starting to see the fruits of that at this point, with our breath business starting to flourish. So we're extremely optimistic for both of our businesses as we go forward.

Operator

There are no further questions in the queue. I'd like to hand the call back over to Mr. Kenny for closing remarks.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO & Director*

Thank you very much, Operator. Well, thank you all for joining the call today. We really enjoyed speaking with you again this quarter. This was an exciting quarter for Meridian and certainly we have a bright future ahead of us. We look forward to sharing with you at future conferences or, quite frankly, on these calls as we go forward. Have a great day. Thank you.

Operator

Ladies and gentlemen, this does conclude today's teleconference. Thank you for your participation. You may disconnect your lines at this time and have a wonderful day.
