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VIVO.OQ - Q3 2020 Meridian Bioscience Inc Earnings Call

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by and welcome to the Meridian Bioscience Fiscal Third Quarter 2020 Earnings Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded. (Operator Instructions)

I would now like to hand the conference over to Charlie Wood, Vice President of Investor Relations. Thank you. Please go ahead, sir.

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

Thank you. Shelby. 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 13, 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 7, 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.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO, Executive VP of Diagnostics Business Unit & Director*

Thanks, Charlie. Q3 was no doubt the most remember 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 delivering flawlessly for our customers, which was our goal heading into this quarter.

As anticipated, Diagnostics has 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 continue to use new product development initiatives. The Revogene COVID-19 assay achieved design lock and had moved into late-stage development and preparation for a downstream clinical study.

The team remains on track to submit for EUA in early Q1 of fiscal 2021 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 towards 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 2 commercial teams under our US 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 posting BreathID training sessions entirely online and leave the foundation for new virtual sales strategies. Curian receive 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 improve throughout the quarter, one example being the award and execution of a new molecular agreement with a national group purchasing organization adding Revogene and is currently -- is 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 the antibody tests SARS-CoV-2 antigens exploded in the quarter as customers included our products in their EUA and CE Mark assays.

Subsequent to the end of the quarter, we launched a high sensitivity monoclonal antibody pair that can be used by diagnostic manufacturers to develop a 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 the demand for the other products while our customers work through their inventory.

Now I want to hand the call over to Bryan to talk more about the financials for the quarter.

Bryan Baldasare - *Meridian Bioscience, Inc. - Executive VP, CAO, CFO & Secretary*

Thank you, Jack. As we reported earlier today, Meridian had the best quarter in the company's history with consolidated revenues of $85 billion, 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 2 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 around the globe impacting noncritical 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 our -- 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 nonmolecular 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 continue to invest in new product development and commercial excellence programs despite the lower sales level. 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. Cost 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 a delivered in the entirety of fiscal 2019. This performance exceeded our expectations due to robust demand for enzyme mixes used in COVID-19 PCR test 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 (technical difficulty) 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 benefits from the large back 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 transactions to fix an additional $25 million of our borrowing under the revolver at 2.02%. Combined with the interest rate swaps already in place, $15 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 million 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 million to $15 million in the fourth quarter, bringing the total impact for the year to $65 million to $68 million. This contributes to full year revenues for Life Science between 127 and $130 million and implies revenue in Q4 $29 million to $32 million. Concerned about supply chain let a number of our customers to secure more inventory than usual, contributing to the record demand in Q3. That, combined with a slower-than-expected ramp of antibody testing will result in lower demand in Q4 as they work through the inventory pushing future demand in the fiscal 2021.

This guidance includes a very limited contribution and 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 and time to place in the bulk orders in the quarter. We expect revenue for the Diagnostics business to be between $118 million to $120 million for the full year, which implies $27 million to $29 million in Q4. This assumes the diagnostic testing continues to rebound, but still see headwinds of roughly 80% of normal volumes.

The slight reduction from our prior guidance range reflects the loss of revenue, we are expecting from the COVID-19 antibody test, partially offset slightly by more favorable expectations on the rebound of our core Diagnostics business. You should expect the 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 margins for the year of between 22% and 23% and adjusted diluted EPS of $1 to $1.5. Based on our year-to-date results, this implies adjusted operating margin for the quarter of between 30% and 16% and adjusted diluted EPS of $0.12 to $0.16. And our calculation of diluted EPS we are using 42.8 million shares for Q4 and 42.2 million shares for the full year of fiscal year 2020.

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 the resurgence of COVID-19 infections in the US and around the globe.

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

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO, Executive VP of Diagnostics Business Unit & Director*

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 suggests that should have been the case for Meridian as well, but the strength of our diversified business showing through and resulted in the best quarter of our 40 plus 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 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 Diagnostics test.

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 plan 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 US.

In parallel, we have been looking for another partner to bring 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 towards 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 remain strong, enabling us to continue to invest in the business, both for the 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.

With that Shelby let's open it up now for any questions that they may have.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from Andrew Brackmann of William Blair.

Andrew Frederick Brackmann - *William Blair & Company L.L.C., Research Division - Associate*

So I guess first I'd like to start on the guidance for the fourth quarter, mainly on the COVID piece of the Life Science segment, I know you said your customers are working through some inventory there. But can you give us maybe an idea of how much inventory is still in the channel here and then what are your customers telling you about the burn -- their burn rate through that inventory and any potential reordering here in the back half of the year.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO, Executive VP of Diagnostics Business Unit & Director*

I'll start Bryan and you can wrap around me. So Andrew, we -- as the quarter was going, we did know that we had customers. If you remember when this was all taking off in in the spring, there was a bit of Pandemonium where everybody was trying to secure whatever supplies that they could. And so, we saw immense demand, especially for the molecular products in that April-May time frame and we were able to scale up and to meet the demand and we knew that it was several months' worth of inventory for these types of customers, which is part of the reason why we said in -- as we are doing the April call that that we would expect the Q3 to be bigger than Q4.

And so that happened exactly as we had thought. The thing that happened a little bit different was the antibody testing if you remember in the May-June time frame that the diagnostic companies were scrambling to try to be able to build millions of antibody tests per month. And we were able to supply those customers. We had anticipated the antibody demand would be in Q3. But quite frankly a lot of it in Q4 that it would ramp up in later Q3 and be in Q4. There was such huge demand upfront from those diagnostic companies, a lot of that demand came into Q3. And so that is what really pushed it where we saw some more of that coming in Q4.

Both on the molecular front and the immunoassay front on the antibody front, they do have inventory. We're starting to see customers on the molecular front start to reengage to order again. But it's not in the same crazy environment where they just want to do it, they have a better understanding of kind of the supply that they want going forward.

So we are starting to have customers re-engage with us and that starting to be the case. We're optimistic, it will see orders here in Q4, but quite frankly it will continue on into Q1, assuming the pandemic goes the direction I think everybody sees it going.

The antibody tests are a different story. The antibody tests they are stocked up, they build capacity and do millions of millions of tests. And as you know the antibody test at the end user level did not get out of the gates as fast. We think antibody testing will be relevant in the future. And we think it'll be an important task, so we think that will start to see demand for that again in in fiscal 2201, but we don't expect significant sales on that front, in Q4.

Bryan, If you want to add to that.

Bryan Baldasare - *Meridian Bioscience, Inc. - Executive VP, CAO, CFO & Secretary*

The only thing that I would add to that Andrew is that I think we believe we are well positioned as a reagent supplier whether it's molecular or immunoassay reagents for antibody tests or rapid antigen tests. We believe we're well positioned to supply the market. So we do see a little bit of a dip here in Q4, as they go through that and the antigen testing would be the thing that would make a difference. But it's hard to predict when customers if they validate a test. They have to go through EUA submission. They have to ramp up. We just, --we're optimistic, but the timing of that is not clear at this point in our guidance reflects what we have clarity on.

Andrew Frederick Brackmann - *William Blair & Company L.L.C., Research Division - Associate*

Okay, perfect. I appreciate all that color. I have some follow-ups on the antigen products here in a moment. But maybe I guess sticking with the theme about sort of the market evolution here, you guys have a pretty unique visibility into different geographic trends here. So maybe I guess the question is, can you talk about how you see the market evolving across the different geographies that you play in here in Europe more prone to using one type of product versus another and then how does that impact your business here as we think about the next few quarters.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO, Executive VP of Diagnostics Business Unit & Director*

So Andrew, we figured that there would be questions on that front. We have in our slide deck. If you go to, I think it's near the last slide, Charlie. One of the last slides actually talks to this topic, the clip note that I would give you is that from a PCR standpoint on the molecular front, we have much more exposure in Europe and then in Asia than we do in the United States. We have some placements with companies here in the United States. But our exposure was stronger in Europe, primarily and then a bit in Asia as well.

On the antibody fronts, really many cases global companies for the antibody test, but it was really more a US based company and many fronts less exposure in Europe and really not much exposure in the rest of the world. So it is different geographically if you look through that. We have seen -- if you look at the cases in Europe, they have not seen the same spike, that they had in the US although they are starting to talk in the UK in other areas of a second wave truly coming in Europe. So as that second wave that hits in Europe as anticipated, we would anticipate to see increased demand on our molecular front for that type of testing.

So I think the slide that we have there will walk you through that, but -- Bryan if there's anything I want to add to that.

Bryan Baldasare - *Meridian Bioscience, Inc. - Executive VP, CAO, CFO & Secretary*

I think that's well said.

Andrew Frederick Brackmann - *William Blair & Company L.L.C., Research Division - Associate*

Okay, perfect. I'll be sure to take a look at that. And then I guess wrapping up here. And switching to the diagnostic testing opportunity, we'll first -- I know you mentioned some of your customers are validating your antibody pair product, but can you maybe talk about some early performance metrics of those products that you're seeing. And then secondly, as you think about making these partnership and bring it then private label. Can you, can you give us an idea of early sensitivity and specificity metrics of that product in your confidence and bringing that through FDA -- a process?

Bryan Baldasare - *Meridian Bioscience, Inc. - Executive VP, CAO, CFO & Secretary*

I can give a -- you can give you some color. I'll start with the antibody pairs, Andrew. So the antibody pairs, as we said, we have dozens of customers that are testing that product. Lourdes and team on the Life Science side have been very enthusiastic because the feedback from customers has been very strong that the performance of these antibody pairs is doing very, very well.

Comments from several customers that they're developing their test that they are very pleased with the performance versus the products that are out there. So I would say that we have strong confidence in the antibody pairs. The question is obviously how many of those customers -- coming to this companies are effectively able to get through the EUA process and so that's a little bit of the wild card. But we have a lot of shots on goal there. So we feel very good.

In regards to the -- one that we partnered with on the Diagnostics front, it is using the antibody pairs that we've talked about which we have high confidence in, so that was part of it. We wanted to use a product that we felt best about and I would describe the performance that we've seen to be equal to or better than what is published from the BD's and quite else of the world that are the first ones out there, so we think that this will be a very strong offering.

Obviously, we've got a -- we'll begin selling this product at CE Mark later this quarter. So the produce is CE approved, so we'll go into Europe with this product. Probably late part of this quarter and the goal would be as we get into Q1 of next year hopefully we have -- they'll have EUA submission will be able to begin bringing that product into the US. But this product also will not require an instrument the, the quid L version and the BD versions both our instrument required. And so this will be ability for a rapid test, you don't need an instrument as well, which we think we'll, we'll be pretty attractive out in the marketplace.

Andrew Frederick Brackmann - *William Blair & Company L.L.C., Research Division - Associate*

Okay, perfect. And then just last one on that, for the manufacturing capacity that you have on that side of things, can you just walk us through how the manufacturing of that product will work? Will that be partner, would that the you guys. And if it is you guys, can you talk about the capacity that you have to manufacture, test.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO, Executive VP of Diagnostics Business Unit & Director*

For the rapid antigen. We selected a partner that we felt number one had a strong product right using the antibody pairs in a strong product, but also one that had the capacity that we felt needed because as you know -- this is of strong demand and this is a -- the partner that we've chosen does have the capability of making a high number million per week or more type of test capability. So that was one of the attractive things of selecting their partner.

So we decided in that case to do it with the partner versus ourselves where it would have been harder for us to ramp up the capacity at the level that these folks have. So high quality product that they had but in addition to that the ability to ramp up the manufacturing were the 2 reasons why we did this partnership with the third-party on the rapid antigen tests.

Operator

(Operator Instructions) Your next question is from Yi Chen of H.C. Wainwright.

Yi Chen - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

So first question, I know you mentioned that your customers is working through the inventory, but do you think that the COVID-19 related growth is somewhat handicapped by shortages in other testing supply such as RNA extraction kits?

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO, Executive VP of Diagnostics Business Unit & Director*

So we -- we have heard the concern of people that do the RNA extraction kits capacity issues impact our customers, we have not had significant feedback from our customers that the lack of those RNA extraction kits is impacting them. With that said, theoretically if they can't do the extraction, then it would impact our ongoing purchases, but we have not had significant feedback from customers of that being a limiting factor at this point.

Yi Chen - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Got it. Thank you. And do you think the fiscal fourth quarter, as you've got it was serve as a baseline to understand quarterly Life Science revenue going forward in fiscal 2021?

Bryan Baldasare - *Meridian Bioscience, Inc. - Executive VP, CAO, CFO & Secretary*

So Yi, this is Bryan. I think it's still probably a little early for that. And the reason I say that is we have a line of sight into current orders that we're trying to satisfy over the next several weeks. But I think there is still some to play out here from a supply standpoint in the different market channels. So we'll likely have more to say on that particular question when we do guidance for fiscal 2021. We are trying not to get out over our skis if you will, in terms of how we're guiding around the business right now.

Yi Chen - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Okay. Thanks. And my last question is in the current quarter, have you observed any signs or indicators showing that the Diagnostics segment could resume grows as hospitals and labs that on the longer COVID-19 hotspots and start to resume their daily activities?

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO, Executive VP of Diagnostics Business Unit & Director*

We absolutely have started to see signs of rebound in the Diagnostic business. The initial sign we mentioned was under LeadCare. We started to see it in June where the LeadCare business started to rebound and started to move closer to normal and that has continued on in the early part of this quarter.

I would say that the general business has been improving and we have seen improvement as of late even in the early part of this quarter, which is kind of helped us towards our guide of 80% for the Diagnostic business. We are starting to see significant increased interest from customers in regards to Revogene having to do a bit with the EUA submission that we intend to do in the fall but also quite frankly with some customers that are in need of other products and other companies, because they are so focused on COVID are not able to supply reagents consistently.

So we have a significant demand increase recently on our Revogene product as well, which is another good leading indicator for us on the Diagnostic business.

Operator

There are no other questions in queue.

John P. Kenny - *Meridian Bioscience, Inc. - President, CEO, Executive VP of Diagnostics Business Unit & Director*

Thank you. o before we close as we close this call, I want to take a second to thank our long-term shareholders for their belief and trust in our business over the long term, but also to welcome the large number of new shareholders 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, both in the near term and in the long term.

Thank you all for joining our call today and we look forward to speaking to you again next quarter. Have a good day.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for your participation, you may now disconnect.